Commercial Health Ins Issues

HealthInsuranceCE
2025

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Preface

I wrote this book as a text version of various lectures I gave to health insurance brokers over the past decade. It describes, briefly, the functions of health insurance then, in more detail, the problems we face implementing it in the US today and some possible solutions to those problems.

Each chapter addresses a stand alone issue or set of issues but these often overlap. I apologize for redundancy but, in health insurance, similar problems appear in different guises.

In addition, I have included summaries of some recent legislation since brokers, and all of us, tend to over-simplify these complex statutes occasionally. Sometimes re-reading detailed summaries helps us better understand the legislation itself. I have also included two Surgeon General advisories at the end of this text for two main reasons: first to introduce two specific healthcare risks to brokers and second to indicate the types of research materials available from public sources. There is an astonishing amount that brokers can use.

Health insurance brokers are generally expert at applying regulations and understanding financial concepts but weak at understanding how the benefits they sell actually affect people medically. I hope this book will address some of that deficiency.

I take the issues discussed here personally and seriously. As a child of the 1960s who, among other things, worked for CARE in Chad, Africa building primary schools and planting orchards - the latter in a leaper colony outside N'Djamena - I have a great passion for activities that improve people's lots in life. I have an equal passion for opposing destructive activities, with unnecessary and overly expensive medical care being prime examples.

I hope you find reading this book a worthwhile experience.

Gary Fradin

January 2025

Commercial Health Insurance Origins and Structures

Our healthcare financing system evolved from a vertically integrated 'financing + care provision' system to a non-vertically integrated one. This theme runs throughout today's course.

- Vertical integration means that medical care and medical financing are the same entity, with physicians on salary. Both the financing arm and medical care arm work together to generate the best patient outcomes at the lowest cost. This is the basic concept of a Managed Care Organization or a Health Maintenance Organization (HMO).

  'Managed competition' is competition among vertically integrated healthcare providers. Those generating the best outcomes at the lowest costs will gain customers; those operating at higher costs and generating poorer outcomes will lose. [1]

  Vertically integrated healthcare entities compete with each other on ***value***: outcomes per dollar spent. This incentivizes Managed Care Organizations to improve patient outcomes (life expectancy, diabetes control, post-surgical functionality and similar) without unduly raising prices. It ***dis***incentivizes Managed Care Organizations from providing excessive, unnecessary or low quality care, or raising prices too aggressively. Vertically integrated entities are, therefore, more ethically structured than the alternatives.

  The better a Managed Care Organization improves patient outcomes without raising prices, the more value it creates, the greater the company's market share and the bigger its business. This fits the Utilitarian view of an ethical healthcare system; it provides the greatest good for the greatest number. Good ethics, from this point of view, equals good business. So goes the theory at least.

- A 'non-vertically integrated system' has separate companies handling financing and medical care. Today we call financing companies 'insurance carriers' and medical care provision companies like hospitals and physician groups 'providers.'

  In this non-vertically integrated system, financiers want to pay service providers less and service providers want to bill more. The relationship between the two is 'war' according to Atul Gawande, professor at Harvard Medical School and staff writer for the New Yorker, 'every step of the way'.[2]

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[1] Alain Enthoven of Stanford University, perhaps our greatest managed care theorist and proponent, has written widely about this which is somewhat outside the scope of this particular chapter. See his seminal article The History and Principles of Managed Competition for more.
http://elsa.berkeley.edu/pub/users/webfac/held/157_VC2.pdf

[2] See Gawande's second book 'Better', chapter entitled Piecework

In a non-vertically integrated system, carriers and hospitals argue over payment amounts and formulas. A very different focus from the vertically integrated model above where the entity's singular goal is outstanding patient outcomes at a reasonable price.

Non-vertically integrated systems, as I suggested above, are designed to generate jobs, incomes, and benefits for participants in it, like doctors, financiers and all the rest.

The more our healthcare system resembles a vertically integrated one, the more ethical it is because it serves the medical needs of patients, creating the greatest health good for the greatest number of patients. The less vertically integrated it is, the less ethical it is because it is designed to serve the needs of relatively few participants.

Ethical brokers, according to the Utilitarians, should help clients emulate the benefits of a vertically integrated system despite the current structure of our healthcare system. This is a heavy lift. We'll address some ways to do this in Chapter 3.

But first, we'll discuss how our healthcare system developed around this vertically / non-vertically integrated idea below. Then, in Chapter 2, we'll discuss various problems that arise from our systemic development.

How Commercial Healthcare Started

As commonly accepted among health insurance historians, commercial health insurance started in Dallas around 1929 as a reaction to the stock market crash and financial meltdown.[3] Baylor University Hospital in Dallas faced a cash crunch and designed a creative solution to pay its bills.

Prior to the stock market cash, hospitals raised funds in two ways. First, they had customers who paid for services rendered - a fairly modest percentage of the population because most people didn't have a lot of money. Second, the community chest, the charitable organizations - the wealthy would donate to the hospital because it was a good place to donate your extra money. Charity made you feel good and was good for the community.

But after the 1929 stock market crash, unemployment reduced the number of patients able to pay, the wealthy didn't have as much money to donate, and the hospital faced a difficult financial landscape. So, Baylor University Hospital made a deal with the Dallas School System. They said, "School system, you always have money; you raise money from taxes. Pay us $.50 per employee per month and when they get sick, they can come to us and we'll take care of them." Commercial health insurance arrived.

A few comments about this.

[3] This suggestion comes from Richmond and Fein, The Healthcare Mess, page 30.

First, it's a nice deal. It's a nice deal for the hospital because they stay in business. They don't have to worry about going out of business. They didn't have to worry about turning people away as long as they got the numbers right, which apparently they did at $.50 per employee per month. The school system payments protected the hospital's cash flow so the hospital stayed in business.

Second, this was very efficient. The hospital signed one contract with one employer group and received back enough money to stay in business. That was a pretty good incentive to look for other large employer groups.

Third, there was no prevention or provider choice, but theoretically the teachers and other employees of the school system were happy because they got medical care essentially for free.

Fourth, this was for hospitalization only; no outpatient or physician office coverage.

Fifth, community rating. The Dallas School System paid $.50 per person per month, regardless of individual medical status. No medical underwriting.

Sixth, there were no quality controls, no outcome-based incentives, no holdbacks for poor hospital performance. Health insurance began simply to save the financial health of the hospital.

This was a vertically integrated system, almost textbook variety. And it exhibited the classic flaw of vertically integrated healthcare systems: lack of consumer choice. As initially developed with Baylor University Hospital, the Dallas school system employees could only go to one hospital. This has advantages and disadvantages.

Advantages:

1. Lower Costs

2. Reasonable medical care from a small number of in-network providers

Disadvantage:

1. Little provider choice as few hospitals are 'in-network'

The Baylor Hospital / Dallas School System deal worked so well that other hospitals copied it. Different hospitals looked for different large employers, offering the same kind of deal. Large manufacturers, the Dallas Morning News, and others. What problem begins to arise?

The Choice Problem

Consumers - school system employees or manufacturing workers, for example - wanted to choose among various hospitals. 'What do I know about Baylor University Hospital? I only know one thing. I know someone who went there and didn't get good care

(whatever ‘didn’t get good care’ means), so I want to go somewhere else.’ Someone always knows of someone else who had a negative experience there. So you want to go somewhere else - consumers want choice.

A different way to understand our demand for choice in healthcare: we don’t *really* trust our own doctor or, indeed, the overall medical system. We somehow think that we – patients – have better medical care insights than the various trained professionals in our network. This uninformed demand for choice has plagued our system since inception.

> The way out of this problem, according to Michael Porter and Elizabeth Olmsted Teisberg in their massive tome Redefining Health Care, is for the government to require results reporting, things like 30-day readmission rates for coronary procedures, 3-6-and-9 month follow-up data on orthopedic patient range of motion and pain, infant and maternal mortality rates and similar. As Porter and Teisberg put it back in 2006: *Mandatory measurement and reporting of results is perhaps the single most important step in reforming the healthcare system*.[4]
>
> We still haven’t made sufficient progress along these lines. That, it seems to me, is a fertile arena for ethical broker interventions. Indeed, that will be our focus in Chapter 3, below.

Remember vertical integration, where finance and service provision are the same company? Once you introduce choice, then you have one group handling finance and another handling service provision. You have a split and you lose vertical integration.

That split happened shortly after the Baylor – Dallas School System deal. A clever entrepreneurial company offered to provide financing for lots of Dallas hospitals. ‘Dallas teachers’ they might have said, ‘you can sign up with Baylor University Hospital only, or, for just a little more money, sign up with us and we’ll give you the choice of many hospitals in Dallas. We contract with lots of hospitals. We have a large network.’

These new companies competed with vertically integrated hospitals, like Baylor University Hospital and the Dallas School System.

The insurance entrepreneurs developed a couple of clever ideas in the 1930s. First, from a marketing point of view, they offered this very attractive provider choice option.

Second, they began searching for the healthiest subscribers. If they could find the healthiest people, they could offer lower priced policies and gain a competitive edge vs. their vertically integrated competitors signing up large employers at a fixed price per person.

Underwriting vs. Community Rating

[4] Porter and Teisberg, Redefining Health Care page 7

The entrepreneurs – we'll call them 'insurance carriers' - figured that they would underwrite better than the competition so people would join them because their premiums would be a little bit lower. The community rating folks faced higher premiums because they took all employees. In a very real sense, underwriting is a form of rationing: people unable to pass the underwriting standard don't get covered. Or they pay a lot more.

Underwriting serves the economic interests of the carriers. It doesn't improve healthcare outcomes. It doesn't improve the healthcare system. It doesn't differentiate medical quality. It doesn't create patient value. It only makes one carrier lower cost than another carrier by having sick people pay more. It's a zero–sum exercise – healthy pay less, sick pay more - since total community medical costs remain the same.

Our private healthcare financing system had little to do with getting people healthy or creating value. That was not its intention. It was designed to protect physician and hospital income, the original Baylor idea. Then carriers came along to make a profit from consumer demand for choice. The demand for choice led to the Split.

The Split and the Provider Payment Problem

Once you split finance from service provision, you have a wider consumer choice and you have to figure out how to pay doctors and hospitals. We're still, today, trying to get this one right.

The original and still most popular payment mechanism is fee-for-service. The doctor gets paid $100 for treating each broken arm and $350 for each rotator cuff surgery, or whatever.

As soon as you split finance and service provision, service providers have an incentive to do more. The more they do, the more they earn.

The insurance carrier, on the other hand, wants to limit the number of treatments only to those necessary to control costs. They ask service providers if they absolutely need to do that procedure. Insurers and providers fight all the time. It's a fight between

- provider clinical judgment, influenced, perhaps, at least psychologically, by the fee-for-service payment formula, and
- carrier financial judgment, influenced, perhaps, at least psychologically, by the same fee-for-service formula. Insurers don't *really* trust provider clinical judgment, at least not without discussion and justification.

That's the conflict between healthcare payers and medical service providers.

Fee-for-service / component financing is inflationary and expensive and not designed to improve patient health. It's designed to reward providers, which it did quite well historically. We, in the US, have traditionally performed more procedures / 1000 of population than similar developed countries around the world. Things today like spinal

fusion surgery, hip replacements, knee replacements, coronary bypass surgeries. The Split between finance and service provision led us down this road. It continues to this day.

The Impact of World War II

World War II plays an important role in our story for three main reasons.

First, the soldiers who received health coverage while in the military wanted to continue with it afterward. They saw the advantages of having health coverage. They married and wanted their families to receive coverage also. This created ***demand*** for health insurance.

Second, our wartime economy devoted significant resources to medical technology improvements. Perhaps most significant was the introduction of sulfa drugs to combat infections and ultrasound, originally used to determine tank structural integrity after battles. Sulfa drugs helped turn hospitals from infection breeding institutions into patient treatment and improvement centers. Ultrasound ultimately became a routine pregnancy evaluation tool. These and other new technologies improved the quality of medical care, or the ***supply.***

Third, the Federal wartime wage and price freezes fostered the development of 'fringe benefits' and the entire benefits industry. That's the financing arm and it's a pretty interesting story.

The government implemented wage and price freezes during the War to avoid domestic economic difficulties and help focus our economy on war production. Employers, in other words, could not raise wages to attract new workers or to reward their best employees. But they could offer 'fringe benefits' such as health insurance. This allowed employers to attract new talent and retain their current employees without raising wages. The concept of 'fringe' meant 'outside the normal compensation' and 'benefits' meant 'advantages of working here'. Employers couldn't simply raise wages, the traditional way of attracting labor, since that was illegal during the war. Fringe benefits were a mechanism to get around the wartime wage freeze.

These 3 factors – increased demand, improved supply, and creative financing - led to a tremendous increase in our insured population. Some coverage data points:

1942: 10 million hospital insurance / health insurance subscribers

1946: 32 million

1951: 77 million[5] out of a total US population of 150 million.

The health insurance industry arrived, grew and gained political power.

[5] Richmond and Fein, The Health Care Mess pages 30 - 38

The Hill Burton Act and an IRS decision strengthens hospitals

Congress, just after World War II, passed the Hill Burton Act to fund hospital expansion. This increased the number of hospital beds in this country by about 40%, from 3.2 per 1000 people to 4.5. It also made hospitals the centerpiece of our medical care system; the travelling doctor who made house calls began to disappear.

Shortly thereafter, in 1953, the IRS decided that fringe benefits were exempt from federal income tax: those became *tax deductible to the employer* but *not income taxable to the employee.* This was essentially a government subsidy for hospital care since that's where most medical care took place. The government stimulated sales of commercial health insurance by subsidizing the price through the tax exemption.

This subsidy for health insurance was so effective that by 1963, 77% of us had hospital coverage, and about 50% had some form of physician coverage.[6]

- Employees liked the system because it appeared free to them.
- Carriers liked the system because the government subsidized their product, tax deductible health insurance policies.
- Hospitals loved the system because they received patients and insurance payments – a wonderful recipe for making money.
- Employers objected somewhat to this system, but not terribly strenuously. After all, the government subsidized their health insurance payments, so they felt the pain only partially.

Through this period, roughly 1930 – 1965, healthcare discussions generally focused on insurance coverage, medical technology, hospital capacity and access. Indeed, access issues took center stage in the mid-1960s because of the potential political power of the elderly and the poor, both of which were left out of the employer based financing system.

Medicare and Medicaid Remove Potential Political Threats to Employer Based Insurance

One potential political threat to our employer based health insurance system could have come from the unemployed – that significant percent of the population that was too old to work or unable to find full time work with benefits. This was potentially a very potent political force that could have lobbied in favor of single payer healthcare, universal coverage or similar, like in other countries.

[6] Enthoven and Fuchs, 'Employment Based Health Insurance: Past, Present and Future' Health Affairs, Nov/Dec 2006

By introducing Medicare and Medicaid in the 1960s, this political force went away. Elderly folks were happy. They didn't demand or need universal coverage because they had Medicare. Ditto the poor with Medicaid. No large, identifiable voting block favored a single payer, universal healthcare system post-Medicare and Medicaid. M & M took that potential voting block off the table.

Here is an estimate of the population size that these two entitlement programs satisfied. I'll use Medicare, because this covers the elderly who vote in particularly high numbers and in particularly important electoral states like Florida.

Medicare Enrollment 1970 – 2020

Year	Number Medicare Enrollees	% of US population
1970	20 million	10%
1980	28 million	12%
1990	34 million	13.5%
2000	39 million	13.8%
2010	47 million	15%
2020	58 million	18%

Medicaid covers about the same population size.

The argument is that Medicare and Medicaid are key supporters of our employer based, commercial health insurance system. They allowed the system to grow and become entrenched nationally in the second half of the last century.

Post passage of Medicare and Medicaid, i.e. by the late 1960s, healthcare costs and cost increases became an issue. Indeed, in 1969 Robert Finch, then Secretary of Health, Education and Welfare warned Congress that "the nation is faced with a breakdown in the delivery of health care unless immediate concerted action is taken by government and the private sector". Both costs and the very structure of our healthcare delivery system became a topic of national debate, leading to a reconsideration of vertical integration.

Nixon's HMO Act of 1973

Nixon had to do something to address the rising costs of healthcare, but felt politically wedged-in. He couldn't support a Democratic healthcare plan sponsored by one of his chief rivals, Ted Kennedy. Nor could support a Republican plan sponsored by another political rival, Nelson Rockefeller – especially a plan that potentially harmed the physicians, hospitals and insurance carriers that supported Nixon politically.

He chose, instead, to pursue Health Maintenance Organizations, then conceived as a prepaid healthcare system that would motivate doctors and hospitals to control costs

and keep patients healthy. Many conservative politicians and organizations agreed with the HMO idea because it was flexible, inexpensive, encouraged private investment in profit-making organizations and imposed few mandates or regulations. It sorta, kinda, almost resembled Baylor's original plan with the Dallas School System.

Nixon's plan faced opposition from both the left and right between 1970 – 1973. Kennedy and the Left consistently fought for higher levels of guaranteed benefits, community rating, open enrollment periods and significant Federal grants and loans to help HMOs proliferate. The American Medical Association and the Right wanted only basic levels of guaranteed benefits, less government funding and individual underwriting.

As a result of these competing pressures and Nixon's determination to implement his own plan (i.e. not Kennedy's or Rockefeller's), the HMO Act of 1973 deviated from our ideal vertically integrated model in three main ways:

First, under Nixon's law, HMO meant simply 'prepayment'. Healthcare delivery and healthcare finance were separate functions handled by separate companies. This satisfied independent insurance carriers, physician groups and general hospitals - all parts of Nixon's political base. But it lacked the key integration feature that made real managed care organizations like Kaiser-Permanente so successful.

Why did carriers, physician groups and general hospitals dislike vertical integration? The short answer: they wanted to compete for revenues with each other.

Carriers hoped to dominate the marketplace and dictate economic terms to providers. The American Medical Association wanted its members to remain free from carrier or hospital meddling so they could protect their incomes. Hospitals wanted to determine patient lengths of stay to protect their own cash flow.

None of these groups trusted the others or the government to protect their interests.

Second, Nixon's law called for a loose physician structure, in which practitioners could opt in or out of any HMO. Again, this satisfied the insurance, physician and hospital groups. But it was the opposite of vertical integration's tight structure in which physicians were fully integrated into both the hospital and financial system. The loose physician structure meant that providers lacked loyalty to any specific HMO.

Third, Nixon's law allowed providers to bill insurance carriers on a fee-for-service basis, not on a capitation basis.

In a capitated system, the vertically integrated HMO only received a specified amount of money per patient per year. The old Baylor – Dallas school system model charged $6 per employee per year. As long as Baylor University Hospital kept its costs below $6 per employee, it made money. But if Baylor's costs exceeded $6, it lost money and potentially went out of business.

Capitation, in other words, forced HMOs to control costs and use their resources efficiently. Absent capitation as in Nixon's Act, much of the underlying financial discipline disappeared.

These three factors – separate companies for finance and service provision, loose relationships between physicians and HMO entities and little-to-no capitation - drastically altered the original vertical integration model. Stanford Medical School Professor Alain Enthoven, for example, a key managed care theorist, argued in 1993, 'Some say that managed care has failed. I say that managed care has not yet been tried' since Nixon's HMO Act so perverted the vertical integration model.[7]

By the early 2000s, American healthcare had given up on the vertical integration / managed care approach in fact, if not in name, in favor of the fee-for-service based billing platform. Stanford's Enthoven articulated the fee-for-service flaws in his 2004 book 'Toward a 21st Century Health System' page xxix.

1. Fee-for-service creates an adversarial relationship between doctors and payers;
2. Fee-for-service has little accountability – poor data collection and provider motivations for economy;
3. Fee-for-service 'free choice of provider' leaves patients to make remarkably poorly informed choices;
4. Fee-for-service generates excess hospital capacity, high tech equipment and open-heart surgeries;
5. Fee-for-service generated an excess supply of specialists;
6. Fee-for-service misallocates resources, as no incentive to use the least costly settings for treatment;
7. Fee-for-service has no capacity to plan care processes from diagnosis to treatment to rehabilitation;
8. Fee-for-service has led to a dangerous proliferation of facilities for complex and costly procedures without the volumes necessary to maintain good outcomes;
9. Fee-for-service cannot practice total quality management due to lack of service integration;
10. Fee-for-service cannot organize the rational use of technology.

We created, in other words, a healthcare structural mess in our quest for patient choice, profits and jobs.[8]

Consumer Driven Healthcare to the rescue (or not)

[7] Enthoven, Why Managed Care Has Failed to Contain Health Costs, Health Affairs, 1993, paraphrased for context here.

[8] 'Mess' comes from the title of Richmond and Fein's 2005 book, The Healthcare Mess, op cit.

With the failure of the HMO movement, our commercial healthcare industry needed a new paradigm. One attempt was CDHC or Consumer Driven Health Care. The term ‘consumer driven health care’ arose from the Medicare Modernization Act of 2003 which established Health Savings Accounts.

‘Consumer driven products’ are high deductible health insurance policies with certain tax benefits. Each consumer spends the deductible as he/she sees fit, for physician visits, medications, tests, therapies etc. Only after satisfying the deductible does insurance pay. Then, depending on the specific plan design, insurance pays all or part of additional medical expenses.

CDHC policies embrace the notion of consumer sovereignty. Consumer sovereignty means each individual consumer makes decisions in ways he or she deems best for themselves; individual patient decision making for themselves, not physician decision making for patients would now drive our healthcare system.

Consumer driven healthcare implicitly accepts The Split between healthcare finance and service delivery as a given. Effectively, HSAs and the entire CDHC movement says ‘The Split exists and we can’t figure out how to fix the problems it causes, so we’ll turf the whole thing onto patients. Maybe they can rationalize our otherwise irrational system’. Maybe, in other words, they can make the system operate more ethically.

It didn’t go well.

Problems equating high deductibles with consumerism in healthcare

Consumer driven healthcare as practiced using Health Savings Accounts, similar tax-deductible programs, and medical care price lists fail in healthcare for two main reasons.

First, an annual $1000 deductible (or even $3000) is too small to act as a real medical spending brake. Once satisfied, and depending on the specific plan design, all other medical care is free.

A patient might satisfy that deductible hurdle in January and then enjoy lots of excessive and unnecessary medical care for free during the next 12 months. Patients could even ‘play’ the system by scheduling all their expensive medical treatments during the same calendar year.

Or the deductible has little impact on a patient facing an expensive procedure. What’s the difference to the patient if the procedure costs $45,000 …. $50,000….$60,000 or $100,000? Once the deductible is satisfied, the rest is free. ‘Consumerism’ fails to affect patient behavior in these expensive cases.

This fundamental flaw in the ‘high deductible = consumer driven healthcare’ thesis exists because the vast majority of healthcare spending goes to a very small group of

high cost patients. Here's spending by percentage of the population. These numbers have remained remarkably constant for years.

Healthcare Consumption by % of Our Population [9]

1% of our population accounts for about 24% of medical spending

5% of our population accounts for about 49% of medical spending

10% of our population accounts for about 64% of medical spending

50% of our population accounts for about 97% of medical spending

50% of our population also accounts for 3% of medical spending.

The healthiest half of our population costs very little medically. These are typically the folks who purchase CDHC products and who often spend less than $1000 annually. Cutting their spending by 20 or 30% would have virtually no impact on *overall* medical spending or trend.

Here's the same chart using 2022 spending amounts, not percentages. In 2022, total US healthcare costs reached about $4.4 trillion for the approximately 333 million of us. Though the average annual healthcare spending per person that year was about $13,400,

The 1% heaviest users (3.3 million people) averaged about $320,000 each;

The 5% heaviest users (16.7 million people) averaged about $129,000 each;

The 10% heaviest users (33 million people) averaged about $85,000 each;

The 50% lightest users (167 million people) averaged about $790 each.

Very few of the 10% of users who account for about 2/3 of all medical spending will change their medical choices based on a $1000 (or even $2500 or $5000) deductible. *Whatever* the deductible, their medical care needs far exceed it.

Second, medical consumers have little meaningful quality information, and even if they have it, they rarely know how to use it. This makes medical decisions different from, say, car purchasing decisions. The car buyer can compare the quality of various cars before deciding which to purchase. Large or small, good gas mileage or poor, lots of luxuries or few, high resale value or low, etc.

But the medical purchaser generally has very little similar information. Which doctor has the best outcomes? Which hospital? How effective is this medication compared to that one? We generally lack detailed answers to these questions.

[9] Yu, et al, 'Medical Expenditure Panel Survey Statistical Brief #81', May 2005, Agency for Healthcare Research and Quality

For these two reasons – unequal healthcare spending and lack of medical quality information / well educated medical consumers - so-called Consumer Driven Health Care had only a small impact on medical trend which has run at our gdp growth rate plus 3 – 5% annually for years. CDH policies became the vogue in the early 2000s. They pretty much ran their course within about a dozen years.

Americans continue to spend about twice as much on healthcare as other developed countries without getting any value for the excess spending, just as we did prior to CDHC policy introduction. Here are estimates for 2019, the last year before Covid hit and altered these statistics with a unique set of circumstances. (I don't know if or how Covid is representative of 'normal' healthcare trends, so I'll leave that out of this analysis.) [10] I could have included more countries but you get the idea from this limited comparison.

2019	Annual spending / capita	Life expectancy at birth
US	$10,855	78.8
Canada	$6,730	82.3
France	$4,014	83
Spain	$2,412	84
UK	$3,334	81.4

These other countries live 4 – 5% longer than us while spending about half as much on healthcare. We clearly haven't figured out how to generate good value for our healthcare system investment. We haven't figured out how to generate the greatest good for the greatest number.

The Affordable Care Act gives up on vertical integration in favor of wider coverage

The 2010 Affordable Care Act, a massive piece of legislation, is more-or-less a business plan for our entire healthcare economy.

Vast in scope and complexity, it's far too big to summarize quickly here. Instead, I'll focus only on 2 components: coverage expansion and patient decision-making assistance.

Why healthcare reform in 2009

[10] OECD Health Data statistic updated annually https://stats.oecd.org/Index.aspx?ThemeTreeId=9

President Obama decided to move aggressively on healthcare because of several disturbing trends. From 2000 - 2006

- Health insurance premiums rose by about 80% while
- Overall inflation only rose by 20%, but
- Median household income was actually down 3% in real (after inflation) terms.

Obama and his aides worried about two different health insurance death spirals especially affecting the individual and small group markets.

The **first** would occur when healthy people decide not to purchase health insurance, thus leaving only sick people in the insurance pool. Premiums would rise quickly forcing 'healthier' sick people opt out, leaving only the sickest of the sick still in. Health insurance then would become a payment program for sick people. It wouldn't, under these conditions, play its traditional role of protection against catastrophic financial calamity due to an unexpected illness for the vast majority of Americans.

The **second**, separate though somewhat related death spiral would occur when young people decide that health insurance is too expensive to purchase. Young 'Invincibles' – so called because they don't think they'll get sick – exit the market, leaving only older and more expensive participants in the pool. Again premiums rise, causing more and more young, healthy people to leave the pool and thus depriving the insurance pool of this healthy, inexpensive population.

Obama worried that continued economic stagnation - as began with the stock market crash in 2007 - would exacerbate both situations. Indeed, the number of uninsured had risen by about a million people per year from under 44 million in 2002 to over 50 million in 2009.

Among the reasons for this huge uninsured problem was our change in national economic circumstances. Our post-World War II economic dominance had lessened and along with it, businesses' ability to generate sufficient margin to cover all employee benefits. Employers responded to the changed economy by shifting benefit costs to their employees and outsourcing. That's why the percent of Americans covered by commercial / employer based health insurance shrunk from 59% to 48% between 2000 and 2020. Meanwhile, the number of Medicaid recipients and uninsured Americans grew. [11] (I included the 2020 numbers to show trend and the ACA impact.)

[11] Medicaid data from stasta.com https://www.statista.com/statistics/245347/total-medicaid-enrollment-since-1966/. Uninsured data from the CDC including https://www.cdc.gov/nchs/data/nhis/earlyrelease/insur201106.htm#:~:text=Results-,Lack%20of%20health%20insurance%20coverage,(Tables%201%20and%202) and https://www.google.com/search?q=number+uninsured+americans+2020&rlz=1C1ONGR_enUS1065US1

Year	Number of Medicaid Beneficiaries
2000	34 million
2010	54 million
2020	76 million

Year	Number Uninsured Americans
2000	39 million
2010	49 million
2020	32 million

Thus, the prime focus and effect of the Affordable Care Act was coverage expansion, perhaps somewhat ethical in that it provided a greater good – health insurance – to a greater number of Americans. I'm underwhelmed by the ethical achievement of giving more people financial access to our otherwise unethical system. Our overall life expectancy numbers – flat since 2010 - support this skepticism. See below pages 25 – 26.

One way the ACA addresses vertical integration and The Split

The ACA also, in a relatively hidden and small way, addressed problems cause by The Split between healthcare finance and service delivery. We have already discussed how this grew out of the Baylor – Dallas School System's initial commercial insurance venture, how Nixon attempted to put this genie back into the bottle, and how the introduction of Health Savings Accounts and similar products cemented The Split into our healthcare system architecture.

Section 3506 of the Affordable Care Act discusses Shared Decision Making. Here is the legislative summary:

> The purpose of this section is to facilitate collaborative processes between patients, caregivers or authorized representatives, and clinicians that engages the patient, caregiver or authorized representative in decision making, provides patients, caregivers or authorized representatives with information about trade-

066&oq=number+uninsured+americans+2020&gs_lcrp=EgZjaHJvbWUyBggAEEUYOdIBCDYwMzdqMGo3qAIAsAIA&sourceid=chrome&ie=UTF-8

> offs among treatment options, and facilitates the incorporation of patient preferences and values into the medical plan.

We can read this as an attempt to circumvent The Split by helping patients make wise decisions in conjunction with but not entirely based on, their physician's recommendations. It harkens back to Porter and Teisberg's position on the importance of publicly available outcome measurement and results reporting. The ACA in this section recommends that patients not rely blindly on their physician's advice for two main reasons:

> First, the ACA recognizes the economic reality of physicians providing excessive care – sometimes – in response to the economic incentives they face.
>
> Second, the ACA understands that preference-sensitive care exists.

Preference-sensitive simply means that various treatment alternatives often exist. Some patients might reasonably prefer orthopedic surgery while others, equally reasonably, might prefer physical therapy. Or medication vs. surgery. Or other options.

Section 3506 implicitly accepts The Split as reality and legislates a mechanism to ameliorate its most negative consequences.

Where We Are Today
Post HMO, post ACA, post Split

Managed care as vertical integration has disappeared from our healthcare landscape. Today, post-Consumer Driven Healthcare and post-ACA, we live in a fee-for-service based medical billing environment. Each individual actor in our healthcare system faces various economic incentives either to provide or control care severity; each individual patient is supposed to make wise healthcare decisions while relying on the advice of financially compromised actors.

We don't do this very well. At $4.4 trillion – our 2022 healthcare spending - our *healthcare* economy was larger than France's total gdp (about $2.8 trillion) or Britain's ($3.0 trillion) and about twice as big as Russia's ($2.2 trillion).[12]

We have the highest healthcare expenditures per capita or as a percentage of our GDP in the world. See below, a list of per capita healthcare spending in countries that live longer than the US national average or any individual US state average:[13]

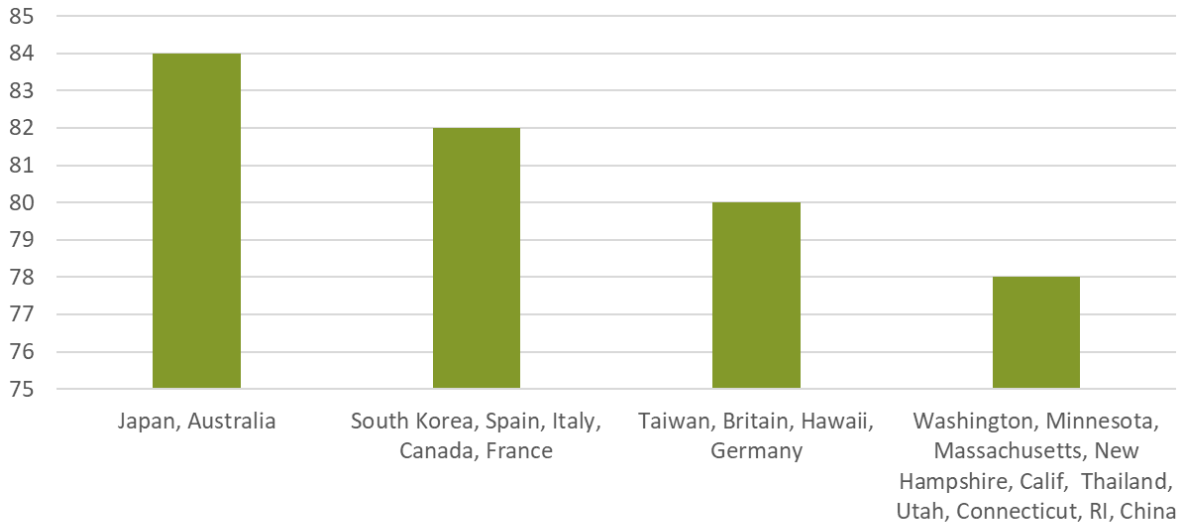
[12] World Bank, Gross Domestic Products 2022 https://data.worldbank.org/indicator/NY.GDP.MKTP.CD

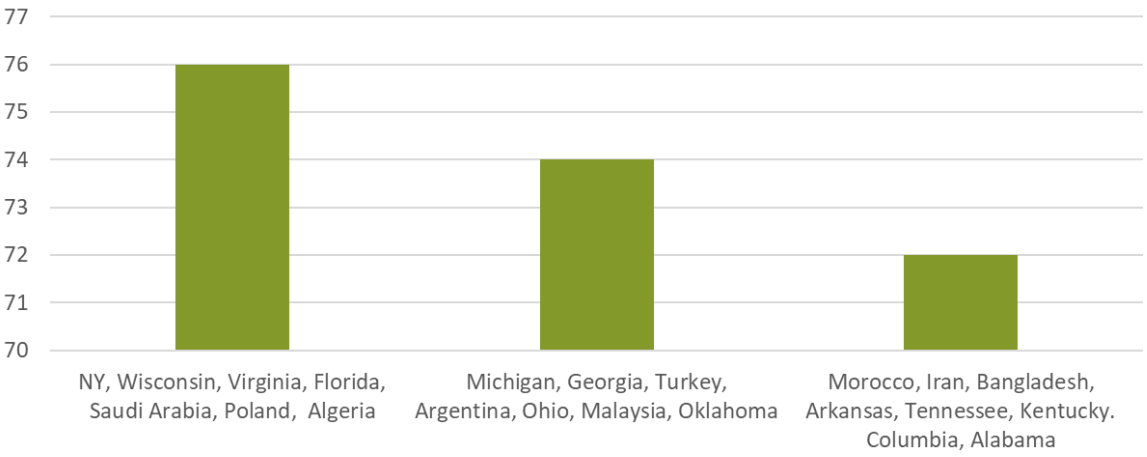
[13] Data from Statistica https://www.statista.com/statistics/236541/per-capita-health-expenditure-by-country/#:~:text=In%202022%2C%20the%20United%20States,highest%20per%20capita%20health%20expenditure.

Country	2022 per capita health spending
US	$12,555
Australia	$ 6,569
France	$ 6,516
Canada	$ 6,319
Japan	$ 5,250
South Korea	$ 4,569
Spain	$ 4,461
Italy	$ 4,290

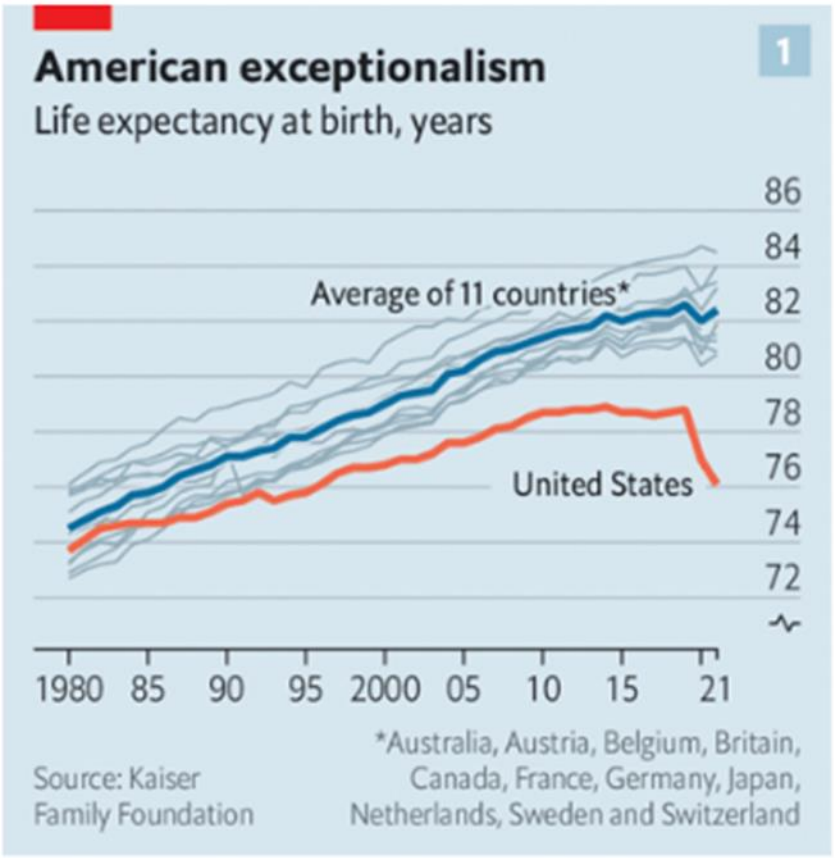
One way to see the magnitude of our healthcare system inefficiency is to see how those various countries compare to US state longevity at birth averages. These data were originally developed by the National Center for Health Statistics at the United Nations and presented by Nicholas Kristof in the New York Times, August 17, 2023. As you review these charts, consider this question: if private, commercial health insurance is as beneficial a system as its proponents claim, then why do we see such mediocre outcomes?

Average Longevity at Birth
Various countries compared to US States
Life expectancy in 2 year age bands on the left
‘82’ means ’82 – 84 years’; ‘78’ means '78 – 80 years’





Equally or perhaps more upsettingly, we have experienced **no** national life expectancy gains since about 2009, despite spending more each year on medical care. This differs from other advanced, industrialized countries. See the chart below published in The Economist, July 13, 2023. Note first that Americans, while spending more on medical care than the others, enjoyed shorter life expectancies. Equally interesting (upsetting), see the 2009 – 2020 period, before Covid, when our life expectancy was flat – despite spending more on medical care each year - while the others improved. Finally, note the relative impact of Covid on American and other life expectancies.



All this looks to me like a living, working, breathing definition of an ineffective, inefficient healthcare system. It *always* rewards the relatively few participants in it but only *sometimes* benefits the huge number of patients who need it.

Why do we have this spending-to-outcome discrepancy? Why does our largely private sector, commercial healthcare system perform so poorly?

Some Commercial Health Ins Structural Problems

Brokers know many of the specific problems that afflict our healthcare system. These range from complicated insurance rules that differ by carrier to complicated billing rules that differ by provider to complicated access rules that differ by policy, to many others. Additional system problems also include high overheads caused by having so many different insurance carriers, providers, treatments, medications and options. I originally thought about simply listing a bunch of problems that brokers face regularly and discussing some ethical issues that arise from dealing with them.

But let's go in a different direction. Instead of simply listing a bunch of problems, let's try to identify a core structural issue caused by The Split that underlies many – maybe even most – of these specific issues. This helps us address our ethical problem and understand why our commercial healthcare system fails to produce the greatest good for the greatest number.

We'll do all this by introducing an economic concept alternately called The Tyranny of Small Decisions or The Tragedy of the Commons. The first – the Tyranny of Small Decisions – often leads to the second, the Tragedy of the Commons.

Consider the visual image of a paradigm old English village to introduce these ideas. In this little village, a bunch of farmers lived in small houses around a central public open space called 'the Common' in which cows grazed. Each farmer had a cow or two and the Common provided sufficient room and grass for them all to graze and grow.[14]

Now imagine that our old English village prospered and grew. Families bought a second, third, fourth or fifth cow. New families moved in, each with a few cows. After a while the Commons became too small to support all these cows. Each individual cow lost weight and produced less milk. Villagers' incomes fell. The Commons became overgrazed. Its topsoil began to erode after each rain and eventually the grass disappeared. It ultimately became useless for grazing. We might call this the Tragedy of the Commons v1, in which everyone uses too many resources so there are not enough for all. [15]

In v1, each individual's small decision, made in each individual's own interest, diminished the overall good. The Tyranny of Small Decisions led to overgrazing and, in turn, to the Tragedy of the Commons in which everyone ended up worse off.

As an alternate version of this story, instead of each villager buying an extra cow, a new person moves to town with 30 cows. The Commons couldn't support this increase and

[14] Many New England towns have a Common today. Think of Boston Common or Cambridge Common in Massachusetts, places where cows grazed in colonial times but today are nice public parks.

[15] Apparently this happened to the Mayans in Central American centuries ago and the environmental degradation led to their civilization's destruction, though I'm not a Mayan historian. I did, however, enjoy a fascinating trip to Belize and Guatamela in 2020.

the tragedy unfolded. In the Tragedy of the Commons v2, one person consuming too much destroys the benefit that everyone enjoyed from their shared resource.

In either case, the Tyranny of Small Decisions, in which people individually made decisions to maximize their own welfare, led to overgrazing and, in turn, to the Tragedy of the Commons.

Another way to phrase this: the Tragedy of the Commons decreases the amount of good for the great number of people.

Let's update this to a real situation in Pomfret Vermont, 2023. Pomfret, a small town, apparently enjoys spectacular foliage each fall. [16] A relative handful of tourists annually enjoyed it. In 2021 or 2022 though, a Tic Tok influencer, apparently one of those tourists, broadcast descriptions of Pomfret's beauty to his or her audience. A few local inns also advertised the town's beauty. Thousands of tourists arrived. The town became overwhelmed. Among the problems:

- Tourists blocked Margarete Pierce's driveway, parked illegally on her land, and used her garden house as a toilet,
- Cathy Emmons watched tourists stroll onto her farm and steal tomatoes from her vine,
- Mike Doten got tired of pulling tourists out of ditches with his tractor.

According to the Boston Globe's description, 'The town's selectboard … voted to block the road to anyone except residents for three weeks at the height of the foliage season, from Sept. 23 to Oct. 15…Windsor County deputy sheriffs will staff checkpoints at the bottom of Cloudland Road in neighboring Woodstock and at the top of the road here in Pomfret." (I don't know how this is legal but that's a separate issue.)

The Tyranny of Small Decisions – individual publicity for individual interests - led to the Tragedy of the Commons, so now no tourists can enjoy Pomfret's beauty during foliage season.

The Tyranny of Small Decisions and the Tragedy of the Commons can provide a framework to understand many of our healthcare system problems. Let's explore some of them.

Medical Care Rationing. Rationing or 'the limiting of goods or services that are in high demand and short supply' per Investopedia, is a classic unintended, indirect consequence of the Tyranny of Small Decisions. We'll consider two case studies.

[16] This story comes from the Boston Globe, Sept 18, 2023 https://edition.pagesuite.com/popovers/dynamic_article_popover.aspx?artguid=04b5fe08-f5ff-489d-acbe-ae0c5035891e

First, pediatric bed rationing in Boston. Tufts Medical Center, Boston, closed its 41 bed inpatient pediatric unit in July 2022, then repurposed them as adult inpatient beds.[17] The justification, according to Dr. Daniel Rauch, Tufts Chief of Pediatric Medicine: “Should we take care of kids we don’t make any money off of, or use the bed for an adult who needs a bunch of expensive tests?...If you’re a hospital, that’s a no-brainer.”[18] Tufts could bill more for adults than kids. A small decision that clearly benefited Tufts’ bottom line. Pretty simple to understand.

But a local Tragedy of the Commons followed, documented with Boston Globe headlines like:

October 21, 2022:

Hospitals scramble to find beds as pediatric admissions rise

By Jessica Bartlett Globe Staff, Updated October 21, 2022, 8:08 p.m. 126

November 10, 2022

Hospitals postpone pediatric surgeries as capacity crunch escalates

By Jessica Bartlett Globe Staff, Updated November 10, 2022, 5:37 a.m. 25

Hospital executives said pediatric intensive care unit beds at Massachusetts General for Children were operating at 150 percent capacity, and there were few signs the surge was nearing an end.

December 11, 2022

Hospital finances play a major role in the critical shortage of pediatric beds for RSV patients

Health Dec 11, 2022 10:33 AM EDT

[17] Boston Globe ‘Who will care for our sickest children’, Oct 26, 2022

[18] NY Times As Hospitals Close Children’s Units…, Baumgaetner, Oct 11, 2022

This Commons Tragedy continued with higher prices. According to the Massachusetts Health Policy Commission report in September 2023, Children's Hospital and Mass General Brigham, representing about 73% of pediatric discharges in Massachusetts, have the highest commercial prices in Massachusetts. Among the data points in that report, the average commercial price per pediatric discharge at Boston Children's was 47 percent higher than at other state hospitals with significant inpatient volume, even after adjusting for the illness of the patient.[19]

Here, the few service providers benefit financially while the rest of us pay higher prices for the same care … if we can find it. Our national total number of inpatient pediatric beds fell by 19% from 2008 to 2018. The Tufts closing followed this trend. Pediatric hospitals have recently closed or partially closed in Richmond Virginia, Colorado Springs Colorado, Raleigh North Carolina, Doylestown Pennsylvania and Shriners New England because 'kids are not lucrative'. [20]

The Tyranny of Small Decisions – each hospital followed its own economic self-interest and closed less profitable beds in favor of more profitable ones to earn more money – led to a tragedy for the rest of us. A few service providers and investors made more money while many sick kids and their families suffered longer waits for care, longer ambulance or med flights to hospitals, higher prices and perhaps ended up medically much worse as a result.

Greatest good for the greatest number? I think not.

Second, maternity ward rationing in central Massachusetts and nationally. Leominster Hospital closed it maternity ward in 2023. Their justification: "reimbursement rates paid to hospitals for treating maternity unit patients on Medicaid are far lower than what private insurance plans pay" particularly harming Gateway cities like Leominster according to the Boston Globe's June 25, 2023 analysis.

Maternity beds in Gateway Cities were, in other words, unprofitable or at least less profitable than other types of hospital wards or other types of patients.

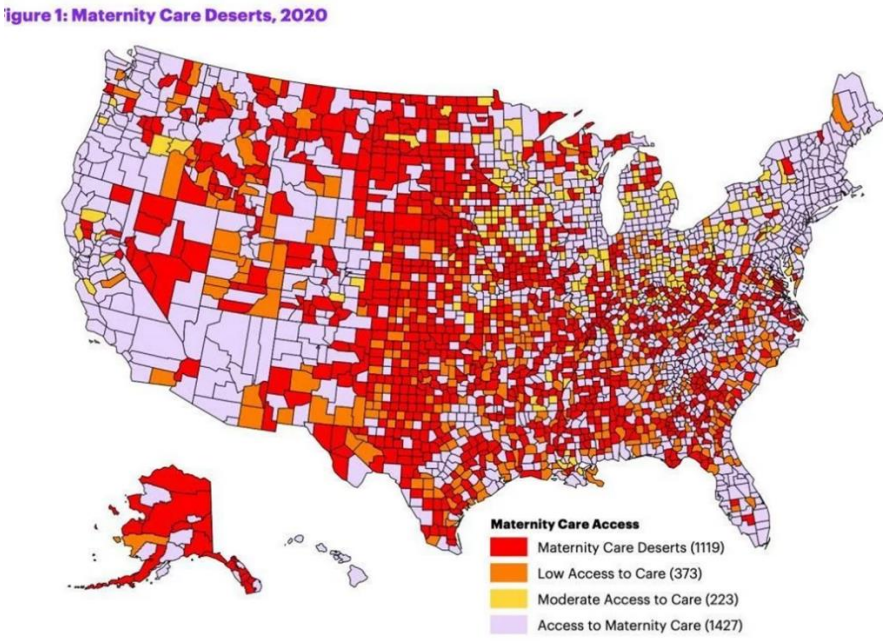
Leominster's closure also followed a state trend. Holyoke Medical Center closed its maternity center in 2020. Harrington Hospital in Southbridge closed its center in 2017.

And all this follows a national trend. According to the March of Dimes, the number of maternity deserts in this country – counties with no hospital providing maternity care, no

[19] Jessica Bartlett, Boston Globe, Sept 10, 2023

[20] Boston Globe 'Who will care for our sickest children', Oct 26, 2022

birth center, OB/GYN, and no certified nurse midwife – has increased over time, mainly in rural areas.[21] Here's their 2020 map



Pregnant women had to drive farther for their appointments and to give birth. This negatively affects them. Health Affairs reported that, after controlling for socioeconomic factors and clinical conditions, "rural residents had a 9 percent greater probability of severe maternal morbidity and mortality, compared with urban residents."[22]

Hospitals made more money – Tyranny of Small Decisions. Patients ended up worse off – Tragedy of the Commons. The same story unfolds time and time again, in specialty after specialty and treatment arena after treatment arena.

Let's switch focus now away from rationing and explore other clinical and ethical implications of the Tyranny and Tragedy.

Excessive care. Excessive care incentives so permeate our post-Split, commercially based healthcare system that Andrew Dreyfus, former CEO of Blue Cross Blue Shield of Massachusetts, claims healthcare today 'is designed around the needs of institutions and health professionals and not around the needs of patients'. [23]

[21] March of Dimes maternity desert report https://www.marchofdimes.org/maternity-care-deserts-report

[22] Rural-Urban Differences In Severe Maternal Morbidity And Mortality In The US, 2007–15, Health Affairs, December 2019

[23] Boston Globe, June 22, 2018

Excessive care through disease mongering. Disease mongering means hyping treatments for little known diseases, more or less advertising diseases for which your company has a treatment. This instills fear among patients, expands markets and positions your product as a solution. Look for disease mongering on TV ads and in your local newspapers.

I want to move on and discuss two other, related concepts: *overdiagnosis* and *overtreatment*. Overdiagnosis means broadening disease definitions so more people quality for medical care. Overtreatment means providing more care than necessary to patients. Both overdiagnosis and overtreatment can cause patients to experience higher care treatment risks and side effects without also enjoying higher chances of treatment benefit.

Excessive care through overdiagnosis. Overdiagnosis means broadening disease definitions so more people quality for medical care. According to H. Gilbert Welch, the overdiagnosis guru, it occurs "when individuals are diagnosed with conditions that will never cause symptoms or death."[24] Overdiagnosed patients, in other words, ***can't*** benefit from care because they weren't sick to begin with. But medical care providers, testers, drug manufacturers and similar *can* benefit financially by treating these patients. We'll consider just one example, overdiagnosis of hypertension.[25]

In 1997, the definition of hypertension (high blood pressure) changed from diastolic blood pressure of 160 over systolic blood pressure of 100 to 140 / 90. That immediately switched about 13 million people from having normal blood pressure to having high blood pressure, or, in our terms, increased the market for blood pressure lowering medications by 13 million people.

The definition of hypertension changed more times, always increasing the number of people so-diagnosed. In 2017, for example, the American College of Cardiology and American Heart Association redefined hypertension as greater than 130 / 80, again increasing the number of hypertension patients and the market for hypertensive medications. I don't know how many people this affected.

During this time period, sales of ACE inhibitors, medications to treat hypertension, grew at an annual compound growth rate of 5%, hitting $6.9 billion in 2023. Ditto for various other anti-hypertensive medications. The hypertension redefinition appears to have stimulated these medication's sales (or, at least, didn't hurt) and again, benefited a few participants in our healthcare system.

Did the redefinition help the Commons? First, some data. The age adjusted heart disease mortality rate fell in this country from 170.5 per 100,000 in 2012 to 161.5 in 2019 or, using my back-of-the envelope calculation, by about 30,000 people annually

[24] H. Gilbert Welch, Overdiagnosed, page xiv

[25] This case study comes largely from Welch, Overdiagnosis pages 20 - 23

nationally.[26] 30,000 fewer deaths divided by 13 million new patients = about 0.2% benefit. That's two tenths of one percent. About 99.8% of the newly diagnosed patients did not benefit from the new hypertension definition while 0.2% did. Maybe. That's the most optimistic reading of these data.

This interpretation assumes the redefinition itself led directly to the 30,000 fewer deaths. We don't know that to be the case. The entire mortality decrease could have been caused by other factors – less smoking, better diets, better overall physician advice or something else. We just don't know. At best 0.2% of the newly redefined-as-sick folks benefited from the redefinition. Perhaps none did.

All this raises some troubling questions, including

- How impactful were the redefinitions in preventing heart disease deaths?
- How impactful were ACE inhibitors in reducing heart disease mortality?
- How important were other medications?
- How many people were harmed either physically, emotionally, or financially by taking these medications after they were redefined as 'sick', not 'normal'?
- Could we have reduced heart disease mortality by a similar amount in less expensive ways than redefining at-risk folks and prescribing medications for them?
- Did the increase in hypertension medication sales and associated corporate profits affect the new hypertension definition?

A disturbing consideration of this last point comes from Otis Brawley, former Chief Medical and Scientific Officer of the American Cancer Society in his book How We Do Harm. He suggests that of our 555 guidelines (555!) for treating hypertension, "some are self-interested and harmful. Many are commercial documents"[27] meaning they're designed to sell products, more-or-less a form of disease mongering. No one, according to Brawley, promulgates good practices for guideline composition or hypertension redefinitions. Might the 1997 and other redefinitions reflect commercial pressures? Might this simply be the Tyranny of Small, Self-Interested Decisions on the part of hypertension treaters?

All we know for sure is that more Americans are now diagnosed with hypertension and that a very small percent of them benefit from redefinition as measured by age adjusted mortality rates per year. Medical statisticians could parse this analysis far better than I – this is simply an introductory overview – but at first cut, a 2/10s of 1% benefit rate appears underwhelming or, in our terms, like overdiagnosis.

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[26] Mortality rate data from the National Center for Health Statics, part of the US Centers for Disease Control and Prevention https://www.cdc.gov/nchs/hus/topics/heart-disease-deaths.htm

[27] Brawley, How We Do Harm, page 243

But the drug makers, labs and related folks made more money.

We could expand this analysis, as Welch did in Overdiagnosed, to include hyperlipidemia (high cholesterol), diabetes, osteoporosis in women and many more. I hope, though, this one example can suggest what overdiagnosis is, why it's a systemic problem and, more directly for our purposes today, why it's an ethical one for brokers.

Excessive Care Through Overtreatment. Overtreatment means providing more care than necessary to patients. Patients can't benefit from overtreatment by definition; overtreatment is care that does not provide benefit. But patients can be harmed by it because all medical treatments involve some element of risk. The more care someone receives, the higher the chance of risk. An overtreated patient gets all the risks without the possibility of benefit.

But the overtreatment *providers* still get paid.

Consider coronary stents as one overtreatment example. According to research from the Lown Institute, between 2019 – 2021, US hospitals performed over 229,000 unnecessary coronary stent procedures, or about 1 every 7 minutes. [28] That's about 22% of all coronary stents and the unnecessary care cost Medicare alone up to $2.4 million. Rates of overuse varied widely by hospital: at some, more than 50 percent of all stents met criteria for overuse, while at others, fewer than 5 percent were unnecessary.

In all cases, the providers got paid – an economic incentive-based Tyranny of Small Decisions. But 229,000 people undertook the procedure risks without much or any likelihood of benefit because the stent was unnecessary, and everyone's health insurance premiums increased. An economic cost and tragedy for the rest of us.

Let's move from a specific to the general case and estimate the size of the overtreatment problem from a 2017 physician survey published by PLOS, an online medical journal. [29] According to physicians themselves, 20% of all medical care is unnecessary, including 22% of prescription drugs, 25% of tests and 11% of procedures. Among the most common excuses for this by the physicians were fear of malpractice and patient pressure or demands. In other words, in our post-Split healthcare system, no one pushes back sufficiently aggressively when patients want unnecessary treatment. That opens the door to our Tyranny and Tragedy.

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[28] Lown Institute Hospital Index 2023, Avoiding Overuse: Coronary Stents. https://lownhospitalsindex.org/avoiding-coronary-stent-overuse/ Lown defines overuse as inserting stents in patients with a diagnosis of ischemic heart disease at least six months prior to the procedure, excluding patients with a diagnosis of unstable angina or heart attack within the past two weeks, and excluding patients who visited the emergency department over the past two weeks.

[29] https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0181970

By contrast, in a vertically integrated system where healthcare finance and service delivery are the same company, there is a brake on overtreatment; the finance arm, in its desire to keep premiums competitive, won't allow it. Unfortunately, though, today in much of America, one large hospital system typically controls 50-75% of the beds in a region, while the largest insurance carriers in a region – organizations potentially able to push back on overtreatment – typically only have about a 15 – 30% market share. This unequal playing field contributes to our unnecessary care problem; organizations incentivized to provide more care dominate.

One personal experience with overtreatment. I had a sore ankle in September 2023 that felt tight early in the morning, then loosened up during the day. I felt under time pressure to resolve the issue as I was going hiking with my kids in November, about 6 weeks in the future. I first tried rest but that didn't work. I then considered my treatment options:

- Option 1, see an orthopedist. That would take a couple months as orthopedists typically book weeks or months in advance. I suspected there was insufficient time to pursue this option. The orthopedist would probably (my uninformed guess here) want to run some tests, then have me return for a second visit and maybe prescribe therapy or medications (my guess again). I expected that the orthopedist would resolve my ankle pain problem but, most likely, after I returned from my hiking vacation.
- Option 2, see a physical therapist. My limited experience with PT suggested that I would visit once or twice a week for a few weeks. My experience also suggested that the therapy would work. I decided to keep this option on hold.
- Option 3, see my local chiropractor. Note here that I am not a shill for the chiropractic industry and do not understand anatomy; I'm just a commentator here. However, I like chiropractic primarily for one, virtually overwhelming reason: I can get an appointment in a day. Plus it's cheap. I had no idea if chiropractic would resolve my ankle pain problem, but I figured 'why not?'. Very low risk. I could learn quickly – in one afternoon since my chiropractor is about 15 minutes from my house – if chiropractic could help and it only cost $8.80 for a copayment. I figured it was worth the time to find out.

My chiropractor felt my ankle, gave me a couple stretches, and sent me home with 'come back if you still feel pain next week'. I did the stretches a couple times and, astonishingly to me, the pain disappeared. Problem solved. In one day. For $8.80.

Would the physical therapist or orthopedist have overtreated my problem? It certainly seems likely to me though I can't know for sure. But I feel like I maneuvered around the tyranny of their own small, incentive based decisions for my own benefit.

Excessive care through lack of high quality, randomize, comparative studies. We'll first discuss Vitamin D supplements to prevent bone fractures or extend life.

Millions of Americans take vitamin D supplements and labs run 10 million vitamin D level in patients tests every year.[30] Vitamin D sales and testing has become a billion dollar industry with about 25% of Americans over age 60 taking vitamin D supplements.[31]

Though use of vitamin D supplements may make biochemical sense – the body needs vitamin D to help it absorb calcium, a mineral necessary for strong bones – a 2022 comparative study of 25,000 people with half taking the supplements and half taking a placebo found little-to-no benefit to the vitamin D supplements.[32] Indeed and perhaps more interesting from our perspective, that 2022 study found that 'no large randomized, controlled trials had previously tested the effects of daily supplemental vitamin D alone (without coadministered calcium) in preventing fractures in the U.S. population.'

Why were there no studies on such a widely prescribed vitamin? One answer may be that the American Clinical Laboratory Association, the trade association for the laboratory and diagnostic health industry, spent around $1 million on political lobbying annually since 2014 [33] though I don't know exactly where all this money went.

Another answer may be that the Endocrine Society – the leading organization in the fields of endocrinology and metabolism according to Wikipedia, that 'influences a wide range of policies' according to its website [34] – argues that "vitamin D deficiency is very common in all age groups" and advocated a huge expansion of vitamin D level testing in patients in the 2010s.[35] Though the Endocrine Society's financial lobbying is relatively small, only about $120,000 in 2020 for example, it plays a large role in 'helping to shape healthcare and research policy in the US and around the world' according to its website.[36]

A third answer maybe be that 'it's obvious' that vitamin D helps people, based on a simplistic, linear, biochemical analysis. 'Bones need calcium, vitamin D helps bones absorb calcium so vitamin D supplements will help bones remain strong'. If only the human body was so simple! We have an extensive history of *medical reversal* in this

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[30] Gina Kolata, Study Finds Another Condition that Vitamin D Pills Do Not Help, New York Times, July 27, 2022

[31] Szabo, Selling American on Vitamin D, Kaiser Health News, August 20, 2018, https://www.nbcnews.com/health/health-news/selling-america-vitamin-d-reaping-profits-n902276

[32] LeBoff et al, Supplemental Vitamin D and Incident Fractures in Midlife and Older Adults, NEJM, July 28, 2022.

[33] Open Secrets https://www.opensecrets.org/federal-lobbying/clients/summary?cycle=2022&id=D000023934

[34] https://www.endocrine.org/advocacy

[35] Szabo op cit

[36] https://www.endocrine.org/advocacy

country; medical reversal means 'high quality comparative studies show that something that makes sense in theory does not provide patient benefit in real life'. See Ending Medical Reversal by Adam Cifu and Vinay Prasad for more on this.

I'll go out on a limb now and suggest that the financial lobbying impact of the American Clinical Laboratory Association, plus the intellectual clout of the Endocrine Society, combined with the 'obviousness' of vitamin D's benefit, supported an environment for continued vitamin D level testing in patients and supplement prescriptions, *always* to the economic benefit of the industry but *only sometimes*, if ever, to the medical benefit of patients. That's one impact of our profit motivated, private sector based medical industry post-Split.

We'll switch focus now to discuss excess care and medical spending on over-the-counter-decongestants**.** The US over-the-counter decongestant market was worth about $1.8 billion in 2023,[37] including common, over-the-counter medications such as Sudafed PE, Vicks Nyquil Sinex Nighttime Sinus Relief and Benadryl Allergy Plus Congestion. The problem with these and similar phenylephrine-based medications: they don't work. That's the unanimous conclusion of an FDA panel that reviewed several existing studies of phenylephrine-based medications in September 2023.

From our point of view, though – the impact of private sector medicine's lobbying for its own financial gain and not necessarily for patient benefit - the back story of how ineffective medications came to market and remained on the market so long is more compelling than the scientific analytics.

We begin in 1976 when the (then new) Food and Drug Administration adopted a 'safe and effective' standard for medications. [38] After an initial purge of unsafe or ineffective drugs in the 1970s, the agency's approval criterion morphed, in real life, from 'safe and effective' to 'safe' with few if any drugs were removed from the market during the ensuing 50 years due to their lack of effectiveness. The agency apparently lacked the resources to police medications as rigorously as, perhaps, it would have liked, and so focused more on product safety.

We'll jump ahead 30 years, bypassing drug reformulations and FDA oversight issues, to 2007 when two University of Florida researchers, Leslie Hendeles and Randy Hatton, filed a citizen's petition for the FDA to review various phenylephrine-based medicine studies. Hendeles and Hatton had themselves reviewed dozens of original studies and determined that over-the-counter, phenylephrine-based oral decongestants performed no better than a placebo. In other words, these medications were safe but ineffective. The FDA, in response, assembled the Non-Prescription Drug Advisory Committee

[37] Berkeley Lovelace Jr, FDA Panel Says Common Over-The-Counter Decongestant Doesn't Work, NBC News, September 12, 2023

[38] Much of this section comes from Haley Weiss, With the Decongestant Snafu, the FDA Tries Something New, Time, September 14, 2023

(NDAC), composed of petitioners, manufacturers and the Consumer Healthcare Products Association, the industry trade group. The NDAC decided that the evidence on phenylephrine was “suggestive of efficacy” so left these drugs on the market. (I’m not sure what ‘suggestive of efficacy’ means, especially after years of patient utilization. ‘Suggestive of efficacy’ is not a standard statistical, regulatory or legal concept.)

Fast forward 8 more years and several new studies, and Hendeles and Hatton again filed a citizen’s petition, this time to remove phenylephrine-based oral decongestants from the market. The FDA reviewed the newest information, this time with enhanced powers granted to it by the Coronavirus Aid, Relief, and Economic Security Act, passed in 2020. Post-2020, the agency could more easily revise over-the-counter approvals and recommendations.

That brings us to September 2023 when an advisory panel to the FDA concluded that phenylephrine-based oral decongestants are ineffective, more-or-less returning to the 1976 ‘safe and effective’ standard. During those 50 years, Americans took a safe but ineffective medication thanks, in part, to weak FDA oversight (lobbying impact?) and weak regulations (lobbying impact?).

> I left out the history of Schering-Plough, since bought out by Merck and the maker of Claritin D. Their internal studies showed that phenylephrine-based oral decongestants were, in fact, ineffective. That’s why they continued making Claritin D, a prescription medication, and didn’t switch to a phenylephrine-based over the counter formulation. The Schering-Plough story suggests that the pharmaceutical industry knew of phenylephrine-based oral decongestant ineffectiveness but still promoted the medications to patients.

The net result of that 50 year lag, according to Hendeles and Hatton:

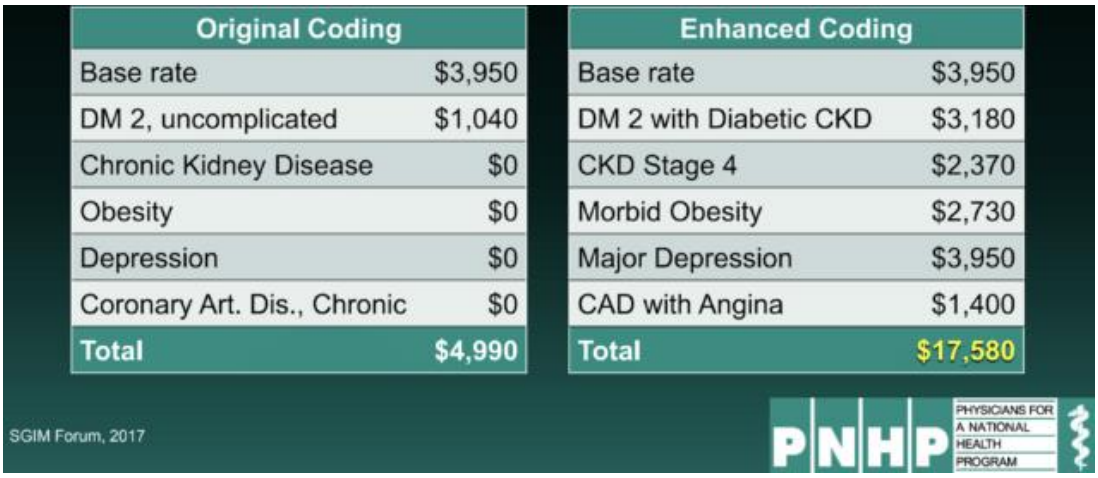
> Americans spend billions on drugs that contain ingredients that will not help them. That’s not just a waste of money — it could mean they are delaying appropriate treatment, which can lead to more severe illnesses.

But the OTC drug provision industry made billions thanks, in large part, to their industry lobbyists.

Excess billing. Somewhat like the excess care problems, our post-Split healthcare system allows for excess billing. In this excess billing case, patients don’t gain additional benefits – they (or their insurance carrier, which ultimately means their premiums) just pay more for the same care…at best. The excess billing problem may ultimately lead to overtreatment.

In our non-vertically integrated, post-Dallas healthcare system, providers typically bill by code. We have, in this country, thousands of codes, many subject to interpretation. The Physicians for a National Health Plan offers one example, below, showing the difference

in potential billing for the same patient.



The players in our health insurance melodrama understand this, as do investors like private equity firms. Private equity firms purchased 355 physician practices between 2013 and 2016 and 578 between 2017 – 2021. Individual physician practices can have dozens or hundreds of doctors. [39]

Private equity investors seek high returns from their investments, up to 20% annually according to some estimates. Our post-Split healthcare system offers only 3 ways to accomplish this: see more patients, provide more treatments and/or bill at higher rates. PE owned firms apparently do all three, according to research published the Journal of the American Medical Association in 2022. [40] That study noted "Following a private equity acquisition, physician practices saw a 20.2 percent increase in charges per claim…and a 37.9 percent increase in new patient visits." Additionally, PE owned firms generated a 16% increase in the total number of encounters. (Encounters = lab tests, imaging, procedures).[41]

Little to none of this helps patients get healthier (personal opinion and probably an overstatement) while all benefit system participants – physicians, nurses, private equity investors, drug companies, etc - just like Andrew Dreyfus observed. This helps explain why we enjoy more healthcare spending year over year, while failing to enjoy improved outcomes as measured by increased longevity.

[39] Robert Pearl, Private Equity And The Monopolization Of Medical Care, Forbes, Feb 20, 2023

[40] Association of Private Equity Acquisition of Physician Practices With Changes in Health Care Spending and Utilization, JAMA, Sept 2, 2022.

[41] Discussion with Jane Zhu, co-author of the JAMA study and assistant professor of medicine at Oregon Health & Safety University https://www.opb.org/article/2022/09/16/what-happens-to-healthcare-spending-and-use-under-private-equity-ownership/

Medical procedure approvals. Let's turn now to a case study of spinal fusion surgery research and information dissemination to see how the Tyranny of the few can affect the well being of the Common. This comes from research published in Scientific American[42] by two researchers, Sanjaya Kumar, Chief Medical Officer at Quantros, a healthcare analytics company, and David Nash, dean of the Jefferson School of Population Health at Thomas Jefferson University.

We'll start in the 1990s when the Federal Agency for Health Care Policy and Research (now the Agency for Healthcare Research and Quality) released findings from a five-year investigation of the effectiveness of various treatments for low back pain. Here's Kumar and Nash's summary from their Scientific American article:

> Between 1989 and 1994, an interdisciplinary Back Pain Patient Outcomes Assessment Team (BOAT) at the University of Washington Medical School in Seattle set out to determine what treatment strategies work best and for whom. Led by back expert Richard A. Deyo, MD, MPH, the team included orthopedic surgeons, primary-care physicians, physical therapists, epidemiologists and economists. Together, they examined the relative value of various diagnostic tests and surgical procedures.
>
> They conducted a comprehensive review of clinical literature on back pain. They exhaustively examined variations in the rates at which different procedures were being used to diagnose and treat back pain. Their chief finding was deeply disturbing: what physicians thought worked well for treating low back pain doesn't. The implication was that a great many standard interventions for low back pain may not be justified. And that was immensely threatening to physicians, especially surgeons who perform back operations for a living.
>
> Among the researchers' specific findings: no evidence shows that spinal-fusion surgery is superior to other surgical procedures for common spine problems, and such surgery leads to more complications, longer hospital stays and higher hospital charges than other types of back surgery.
>
> Disgruntled orthopedic surgeons and neurosurgeons reacted vigorously to the researchers' conclusion that not enough scientific evidence exists to support commonly performed back operations. The surgeons joined with Congressional critics of the Clinton health plan to attack federal funding for such research and for the agency that sponsored it. Consequently, the Agency for Healthcare Policy and Research had its budget for evaluative research slashed drastically.

[42] Kumar and Nash, 'Myth: There is a high degree of scientific certainty in modern medicine', Scientific American, March 25, 2011.

> The back panel's guidelines were published in 1994. Since then, even though there are still no rigorous, independently funded clinical trials showing that back surgery is superior to less invasive treatments, surgeons continue to perform a great many spinal fusions. The number increased from about 100,000 in 1997 to 303,000 in 2006.

In 2023, twelve years after Kumar and Nash's Scientific American article, I searched for rigorous, independently funded clinical studies on back surgery. The most recent available was a 2018 summary of the evidence about spinal fusion surgery. Those researchers concluded "We found no high-quality systematic reviews and the risk of bias of the randomized controlled trials in the reviews was generally high." [43]

I also googled 'number of spinal fusion surgeries per year' and learned from various sources, that we in the US experienced 500,000 in 2011 and 1.3 million in 2021, though that later number may include a wider definition. [44] These procedures cost about $50,000 each for an annual national total of perhaps $68 billion.[45]

Since the Baylor – Dallas School System initial foray into health insurance, medical providers, suppliers, financiers and others have made Small Decisions for their own financial benefit. Many have harmed The Commons. That's the tragedy of commercial health insurance today.

[43] Harris, et al, Lumbar spine fusion, what is the evidence? Internal Medicine Journal, Dec 5, 2018

[44] iData Research 8/16/23

[45] Cost of spinal fusion surgery in the 30 biggest US cities, Becker's Spine Review, Carly Behm, Feb 21, 2022 https://www.beckersspine.com/spine/53684-cost-of-lumbar-spinal-fusion-in-the-30-biggest-us-cities.html . Boston's cost was $50,150

Employer Based Health Insurance Features and Issues

The US is the only advanced industrialized country to finance medical care primarily through employment. Most other countries use employer based financing either to supplement a national healthcare system (e.g. the United Kingdom) or ban it from competing with the national system (Canada).

About 160 million Americans receive health insurance from work. That's about half of our population. The other half either receives health insurance through a government program – Medicare, Medicaid for example – from a state exchange or is uninsured. About 30 million Americans are medically uninsured.

Employers who offer health insurance worry about the costs. They need to balance their firm's financial health with their employee's medical health so provide plans that are good enough to comply with the various state and federal regulations and provide satisfactory employee coverage without costing too much. It's a delicate and confusing balance.

Employees should also worry about their employer's health insurance costs but too few actually do. Most employees think health insurance is a 'benefit' – a freebie that the employers offer. Labor economists virtually universally reject this assumption. They claim that the actual cost of each employee is the total of salary plus benefits, so if the employer pays less in benefits, the employee will receive more in salary.

In other words, the employee actually pays for employer-based health insurance via foregone wages.

Employer based health insurance has set the paradigm of healthcare financing in this country. We rely on 1 year long insurance policies to finance medical care even though 70% of healthcare spending goes to chronic disease treatment, i.e. treatments that take longer than 1 year. This sets up a fundamental inefficiency, treating long term problems with short term financing, a mismatch resulting in higher costs and, apparently, poorer outcomes than optimal.

Other healthcare financing systems, most notably Medicare, follow this one year long policy format. I'll discuss this in more detail below.

Three structural problems with employer based healthcare financing
#1: Moral hazard

Our employer based system finances all medical care with **insurance** rather than **payment plans** probably for historical reasons that we'll discuss shortly.

This confuses *insurance* (protection against financial harm caused by random events) with financing normal, routine and expected medical events like flu shots and knee replacements.

Compare health insurance to auto insurance. Auto insurance pays for *un*expected events, like crashes; it doesn't pay for expected events like oil changes, tire rotations or transmission rebuilds. Yet we expect health insurance to cover all medical events, from the most routine and predictable to the most random and unpredictable. This leads to enormous inefficiencies because, many argue, insurance is the wrong financing mechanism for routine medical events.

- Insurance pools risk inefficiently based on timing; those *not having* medical events this year pay for those having.
- This suppresses any market mechanisms from pooling more efficiently and developing better, more targeted, more actuarially based medical financing products - orthopedic payment plans for example, or pediatric immunization payment plans.

  We can imagine lots of medical payment programs, underwritten and priced for individuals or banded for groups. Middle aged men might buy 5 or 10 year orthopedic and urologic plans but not birthing; younger women the opposite.

  This kind of program pools need more efficiently than blanket insurance plans that cover every possible medical situation, for all people, that might occur this year. 'Insurance' then provides a safety net for the unexpected or random events not covered by specific payment plans.[46]

A fundamental problem using insurance to finance all medical activities is **moral hazard**. Insurance programs *always* face concerns about moral hazard. Moral hazard is the phenomenon in which people get more care than they need because it appears free to them. Insurance financing that includes this moral hazard component is a great foundation for a healthcare jobs program but a poor one for an efficient medical care financing system.

The moral hazard concept originated when home fire insurance was developed centuries ago. Underwriters were concerned that people with 'poor moral character' would burn their houses to collect the insurance proceeds then rebuild a less expensive house and pocket the difference. This translates in the health insurance arena to people having tests and treatments because –why not? It's free to me and may offer some benefits.

Medical care providers understand this issue and can generate income from it: 'let's send you for another test just to rule something out. Don't worry – it's covered by insurance' and medical testing and treatment industries develop. Dr. Sandeep Jauhar, Director of the Heart Failure Program at Long Island Jewish Medical Center, has written

[46] Regina Herzlinger has written extensively and creatively about this type of program. See especially her book Who Killed Healthcare.

eloquently and painfully about this. Consider these various quotes from his 2014 book Doctored:

> Bob and Joe and Dave have an unwritten agreement to call one another when patient issues arise outside their scope of expertise. If Bob, the nephrologist, sees a patient, he finds a cardiac and a gastrointestinal issue and consults the other two specialists and vice versa…a mutual scratching of backs…**Insurance companies can restrict medications, tests and payments. But they still cannot tell us who or when we can ask for help.** (page 97, emphasis added)
>
> A large percentage of healthcare cost is a consequence of induced demand – that is, physicians persuading patients to consume services that they would not have chosen if they were better educated. (page 107)
>
> [Describing one particular physician] …he was doing a plethora of tests – eye exams, audiometry, pulmonary function tests, even Holter monitoring – to generate revenue … he avoided the high-risk cases… 'Those we would send to a cardiologist' …[and, quoting a gastroenterologist] 'If a doctor doesn't do excess testing, forget it, he isn't going to be able to live.' (page 167)

Dr. Jauhar's unsettling conclusion about the impact of moral hazard:

> In our healthcare system, if you have a slew of physicians and a willing patient, almost any sort of terrible excess can occur. (page 94)

Others have, of course, also written expansively about the impact of moral hazard on our healthcare system. My point in this discussion: by relying on insurance to finance all aspects of healthcare, the employer based model exacerbates, rather than ameliorates, this problem. By basing our entire healthcare financing system on and around the employer model, the moral hazard problems permeate all aspects of American healthcare financing, creating more healthcare jobs and less healthcare value.

While we can't calculate an exact cost of moral hazard in our healthcare system, credible research suggests that 30% + of all medical spending is wasted on unnecessary care. That's generally estimated at about $700+ billion annually or $2500+ per employer based policy. The Dartmouth researchers primarily responsible for that estimate, though, are quick to note that we 'view these as an underestimate given the potential savings even in low cost regions' [47] meaning that even they have no real solid idea how much moral hazard exists in our system.

But they and others admit that it's a lot.

[47] Dartmouth Atlas of Healthcare, Reflections on Variation, answer to the question 'The Atlas is often cited as a source for the estimate that 30% of the nation's spending is unnecessary --- what is the evidence? http://www.dartmouthatlas.org/keyissues/issue.aspx?con=1338

A very lot.

Structural problem #2: Disconnecting payers from users

Payers in the employer based model are employers, often acting through their benefits department. Payers decide what network size employees want, what deductible levels, what drugs to include in the formulary and what copayments to have. This is particularly true in small companies covering the bulk of American workers that may offer only 1 policy to all employees.

Consider the impact of payer's decisions. A company opting for a wide provider network decides that each employee would prefer *paying more for health insurance* to *having more disposable income available* (and using a smaller network).

Or a company opting for a smaller network decides that employees prefer *more disposable income* to *having the most expensive doctors and hospitals available in-network.*

Employees, though, are the consumers and each may seek different things from our healthcare financing system. One may want higher deductibles or lower, wider networks or smaller, bigger drug formularies or not. Each facing his or her own specific medical issues can reasonably have his or her own set of preferences.

We call this 'consumer sovereignty' meaning that the most efficient economic distribution system is one in which consumers express their desires through purchases. We have seen this work quite effectively in other markets for hundreds of years.

Take the grocery market for example. A typical supermarket has thousands of products available because some people like expensive cuts of meat while others are vegetarians. Some people like ice cream while others are lactose intolerant. Some people like rye bread, others white bread and still others prefer bagels. And so on, for canned foods, soups, fruit and many other food products.

Our food distribution system is 'efficient', or so goes the argument, because individual consumers, casting their own dollar-votes, decide which products should be available and how much shelf space stores should allocate to each product. As consumers demand more soup, the store supplies more soup. Ditto for apples, mangoes and bread.

Imagine the impact on our food choices if these decisions were made by your employer! 'Apples are good for my employees, so stock a lot. Cut down on cookies and fatty meats. And, since more and more people are lactose intolerant, switch to carrying more skim milk.' (As if your employer had any interest in making those decisions. Your employer wants to make and sell widgets, not decide what you should eat. Hmmm, sounds like healthcare, doesn't it?)

Restrictions on consumer sovereignty lead to higher prices, less choice and sometimes poorer quality. Would apple producers focus as much energy on their product quality if they knew that all stores had to buy more apples from them? Maybe – or maybe they'd focus more on quantity and price.

In the employer based health insurance model, consumers have far less sovereignty than many would like, since benefits administrators make many of their key consumption decisions. But remember the economic axiom: the more consumer sovereignty, the more efficiency. And vice versa.

Structural Problem #3: One year long policies

Some 70% of healthcare expenditures go toward chronic, long term and on-going medical care as opposed to episodic, acute care. A chronic condition is, for example diabetes and an on-going care example might be post-operative cancer treatment. Dozens more examples exist. The best outcomes result from continuity of treatment from the same provider. Medically, thus, *long term financing programs* tend to generate the best outcomes, generally at the lowest costs since care discontinuities can lead to errors, which add treatment costs.

Employers, however, oppose funding multi-year health insurance policies. Business conditions may change they reason, their employee census may change, prices may fall – why encumber themselves with long term liabilities? Employers like 1 year long policies so they can change the program if business conditions warrant.

This creates a conflict between *employee medical needs* and the *employer's business considerations*. We have, nationally, adopted the employer's position as the basis of our healthcare financing system, not the medical need position. Financing medicine based on anything other than medical concerns adds inefficiencies (costs) to the system without any related benefits or value increases.

The employer financing model forces health insurance carriers to compete on short term medical cost controls rather than long term patient outcomes. I'll explain how all this works and some impacts later in this chapter.

These three structural problems – financing routine medical care through insurance, disconnecting payers from users and embracing 1 year health insurance plans - lead to an inefficient system with skewed incentives. Good for healthcare jobs growth but bad for system value creation.

But that's what we get with employer based financing as the core of our national healthcare financing system.

Three consequences of employer based health insurance

Uwe Reinhardt, professor of healthcare economics at Princeton, suggests 3 consequences of placing employer based health insurance at the center of healthcare financing. [48]

First, it is tremendously expensive. In 2021, for example, the average family health insurance annual premium was $22,221 [49] up about $17,000 from $4,969 in 2011.[50] This compares to a median annual family income in 2021 of about $79,900. That's 28% of the average annual family income going to health insurance. Under what definition of 'affordable' does this make any sense?

Reinhardt wonders how any employer who finances employee healthcare, carrier that designs plans or broker who implements benefit programs can take pride in his/her work product. So do I.

Second, having employment at the center of our healthcare financing system requires lots of 'fill in' programs for people unable to obtain employer based insurance. Each of those programs – Medicare and Medicaid, for example, or SCHIP – develops their own regulations, licensure requirement, codes and prices resulting in overlapping and confusing payment categories.

We have, as a result:

- One healthcare system for fulltime, employed people. This system has its own access rules, reporting rules, prices and payment rules.
- A second healthcare system for elderly people, with its own (different) access rules, reporting rules, prices and payment rules.
- A third healthcare system for very poor, unemployed people who (for lots of bureaucratic and political reasons but no medical ones) must *also* be either i children, ii blind or disabled, iii elderly, iv mentally ill, v pregnant or vi mothers. [51] This system, as the two previously mentioned, also has its own access rules, reporting rules, prices and payment rules
- A fourth healthcare system for slightly poor, partly employed people (we sometimes call this 'non-group', a financial distinction but not a medical one)
- A fifth system for children not otherwise accounted for

[48] This section based on Reinhardt's lecture at the Pioneer Institute in Boston, 2014. I updated the premium numbers in this text but his core argument remains valid.

[49] KFF.org 2021 Employer Health Benefits Survey

[50] How much does health insurance cost, Nov 2, 2011, eHealth news release

[51] Ezekiel Emanuel makes this point in Redefining American Healthcare, page 47

- A sixth system for military veterans, but only if they're also either old or accessing medical care as a result of combat injuries, or both, and finally
- A seventh system for people with kidney disease, provided it's end-stage.[52]

Inefficient and irrational are two polite ways to summarize this chaos: nuts might be more appropriate. Having all these overlapping, irrational categories creates confusion and complexity that makes our system far less efficient and effective than we would like or hope for, leading to more jobs, higher costs and, unfortunately, poorer outcomes than patients would hope for.

I wonder if that's the system goal.

These different categories exist, again, because of the employer basis of healthcare financing. We needed to develop all these programs to address groups left out of the employer coverage model.

And **third**, having all these different categories has led to different prices for the same service. [53]

- The **List Price** exists though is rarely paid. It's reserved for rich foreigners and uninsured Americans. It's the highest price hospitals charge.
- The **Medicare rate**, completely transparent, is stipulated by Medicare. It's generally about 80% of hospital costs, meaning hospitals must overbill some other category of patients to remain financially solvent.
- The **Commercial Insurance rate**, higher than Medicare and lower than List Price, varies by carrier based on their market clout and negotiating skills. It tends to run about $135% of hospital costs though this can vary significantly.

  One reason for the high price and variation: market clout. A carrier with 8% of the market generally negotiates relatively ineffectively with a hospital network that controls 60% of the beds.
- The **Usual and Customary rate** is the rate hospitals charge carriers with which they don't have a contract – a Colorado hospital that treats Florida insureds who injures themselves while skiing for example.
- The **Medicaid rate** is typically the hospital's lowest rate, often quoted as a percentage of Medicare's rate.

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[52] We also have the Indian Healthcare System which, you'll be pleased to read, is funded under the Indian Healthcare Improvement Act, signed by President Obama in 2010 and which is included in the Affordable Care Act. Probably others too, but that falls outside my area of expertise.

[53] This section comes from Ezekiel Emanuel's book Reinventing American Healthcare, pages 72 -76. It follows from Reinhardt's analysis.

- The **Actual Cost** of providing the service is generally unknown. Many medical professionals interact with each patient, requiring detailed time-and-motion studies which are expensive to produce.

Note that in other – efficient – parts of our economy, the service provider determines his/her price for the service and then sells it to anyone who will buy with, perhaps, some quantity discounts to account for scale. But in medical care, the same service varies in price by patient and the same patient can switch from category to category, thus inducing different prices from the same providers for the same care. See why I suggested this is nuts?

This huge, complex, irrational and inefficient system exists, again, because of the employer centric structure of our healthcare financing system.

Two problems that employer based health insurance fails to address
#1: Unnecessary Care

Unnecessary care, defined as care that does not improve patient health, is the largest single category of medical spending in this country. Credible estimates, as from the Dartmouth Atlas of Healthcare and Dartmouth Institute for Health Policy, suggest that up to about 1/3 of all healthcare spending or some $700 billion annually is unnecessary. I think this a low estimate, but at 30% of medical spending, it trumps

- Heart disease, about 10% of medical spending
- Diabetes and cancer, about 5% of medical spending each.

In fact, according to Jonathan Bush, founder and CEO of Athenahealth, 'unnecessary care is part of the hospital business model'. [54]

The interesting question for this section: who, in the employer financing model, tackles unnecessary care as a function of his/her job?

- **Does the benefits administrator care?**

  Probably not. The benefits administrator generally wants to keep premium inflation around 'trend', the industry definition of healthcare inflation.

  If his/her company's premiums inflate at trend, then he or she can take a CYA approach: 'I did my job. Our premiums reflect trend.'

  If his/her company's premiums inflate faster than trend, then alter plan designs, generally by increasing deductibles and copayments and shrinking the provider network.

[54] Jonathan Bush, Where Does It Hurt?

Engaging with carriers and providers to reduce unnecessary care is time consuming, a task for which the benefits administrator probably doesn't get paid and is probably ill-equipped. It will likely be an unsuccessful effort anyway. That's why most benefits people tend to take the CYA approach and settle for the 'we're at trend' justification for mediocrity.

- **Does the CFO care?**

  Again, probably not. The CFO is busy, responsible for the company's financial health and less interested in the internal operations of a hospital. As long as premiums inflate at an 'appropriate' rate, then the CFO will focus on his/her company's core business, making widgets for example, and generate profit on those.

  CFO's lacks both the time and expertise to work with doctors and hospitals on reducing unnecessary care. A huge company CFO might have the time and interest to work with a select group of providers on this issue. But hospitals that engage with this particular large company may well then turn around and bill other, smaller companies more to make up the difference.

- **Does the employer care, especially the small and mid-sized ones?**

  Again, probably not. Most economists argue that employers simply reduce wage increases to fund health premiums. (See below). If premiums rise quickly, wages rise more slowly.

  The employer corporation doesn't care – economically – if it pays employees wages or premiums. It's only concerned with the total employee costs.

#2: Underfunded Social Programs

Among developed countries, the US has the highest rates of diabetes, sexually transmitted diseases, teen pregnancy and auto mortality. We also have the second highest rates of heart and lung disease and lose more years of life before age 50 to drug and alcohol abuse. [55]

Are sexually transmitted disease and teen pregnancy the *employer's* problem? The patients typically don't work for the employer but the employer pays for treatments through 'trend'.

We know that social and behavioral factors affect more than

- 70% of colon cancer and strokes.
- 80% of coronary heart disease

[55] For Americans Under 50, Stark Findings on Health, Tavernise, NY Times, Jan 9, 2013

- 90% of adult on-set diabetes, and
- Probably most leg amputations (we lead the developed world)

But the underlying social and behavioral factors exacerbating these problems are not addressed by employer based health insurance. These are 'social' problems, appropriate for some government agency or non-profit to address – or so believe many employers and benefits administrators.

Perhaps as a result, we spend far less on social determinants of health (housing and rent subsidies, training programs for poorly educated or unemployed folks, disability cash benefits and social services in general) and far more on medical treatments after someone gets sick than do most other developed countries.

In fact, though we're #1 in medical spending per capita in the world, we're #13 in 'medical and social spending' combined. We have the ratios reversed from most others. The OECD average is about 2/3 of combined 'medical and social spending' going to social and about 1/3 going to medical; we're the opposite, joining only Korea and Japan as spending the majority of 'medical and social' on medical. [56]

This situation developed largely because employers lobbied more successfully for health insurance premium tax breaks than did social service agencies for funding. (More on this below when we discuss the history of employer based health insurance.)

How well do employers negotiate for their employees?

In 1964, the average wage in this country was $2.53/hour and the average health expenditure $197 per person per year, requiring the average person to work about 78 hours (2 weeks) to pay for healthcare. [57] Divide $197 by $2.53 to see this.

In 2019, the last year before Covid, the average wage had risen to $22.98 / hour, healthcare cost to about $11,500 per person, requiring the average person to work 500 hours (12.5 weeks) to pay for healthcare.[58]

This strikes many as a pretty poor track record. One wonders if individuals, negotiating for their own policies, might have done better than employers and brokers working together. [59]

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[56] See The American Healthcare Paradox by Bradley and Taylor for more on this. I only summarized their research here.

[57] This example comes from Philip Longman's excellent book on the Veteran's Administration Healthcare system, Best Care Anywhere

[58] Wage estimates from the Bureau of Labor Statistics 'Usual Weekly Earnings of Wage and Salary Workers, Third Quarter 2019'

[59] See in particular David Goldhill's Catastrophic Care. Philip Longman compares cost inflation in the Veteran's Healthcare Administration system to the employer based system in his book Best Care

‘But my employer pays 75% of my premiums’

This misconception pervades the employer based health insurance model. Let me explain what most people believe first, and then show the real costs. [60]

Consider Mary, a single woman who earns $35,000 a year. In this hypothetical example, the company’s single premium is $649/month ($7791 annually) of which Mary pays 27% or $2112 per year. She also pays a $250 annual deductible and has 4 office visits at $25 each.

Mary thinks her healthcare costs about $2462, or roughly 7% of salary. Not too bad.

There’s only one problem with this analysis: it’s completely wrong. Not even close to correct.

Here’s what Mary actually pays:

- The entire **$7791** premium in foregone wages. Remember that her employer doesn’t care if Mary receives compensation as salary or benefits. The employer only cares about the total annual cost of employing Mary.
- $1276 in state taxes at a 3.6% state tax rate. Since states average spending about 10% of their budgets on healthcare costs for employees and Medicaid, Mary pays about **$128** in healthcare costs to the state.
- $3827 in Federal taxes, about 11% of her income. Since 20% of the federal budget goes to healthcare, Mary pays another **$765** here.
- Medicare taxes (1.45%) plus the employer match (foregone wages again), another **$1015**.

Mary actually spends about **$10,000** on healthcare annually, not $2462. See why all the healthcare system inefficiencies we’ve been discussing really matter?

Part 2: How Employer Based Health Insurance Developed

An historical accident

Let’s consider two historical themes to understand both why we have an employer-centric healthcare financing model and why it works so poorly.

First, remember that healthcare and social services evolved independently and differently. Healthcare was a profitable industry, supported by powerful special interests;

Anywhere. The VHA did a better job controlling costs while, according to Longman, generating better outcomes.

[60] This analysis comes from David Goldhill’s ‘Catastrophic Care’, chapter 2 ‘The Hidden Beast’. I’ve adjusted the numbers slightly and changed the woman’s name to Mary, though unclear exactly why.

social services were not but, but rather were disorganized, politically weak and stigmatized for helping the 'undeserving'. [61]

Consider this story from Bradley and Taylor's book The American Healthcare Paradox about Joe, a 28 year old, very low income diabetic: [62]

- His poor diet, including very little fresh food, exacerbates his condition
- He wears old, holey shoes that keep his feet constantly damp.
- His doctor admonishes him to eat better, take his insulin and keep his feet dry, but he can't afford to do these things often enough
- Last year he had 2 toes removed costing $7000 and next year likely two more for $14,000
- His doctor discussed the possibility of a foot amputation ($18,000) plus rehab (total medical costs about $30,000), plus a wheelchair ($1000). This would make finding a job far more difficult, reducing Joe's chance of earning much income and consequently paying taxes (more or less paying for the social welfare of others). A leg amputation might permanently relegate him to surviving on government benefits, not a job.

Perhaps the most ironic or depressing part of this story: new shoes cost $75 and an apple costs $1 per day. Our (underfunded, disorganized) social services can't manage these minimal costs while our (well funded, powerful) medical system racks up tens of thousands in fees by implementing medical solutions to social problems.

Second, our healthcare financing system evolved inefficiently, from a vertically integrated 'financing + care provision' system to a non-vertically integrated one.

- Vertical integration means medical care and medical financing are the same entity with salaried physicians. Both the financing arm and medical care arm work together to generate the best patient outcomes at the lowest cost, at least in theory.

  'Managed competition' is competition among vertically integrated healthcare providers. Those generating the best outcomes at the lowest costs will gain customers; those operating at higher costs and generating poorer outcomes will lose. [63]

[61] See Bradley and Taylor, The American Healthcare Paradox for a longer explanation of this point.

[62] Ibid. page 1

[63] Alain Enthoven of Stanford University, perhaps our greatest managed care theorists and proponent, has written widely about this which is somewhat outside the scope of this particular chapter. See his

Vertically integrated healthcare entities compete with each other on *value*: outcomes per dollar spent, since they control their own income (i.e. the premiums they charge customers.)

- A 'non-vertically integrated system' has separate companies handling financing and medical care. Today we call financing companies 'insurance carriers' and medical care provision companies 'providers', generally hospitals and physician groups.

  In this system, financiers always want to pay service providers less and service providers always want to bill more. The relationship between the two is 'war' - according to Atul Gawande, professor at Harvard Medical School and staff writer for the New Yorker – 'every step of the way'. [64]

  In a non-vertically integrated system, carriers and hospitals argue over payment formulas since hospitals do not control premiums. A very different focus from the vertically integrated model above.

How Employer Based Healthcare Started

(A version of this section appeared previously in this text. Readers may wish to skim the next 10 pages. GF)

The myth – or perhaps truth - is that it started in Dallas around 1929 as a reaction to the stock market crash and financial meltdown. [65] The business problem for Baylor University Hospital in Dallas was that it didn't have enough money to pay its bills.

Prior to the stock market cash, hospitals raised funds in two ways. First they had paying customers who were billed for services rendered - a fairly modest percentage of the population because most people didn't have a lot of money. Second, the community chest, the charitable organizations - the wealthy would donate to the hospital because it was a good place to donate your extra money. Charity made you feel good and was good for the community.

But with the stock market crash, the wealthy didn't have as much money to donate, unemployment increased (reducing the number of patients able to pay), and the hospital faced a difficult financial landscape. So Baylor University Hospital made a deal with the Dallas School System. They said, "School system, you raise money from taxes. You

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seminal article The History and Principles of Managed Competition for more. http://elsa.berkeley.edu/pub/users/webfac/held/157_VC2.pdf

[64] See Gawande's second book 'Better', chapter entitled Piecework

[65] This suggestion comes from Richmond and Fein, The Healthcare Mess, page 30.

always have money. Pay us $.50 every other week, $.25 a week, for each of your employees and when they get sick, they come to us and we'll take care of them." Employer based health insurance arrives.

A few comments about this.

First, it's a nice deal. It's a nice deal for the hospital because they stay in business. They don't have to worry about going out of business. They don't have to worry about turning people away as long as they get the numbers right (which apparently they did), $.50 per employee every other week. That was the true cost. The school system payments protected the hospital's cash flow, so the hospital stayed in business.

Second, this was very efficient. The hospital signs one contract with one employer group and received back enough money to stay in business. Sweet. That's a pretty good incentive to look for more large employer groups.

Third, there was no prevention or provider choice, but theoretically the teachers and other employees of the school system were happy because they got medical care essentially for free.

Fourth, this was for hospitalization only. There was no outpatient doctor's coverage.

Fifth, community rating. The Dallas School System paid $.50 per person every other week, regardless of individual medical status. There was no medical underwriting.

Sixth, there were no quality controls, no outcome based incentives, no holdbacks for poor hospital performance. Health insurance began simply to save the financial health of the hospital.

This was a vertically integrated system, almost textbook variety. And it exhibited the classic flaw of vertically integrated healthcare system: lack of consumer choice. As developed initially with Baylor University Hospital, the Dallas school system employees could only go to one hospital. This has advantages and disadvantages.

Advantages:

1. Lower Costs

2. Reasonable medical care from a small number of 'in-network' providers

Disadvantage:

1. Little provider choice as few hospitals 'in-network'

The Baylor Hospital / Dallas School System deal worked so well that other hospitals soon copied it. Different hospitals looked for different large employers, offering the same kind of deal. Large manufacturers, the Dallas Morning News, and others. What problem begins to arise?

The Choice Problem

Consumers (school system employees or manufacturing workers, for example) wanted to chose among various hospitals. 'What do I know about Baylor University Hospital? I only know one thing. I know someone who went there and didn't get good treatment, so I want to go somewhere else.' Someone always knows of someone else who had a negative experience there. So you want to go somewhere else - consumers want choice.

Remember vertical integration, where finance and service provision are the same company? Once you introduce choice, then you have one group handling finance and another handling service provision. You have a split and you lost vertical integration. (More on this coming up soon.)

Back to Dallas. The hospitals are cranking along with the employer based financing model. They're very happy. They're making money. And then one of the Blues brothers comes along – Cross or Shield, I don't remember which – and offers to provide financing for lots of Dallas hospitals. 'Dallas teachers' they might have said, 'you can sign up with Baylor University Hospital only, or, for just a little more money, sign up with us and we'll give you the choice of many hospitals in Dallas. We contract with lots of hospitals. We have a large network.' Sounds pretty appealing, right?

Doctors looked at this and said, "Hey, we want in on this too." They organized a second Blues brother so doctors could get paid because the same depression was affecting all medical providers, both hospitals and physicians. Blue Cross for your doctor's bills and Blue Shield for your hospital bills (or maybe the other way around. Wikipedia didn't say when I looked it up.) Both organized to protect provider incomes.

And both – conceptually, if not in real life – competed with vertically integrated hospitals, like Baylor University Hospital was at the beginning with the Dallas School System.

The Blues developed a couple of very clever ideas in the 1930s. First, from a marketing point of view, they offered this very attractive provider choice option. Very appealing to many consumers.

Second, they began searching for the healthiest subscribers. An interesting business idea: if they could find the healthiest people, they could offer lower priced policies and gain a competitive edge vs. their vertically integrated competitors signing up large employers at a fixed price per person.

Underwriting vs. Community Rating

The Blues figured that they would underwrite better than the competition so people would join them because their premiums would be a little bit lower. The community rating folks faced higher premiums because they took all employees.

Underwriting serves the economic interests of the carriers. It doesn't improve healthcare outcomes. It doesn't improve the healthcare system. It doesn't differentiate medical quality. It doesn't create patient value. It only makes one carrier lower cost than another carrier by having sick people pay more. The healthy pay less, the sick pay more but there's no value created: the total medical costs remain the same. But some people win and others lose.

This financing system has little to do with getting people healthy, or creating value. That was not its intention. It was designed to protect physician and hospital income. That was the original Baylor idea. Then carriers came along to make a profit on consumer demand for choice. The demand for choice leads to the Split.

The Split and the Provider Payment Problem

Once you split finance from service provision, you have a wider consumer choice and you have to figure out how to pay doctors and hospitals. We're still, today, trying to get this one right.

The original and still most popular payment mechanism is fee-for-service. The doctor gets paid $100 for treating each broken arm and $350 for each rotator cuff surgery.

As soon as you split finance and service provision there's an incentive on me, the doctor, to do more treatments. You're paying me by treatments, so I will do more treatments. 'That guy's got a sore shoulder that's probably due to a rotator cuff tear, so I'll operate on his rotator cuff.' Fee for service provides an incentive for doctors to do more procedures and hospitals to admit more people.

You, on the other hand, the carrier, want to limit the number of treatments. You want to ask if I have to do that procedure. We fight all the time. My clinical judgment (influenced, perhaps – at least psychologically – by the fee-for-service payment formula) vs. your financial judgment (influenced, perhaps – at least psychologically – by the same fee-for-service formula. You don't really trust my clinical judgment.) That's the conflict between healthcare payers and medical service providers.

Let's remember where we are. We're still in the 1930's and we're talking about the growth of the employer based system. Little cost control. We've developed the split between finance and service provision. Finance people will say, "You really don't need to do that procedure," and the service provider says, "Yes I do. Yes I do."

The Problem of Measurement in Fee for Service Medicine

There's a related problem in fee-for-service medicine – the problem of measurement. How well does a particular physician treat his/her patients? How well does a particular hospital perform certain surgical procedures? How well does a particular treatment work?

These are enormously difficult questions to answer. We do not even today have good measurement criteria or good data – and we had even poorer criteria and data in the 1930s. The data that we can measure might not be the most important. Remember that our healthcare goal is to extend life or improve life quality. We do not yet fully understand which treatments today will lead to longer lives in 30 or 40 years. Nor do we fully understand which treatment qualities will lead to long term life quality improvements.

We can only measure some aspects of medical treatments – surgical mortality rates, hospital infection rates, 30-day hospital readmission rates, for example. These may not always be the most significant outcome data, though they may be useful for some patients.

Whose interests are served by measuring or publicizing this information? Not the providers. They get paid fee-for-service for the *quantity* of medical care, not the *quality*. Publicizing outcome data may harm them economically. Thirty day hospital readmission rates may show that Hospital A provides poorer patient treatments than Hospital B. Or that Surgeon Z has a higher mortality rate than Surgeon X.

The risks of either inappropriate or unflattering outcome data becoming public were so great during the inception of our employer based system that providers fought against its release. The fee-for-service system suited their interests far better than any outcome based payment mechanism.

The fee-for-service / component payment structure suited their interests in a different way also. Absent good data collection, each physician – responsible only for his/her specific tasks – can argue 'I did my job correctly. The fault lies elsewhere.' Physicians act as subcontractors, narrowly defining their individual tasks, rather than as general contractors responsible for the life of the patient. This follows directly from payment systems that developed from the Split between finance and service delivery.

Fee-for-service / component financing serves provider interests, is inflationary and expensive, and is not designed to improve patient health. It's only designed to reward providers, which it did quite well historically. We, in the US, have traditionally performed more procedures / 1000 of population than similar developed countries around the world. Things today like spinal fusion surgery, hip replacements, knee replacements, coronary bypass surgeries. The Split between finance and service provision led us down this road.

The Impact of World War II

Let's continue with our historical / conceptual history of employer based health insurance.

During World War II, or perhaps as a function of it, more and more people got insured, most notably people in the military. They continued with insurance coverage after the

war. In the relatively short post-war period we get lots more Americans covered for hospitalization insurance.

1942: 10 million hospital insurance / health insurance subscribers

1946: 32 million

1951: 77 million [66]

World War II plays an important role in our story for three main reasons.

First, the soldiers who received health coverage while in the military wanted to continue with it afterward. They saw the advantages of having health coverage. They married and wanted their families to receive coverage also. This created demand for health insurance.

Second, our wartime economy devoted significant resources to medical technology improvements. Perhaps most significant was the introduction of sulfa drugs to combat infections. These helped turn hospitals from infection breeding institutions into patient treatment and improvement centers. Other technological innovations followed. These improved the quality of medical care, or the supply.

Third, the Federal wartime wage and price freezes fostered the development of 'fringe benefits' such as health insurance. These reduced the cost of insurance to the individual consumer and further helped stimulate demand. It's a pretty interesting story just how these developed.

The government decided during the War to freeze wages and prices - to avoid domestic economic difficulties and help focus our economy on war production. Employers could not raise wages to attract new workers or to reward their best employees. The government controlled this aspect of employee compensation very tightly.

But the government allowed employers to offer fringe benefits such as health insurance. This was how employers could attract new talent and retain their current employees. The concept of 'fringe' meant 'outside the normal compensation' and 'benefits' meant 'advantages of working here'. Employers couldn't simply raise wages – the traditional way of attracting labor – as that was illegal during the war. Fringe benefits were simply a mechanism to get around the wartime wage freeze.

As we grew in 9 years from having 10 million to 77 million insurance subscribers in this country, the health insurance industry developed and gained political power. It lobbied Congress for favorable legislation. It applied political pressure. It acted, in short, just like all other powerful industrial groups.

The Hill Burton Act and IRS decisions strengthen hospitals

[66] Richmond and Fein, The Health Care Mess pages 30 - 38

Congress, just after World War II, passed the Hill Burton Act to fund hospital expansion. This increased the number of hospital beds in this country by about 40%, from 3.2 per 1000 people to 4.5. It also made hospitals the centerpiece of our medical care system; the travelling doctor who made house calls started to disappear.

Shortly thereafter, in 1953, the IRS decided that fringe benefits were exempt from federal income tax: those became *tax deductible to the employer* but *not income taxable to the employee.* **This was essentially a government subsidy for hospital care,** since that's what health insurance ultimately financed. The government stimulated sales of employer based health insurance by subsidizing the price through the tax exemption.

To understand how this is a subsidy, let's look at both the employer and employee tax situations. The employer buys a $100 insurance policy for an employee, and, prior to the IRS regs, pays corporate income tax on the $100 ---- let's say that was 50%. So the employer's total cost was $150: $100 for the policy and $50 for the income tax on that $100.

By making the payment tax deductible to the employer – that means by foregoing the corporate income tax on that $100 - the government reduced the cost. Health insurance now only costs the employer $50; the employer takes a 50% tax deduction on the $100 payment. That's a big savings compared to the previous $150 expense.

The employee received this $100 employment benefit. Prior to the IRS regulatory change, he/she would have paid their marginal tax rate on this income --- let's say 30%. By making this tax free to the employee – that means by foregoing the personal income tax on the $100 – the government contributed $30. In other words, the government subsidized the employee who received health insurance by $30.

An interesting note from the employee point of view. $100 in benefits is more valuable than $100 in salary. The $100 in salary is taxable, so nets only $70. Remember our discussion above that 'My employer pays 75% of my premium.' I suggested that the employer doesn't care if he/she pays salary or benefits – the employer only cares about the total cost.

But the employee, according to many economists, does care. The employee prefers benefits since they're not taxed. The employee's foregone salary, according to this argument, is more valuable than benefits since it's not taxed. (I'm not sure I buy this argument completely but it does give me pause to consider.)

This subsidy for health insurance was so effective that the rate of Americans with hospital coverage skyrocketed. In the mid-1950s, about 45% of Americans had hospital

insurance. By 1963, 77% had hospital coverage, and an additional 50% had some form of physician coverage.[67]

The favorable tax treatment of fringe benefits led to healthcare inflation from higher *hospital* prices – because more people could afford to use hospitals.

Over this time period two strange incentives evolved in our healthcare marketplace: an *excessive hospitalization* incentive and an incentive to *cover the unemployed*. These two conditions merged in the late 1960s and 1970s. Their combined effect became clear by the 1980s as our health insurance costs skyrocketed and our employer based financing model became even more firmly entrenched.

Excessive Hospitalization Incentives

By the mid-1960s over three quarters of Americans had hospitalization insurance, paid for by employers and subsidized by the government. Hospitalizations became essentially free to patients, creating, in the words of Harvard Professors Richmond and Fein a 'not-so-subtle perverse incentive to hospitalize individuals.'

This was the case even for diagnostic tests that could have been performed on a less costly outpatient basis, they say. Over time the hospital became all the more important and central to the delivery of healthcare services.

This increased the need for health insurance:

Since medical care became more costly, insurance became more useful (indeed, necessary). In turn, the presence of insurance helped underwrite a buildup of resources and an upgrading of technology that added to costs and made insurance even more valuable. [68]

Remember the incentives here.

- Employees liked the system because it appeared free to them;
- Carriers liked the system because the government subsidized their product (health insurance policies);
- Hospitals loved the system because they received patients and insurance payments – a wonderful recipe for making money.
- Employers objected somewhat to this system, but not terribly strenuously. After all, the government was subsidizing their health insurance payments, so they felt the pain only partially.

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[67] Enthoven and Fuchs, 'Employment Based Health Insurance: Past, Present and Future' Health Affairs, Nov/Dec 2006

[68] Richmond and Fein, op. cit., pages 38 - 39

Our healthcare system was hospital based – not really interested in preventive care (hospitals couldn't charge much for that); not really interested in public health (the field was only just developing); not really interested in outpatient or chronic care. Providers focused on hospital care because that's where the money was.

Hospital insurance stimulated the excess use of hospitals, which created more need for hospital insurance. Three byproducts:

- First, we used hospitals for almost all medical care, even if less expensive setting existed;
- Second, we developed fewer outpatient, home based, preventive or non-hospital types of medical care;
- Third, we continued to underfund social program. All this hospital growth and funding (largely from government programs and tax subsidies) crowded out social service investments.

Yet this third issue was tremendously important. Let me quote Professors Richmond and Fein on the relative importance of hospital investment and public health investments. [69] And remember: these were two highly respected Harvard Medical School professors. Richmond, in fact, was US Surgeon General in the Carter administration.

- 'A growing professional consensus holds that the health gains since WWII were largely **the consequence of applying our knowledge of health promotion and disease prevention rather than improved clinical care…' (**i.e. public health investments**)**
- 'The revolution in biology subsequent to World War II, a revolution that had brought many advances to clinical care, as yet **had only marginal effects on improving our vital statistics'**

Social spending had a bigger impact on our national health gains than did hospital investments! We invested the wrong way (assuming our healthcare investments were aimed at promoting health).

How Could Employers Afford Health Insurance Premiums after World War II?

What set of circumstances allowed this system to develop? Why was the employer based system healthy and growing until the late 1900's, then in decline?

It turns out that for a number of years, this 40 year period more or less, many countries were (a) recovering from World War II or (b) gaining independence and expanding their

[69] Richmond and Fein, op cit, pages 92 and 94

educational systems. They were not economic threats to the United States – countries like Japan, India, Korea, China, or Western Europe. We dominated economically.

Our big firms in particular were very profitable. They didn't have much foreign competition. They could afford to pay for employee healthcare. They could raise prices because nobody was competing with them to keep prices low. That's the trend that you see from World War II to about the 1980s or so. Big firms could set the standard and then small businesses filled in the holes. All competed for labor based on offering attractive 'salary + benefits packages' and all could because the big firms were managing the world economy.

This allowed the U.S. to have an extra cushion of money available for healthcare benefits. Even though people complained, the economy could support the excess premiums. Regulated industries - for political and various other reasons - were able to pass on the cost because our economy was stronger than any other. Unions were strong. They could demand health insurance and the big firms could afford it.

The key factors that fostered employer based health insurance post World War II all changed in the 1980s and 1990s:

<u>World Economy, 1945 – 2000 +/-</u>

Little foreign competition for American manufacturers;

Japan and Western Europe needed time to rebuild;

US manufacturers could keep prices high and afford health benefits

<u>Importance of Large Firms, Regulated Industries and Unions</u>

GM, US Steel, ALCOA, etc – profitable with little foreign competition. Able to share profits with employees as benefits;

Regulated industries (AT&T) – regulated monopolies were able to pass health insurance costs to consumers; they had little or no competition;

Unions were relatively strong, could bargain effectively for benefits

All these conditions changed in the 1980s and 1990s. Our ability to generate excess profits, if you will, to afford for the employers to pay for healthcare starts to disintegrate as foreign competition gets going. From World War II until about 1980 or 1990 we could afford employer based health insurance and there was no significant political group that was lobbying or arguing against it.

Medicare and Medicaid Remove Potential Political Threats to Employer Based Insurance

One major potential political threat to our employer based health insurance system could have come from the unemployed – that significant percent of the population that is

too old to work or unable to find full time work with benefits. This is potentially a very potent political force that could have lobbied in favor of single payer healthcare, universal coverage or something like that – like in other countries.

By introducing Medicare and Medicaid in the 1960s, this political force goes away. People are happy. They're not under pressure. They're not demanding universal coverage because they've got coverage. Where are politicians going to find a block of supporters who are going to argue for single payer systems, universal healthcare? They don't exist because Medicare and Medicaid took the potential block off the table.

Here is an estimate of the population size that these two entitlement programs satisfied. I'll use Medicare, because this covers the elderly who vote in particularly high numbers and in particularly important electoral states like Florida. This large voting bloc could have become a potent political force for universal coverage. Instead it became satisfied with Medicare.

Medicare Enrollment 1970 – 2000

Year	Number Medicare Enrollees	% of US population
1970	20 million	10%
1980	28 million	12%
1990	34 million	13.5%
2000	39 million	13.8%

Medicaid covers about the same population size.

The argument is that Medicare and Medicaid are key supporters of our employer based health insurance system. They allowed the system to grow and become entrenched nationally in the second half of the last century.

The employer based system reaches its peak of 165 million people in 2000 and then it starts to decline. Why did it decline? Because the international economic conditions changed. American firms could no longer pass on benefit costs to their customers.

At the same time, the hospital lobbies and related groups had done such a good job of protecting their constituencies that healthcare became hugely expensive. Healthcare grew from about 4% of US GDP in 1950 to 14% in 2000 to about 19% today.

Lower cost alternatives to large general hospitals – freestanding outpatient clinics, for example – never took hold, presumably due to hospital lobbying efforts. Similarly, specialty hospitals – local diabetes clinics, for example – also failed to establish themselves, again presumably, for the same reasons. The Affordable Care Act, for example, didn't actually prohibit establishment of physician-owned specialty hospitals, but placed such burdensome requirements on their establishment as to destroy this as a potential market force.

By the early 2000s we had developed a perfect storm for healthcare system financial catastrophe. Our healthcare costs – primarily hospitalizations due to the government subsidies of fringe benefits – rose far faster than GDP. Meanwhile, American businesses' abilities to pay for their employee's health coverage diminished in the face of foreign economic competition.

Mandates

As healthcare became increasingly costly, carriers (reflecting employer's interests) tried denying services to patients. This spurred a political reaction, pitting patients and medical provider interests against employers. Perhaps the most impressive display of patient and special interest power presented itself by the growth of healthcare mandates.

The number of state mandated services grew from 7 in 1965 to 1961 in 2008. These reflected the political power of special interests to protect the incomes of their members. Chiropractors lobbied for chiropractic to be included as a benefit in insurance policies. Nurses lobbied for minimum nurse-to-patient ratios. Voters generally supported mandates as protection against insurance carrier abuses.

Mandates raise prices. This increases the need for insurance but makes insurance less affordable, which increases the need for government subsidies (tax breaks and, in some states like Massachusetts, premium supports), which reduces the amount of money available for social programs and 'health promotion and disease prevention' activities (in the words of Richmond and Fein [70]) which in turn medicalizes social problems and raises costs.

But perhaps most disappointing of all, mandates don't improve patient health much. Consider this graph comparing American life expectancies to French and Canadian as we increased the number of healthcare mandates between 1965 and 2010. You can see how our life expectancy rates fell slightly below the trend line of the French and Canadians even as we required more healthcare services for our patients.

Instead, healthcare mandates are political reflections of the economic power of various healthcare groups. They have, apparently, little impact on health. But they ensure that the various medical interest groups get paid.

Consumer Driven Healthcare to the rescue (or not)

The first major attempt to adapt employer based healthcare to these new economic realities was CDHC or Consumer Driven Health Care. The term 'consumer driven health care' arose primarily from the Medicare Modernization Act of 2003 which established Health Savings Accounts.

[70] Richmond and Fein, The Healthcare Mess, page 92

'Consumer driven products' are high deductible health insurance policies with certain tax benefits. Each consumer spends the deductible as he/she sees fit – for physician visits, medications, tests, therapies etc – more or less employing the consumer sovereignty idea we discussed earlier in this chapter. Only after satisfying the deductible does insurance pay. Then, depending on the specific plan design, insurance pays all or part of additional medical expenses.

Problems equating high deductibles with consumerism in healthcare

Unfortunately, CDHC policies as 'consumer sovereignty light' fail in healthcare for two main reasons.

First, an annual $1000 deductible (or even $3000) is too small to act as a real medical spending brake. Once satisfied, and depending on the specific plan design, all other medical care is free.

A patient might satisfy that deductible hurdle in January and then enjoy lots of excessive and unnecessary medical care for free during the next 12 months.

Or the deductible has little impact on a patient facing an expensive procedure. What's the difference to this patient if the procedure costs $45,000 …. $50,000….$60,000 or $100,000? Once the deductible is satisfied, the rest is free. 'Consumerism' fails to affect patient behavior in these expensive cases.

This fundamental flaw in the 'high deductible = consumer driven healthcare' thesis exists because the vast majority of healthcare spending goes to a very small group of high cost patients. Here's spending by percentage of the population. These numbers have remained remarkably constant for the past several years.

Healthcare Consumption by % of Our Population [71]

1% of our population accounts for about 24% of medical spending

5% of our population accounts for about 49% of medical spending

10% of our population accounts for about 64% of medical spending

50% of our population accounts for about 97% of medical spending

So the healthiest 50% of our population accounts for only about 3% of medical spending. These are typically the folks who purchase CDHC products and who often spend less than $1000 annually. Cutting their spending by 20 or 30% would have *virtually no impact* on *overall* medical spending or trend.

[71] Yu, et al, 'Medical Expenditure Panel Survey Statistical Brief #81', May 2005, Agency for Healthcare Research and Quality

Here's the same chart using 2010 spending data. In 2010, total US healthcare costs reached about $2.7 trillion for the approximately 310 million of us. Though the 2010 average annual healthcare spending per person was about $8,700,

The 1% heaviest users (3.1 million people) averaged about $209,000 each;

The 5% heaviest users (15.5 million people) averaged about $85,000 each;

The 10% heaviest users (33 million people) averaged about $52,000 each;

The 50% lightest users (155 million people) averaged about $500 each

Very few of the 10% of users who account for about 2/3 of all medical spending will change their medical choices based on a $1000 (or even $2500 or $5000) deductible. *Whatever* the deductible, their medical care needs far exceed it.

Second, medical consumers have little meaningful quality information, and even if they have it, they rarely know how to use it. This makes medical decisions different from, say, car purchasing decisions. The car buyer can compare the quality of various cars before deciding which to purchase. Large or small, good gas mileage or poor, lots of luxuries or few, high resale value or low, etc.

But the medical purchaser generally has very little similar information. Which doctor has the best outcomes? Which hospital? How effective is this medication compared to that one? We generally lack detailed answers to these questions.

For these two reasons – unequal healthcare spending and lack of medical quality information / well educated medical consumers - so-called Consumer Driven Health Care had only a small impact on medical trend which has run at our gdp growth rate plus 3 – 5% annually for years. CDH policies became the vogue in the early 2000s. They pretty much ran their course within about a dozen years.

Americans continue to spend about twice as much on healthcare as other developed countries without getting any value for the excess spending, just as we did prior to CDHC policy introduction. Here are the estimates for 2019, the last year before Covid hit and altered these statistics with a unique set of circumstances. (I don't know if or how Covid is representative of 'normal' healthcare trends so try to leave that out of this analysis.) [72] I could have included more countries but you get the idea from this limited comparison.

[72] OECD Health Data statistic updated annually https://stats.oecd.org/Index.aspx?ThemeTreeId=9

2019	Annual spending / capita	Life expectancy at birth
US	$10,855	78.8
Canada	$6,730	82.3
France	$4,014	83
Spain	$2,412	84
UK	$3,334	81.4

We clearly haven't figured out how to generate good value for our healthcare system costs.

Three additional problems with having employer based health insurance as the centerpiece of our healthcare financing system

Price structure: Today's health insurance policies are priced at 'employer contribution + employee contribution'. Losing your job may lead to a quadrupling of your health insurance premiums, assuming that your employer pays 75% of the premium.

Labor market distortions: Some employees either choose jobs or remain on their jobs for the health insurance. Two main reasons for this are

- cost – employer contributions reduce employee costs, and
- access – pre-existing conditions traditionally made health insurance unavailable to some people if they changed from their current jobs, though the Affordable Care Act has changed much of this.

One research paper estimated that employer based insurance reduced job mobility by 25 – 40% [73] at least until the ACA impacts work their way through our healthcare system.

Impact on the Federal budget: Tax breaks for employer based health insurance (not income taxable to the employer or employee) constitute the biggest tax break / loophole in the federal budget, an estimated $260 billion annually. [74] This is roughly 3x the mortgage interest tax deduction.

[73] Gruber & Madrian, 'Health Insurance, Labor Supply and Job Mobility' Workng Paper 8817, NBER, March 2002

[74] Health Affairs *Health Policy Brief*, August 1, 2013 'Premium Tax Credits', http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=97

This tax break is regressive: higher income people with expensive policies are subsidized by lower income people with less expensive policies.

Many on Capitol Hill seek to reduce this tax break. Here, for example, is Representative Paul Ryan who ran for Vice President in 2012 with Mitt Romney. The tax deductibility of employer based health premiums

> tilts the compensation scale toward ever-greater (tax free) benefits and away from higher (taxable) wages. This isn't just a big driver of runaway healthcare costs, as more dollars chase the same amount of services. It's also a big reason why too many Americans haven't seen a raise in a long time. [75]

Ryan, among other things, echoes my suggestion that employers pay premiums by withholding wage increases from employees. $1 of benefits is worth more to the employee than $1 of wages since the wages are taxed.

Paul Starr, Princeton Professor of Sociology who normally sits far to the left of Ryan, agrees with him on this point, saying the employer based premium tax exclusion has

> long been the target of criticism on both distributive and allocative grounds: it provides the biggest subsidies to higher income employees with the most generous insurance, and it contributes to America's inflated health spending by obscuring the true costs. Nixon and Clinton considered limiting the exclusion, but each rejected the idea because of political opposition.[76]

Summary: Employer Based Health Insurance

Employer based insurance provides some 160 million Americans with health coverage. But it does so remarkably poorly.

- By setting powerful employer business interest groups against far weaker population health interest groups, it's a key cause of underfunding our various (health related) social services
- The employer based structure harms **employers** by putting an unnecessary (for widget production) economic and administrative burden on them.
- It harms **employees** by reducing their medical care options
- It harms **patients** by locking our system into one focused on short term cost control rather than long term outcome improvement, or, in economic terms, value creation

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[75] Turner, Capretta, Miller and Moffit, Why ObamaCare is Wrong for America, Forward

[76] Paul Starr, Remedy and Reaction, page 258

- It harms **carriers** by reducing their ability to develop high value products and by forcing them to satisfy employer needs rather than patient, and
- It harms **providers** – doctors and hospitals – by reducing their ability to focus on long term outcomes and treatment excellence, but rather on short term costs, carrier and network referral requirements and associated administrative tasks aimed at reducing moral hazard.

Where will this take our healthcare system? Stanford Business School Professor Alain Enthoven summarizes in prophetic terms. Our employer based model, he suggests, will unfold 'like a Shakespearean tragedy: known, tragic flaws taking their inexorable toll.' [77]

Or, as Lady Macbeth might put it,

> *The employer based healthcare financing system simply doesn't work. Bandaids and piecemeal reforms cannot not fix this fundamentally flawed model.*

(I've admittedly taken some pretty generous poetic liberties here. Lady Macbeth actually said 'Here's the smell of the blood still. All the perfumes of Arabia will not sweeten this little hand'. It's not easy ending a chapter on employer based healthcare financing with a Shakespearean quote!)

[77] Health Affairs, Forum on Employer Sponsored Health Insurance, 2006 http://content.healthaffairs.org/content/25/6/1537.full

Review Questions

Answers on next page

1. This chapter suggested that Moral Hazard is endemic to health insurance. What is moral hazard?

a. People get more care than they need because it appears free to them
b. People with poor moral standards get more care than appropriate because they are greedy
c. There is a close correlation between high morals and low healthcare costs
d. 'Moral hazard' addresses the mind-body relationship. Basically moral people sleep better so remain healthier than lose moral people who more typically suffer from sleep disorders

2. This chapter suggested that disconnecting health insurance payers from healthcare users leads to inefficiencies. What does 'disconnecting health insurance payers from users' mean?

a. Payers are employers but users are employees
b. Payers are generally government entities that pass rules and legislation but users – who must implement those rules – are employers
c. Payers are, in reality, tax payers who fund most healthcare in this country even though employers are the biggest cohort of users
d. Payers are carriers who actually pay doctors and hospitals for their services while 'users' are all the entities that make up the bills, like pharmaceuticals, device manufacturers etc

3. This chapter suggested that having 1 year long health insurance policies leads to systemic inefficiencies. Why?

a. Carriers and providers try to control short term spending to keep renewal increases low, while some 70% of spending goes to patients with chronic diseases that require a long term focus.
b. Renewing annually creates far more paperwork, and therefore costs, than a more efficient system would have
c. Most employers would prefer longer term policies – 10 or even 20 year long policies – so they could plan and cut overhead
d. One year long policies opens the door to expanded lobbying on Capitol Hill from groups that offer the 'newest and greatest' short term health insurance fixes

4. This chapter suggested that having employment as the core of our healthcare financing system leads to underfunding social programs (that often have a major impact on health). Why is that?

a. Many of the social causes of medical problems – poor nutrition or poor housing, for example – are not the employer's financial responsibility. As such,

they are often left out of our health insurance discussion, since carriers and employers focus so intently on the next year's policy renewal price.
b. Social programs, as many studies have shown, have little to no impact on medical care or spending
c. Employers lobby aggressively to cut social spending programs which might, if they worked well, increase the employer's premium costs
d. Employers, brokers and carriers combine to develop fully comprehensive insurance plans. Anything not included in those plans, virtually by definition, is not relevant to promoting good health.

5. Who pays health insurance premiums?

a. The employee by foregoing wages
b. The employer by foregoing profits
c. The government by crediting the premiums equally to the employer and employee
d. Hospitals by undercharging for their service

6. Why do we have healthcare mandates in this country?

a. To improve care quality. Since the introduction of mandates our 30 day readmission rates have fallen almost to zero
b. To improve care outcomes. Since the introduction of mandates, our average longevity at birth has increased by almost 100 years
c. To reduce infant mortality. Since the introduction of mandates, our infant mortality rates have fallen to the lowest in the world
d. To reward lobbying by influential groups like nurses (who lobby for nursing mandates), chiropractors (who lobby for chiropractic mandates), pharmaceuticals (who lobby for pharmaceutical mandates) and similar.

7. Which country exhibits the shortest life expectancy at birth?

a. US
b. France
c. Canada
d. Britain

8. Which country uniquely bases healthcare financing on employment?

a. Britain
b. Canada
c. US
d. France

9. About how much medical care is 'unnecessary' according to scholars at Dartmouth and other research institutions?

a. 1%
b. 30%
c. 90%
d. 95%

10. Who actually pays the employee's premiums in our employer based system?

a. The employer
b. The employee via foregone wages and the government via foregone taxes
c. The insurance carrier
d. The primary care doctor

11. How does our employer based healthcare financing system affect job mobility?

a. It has no impact on job mobility
b. It increases job mobility
c. It reduces job mobility because people may be reluctant to switch insurance types and coverage because the switch may lead to provider and treatment differences
d. It increases job mobility in the public sector but reduces it in the private sector

12. Which is the biggest tax break allowed by the IRS?

a. Employer based healthcare premiums
b. State sales taxes
c. Foreign travel
d. Home office deduction

Review Questions

Correct answers in bold

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Managed Care

Managed care is classically defined as:

> large multispecialty group practices [that] provide a comprehensive set of healthcare services at a per capita price set in advance.[1]

These large practices include both a financial and service provision component. According to the theory, managed care organizations include both the insurance function and healthcare treatment function in the same company. Thus in a true managed care society we would no longer have separate health insurance carriers, independent physicians, independent general hospitals and fee-for-service billing. Instead, we would have large organizations that integrate finance and treatment functions for the good of the subscriber / patient.

In the ideal model managed care organizations compete with each other to provide the best value to subscribers.[2] Members of one organization could use all facilities owned by, or integrated into, that practice, but none of a competitor. Each local hospital, for example, would join only one managed care organization. Competition among these is called 'managed competition' and follows a set of prescribed rules. More on this below.

Managed healthcare differs from the three other forms of healthcare financing.

First, managed care differs from indemnity insurance. The traditional US medical insurance until about 1990 was indemnity coverage. Insurers indemnify – or pay back - subscribers for medical treatment after-the-fact. The subscriber receives treatment, pays the provider, and then submits the bill to the carrier for indemnification. Carriers indemnify (pay) the subscriber according to coverage provisions. (Carriers might bill the hospital directly and then balance bill the subscriber.) Typically indemnification plans include a deductible and a co-insurance rate. For example, the subscriber might have an annual deductible of, say $500 and 80% co-insurance - means the carrier pays 80% of all allowed costs above the deductible.

Carriers often pay 'usual and customary' or 'cost plus' fees to providers according to the carriers' fee schedule, and will generally pay any licensed healthcare provider. Under indemnity financing, there is no particular corporate or cultural relationship between any particular healthcare financing entity and provider. The relationship is entirely financial.

Indemnity health insurance plans only pay for medical services provided, creating a potentially powerful financial incentive for physicians and hospitals to perform tests and procedures. Indemnity plans typically pay very little (or nothing) for <u>preventing</u> medical treatments. With cost-plus reimbursement, providers have little financial incentive to offer low cost treatments, and a significant financial incentive to perform the most expensive available procedures. At the same time, indemnity carriers typically allow physicians and hospitals wide latitude to use their best judgements when designing medical treatments.

Indemnity insurance has three major drawbacks. **First**, it is very inflationary. Fee-for-service indemnification offers hospitals incentives to perform unnecessary or excessive treatment; it is a major contributor to Moral Hazard and the Medical Arms Race.

Second, indemnity results are often relatively poor, as we see above with Uneven Treatment Quality and Poor Safety Investments. It does not invest in prevention. Its' fee-for-service model is inappropriate for chronic disease care.

And **third**, indemnity insurance offers little, if any, data collection resources to inform carriers or providers which treatments generate which results. This makes results-based competition among carriers exceedingly difficult to implement.

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Second, managed care differs from single payer healthcare. Under single payer financing, one entity – often the government – pays for all healthcare for all citizens. Most advanced industrialized countries use some form of single payer healthcare financing as we do in the US with Medicare and the Veterans Administration Healthcare system.

Proponents of single payer financing argue that it is more equitable than any other form of healthcare financing, for all citizens are treated the same. Indeed, a key positive element of single payer financing compared to our current healthcare system is the universal nature of health coverage. In addition, supporters claim that single payer overhead is far less than private insurance, often citing Medicare's 2% overhead factor compared to private carriers 10 – 15%.

Interestingly, proponents of single payer systems sometimes use international outcome statistics to bolster their case. The British and Canadians for example, live longer than we do, exhibit lower infant mortality rates than us but spend less on healthcare. The conclusion offered by single payer advocates: the British or Canadian healthcare financing system is not only cheaper, but also better than ours. (We evaluate this argument in our course on Single Payer systems.)

Opponents of single payer financing claim that public financing leads to underfunding of healthcare. This in turn leads to less investment in medical technologies and long waits for medical services. Opponents of single payer systems often point to the relative dearth of the latest technologies available in the UK or Canada, or to the extensive waits for many services in these countries.

Opponents also claim that single payer financing eliminates competition from healthcare to the detriment of the entire system. Only through competition, many believe, can we simultaneously reduce healthcare costs and improve outcomes. Managed care proponents, as you will see below, subscribe to this position.

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Third, managed care differs from consumer driven healthcare. Under CDHC, consumers make their own decisions about their healthcare. CDHC proponents believe that healthcare is essentially like other goods and services in our economy and that consumers are perfectly able to shop among providers for the best value.

Consumer driven theorists believe that competitive shopping pressures from individuals will control healthcare costs and improve healthcare quality. Impediments to competition such as mandates, regulated term insurance policies and group-based policies reduce consumer sovereignty thus harm our system. Consumer driven advocates want to treat health insurance like typical goods and services in our society such as automobiles, retirement funds or houses.

Managed care theorists disagree. They believe that healthcare is fundamentally unlike other goods and services in our economy, and that consumers by themselves are unable to shop wisely for health services for reasons of information availability, risk and price.

Consumers, according to managed care theory, cannot access good information about important aspects of our healthcare system. They cannot self-diagnose nor determine which specialists are 'better' than others. They can't determine which treatment is most appropriate, which hospital is best for a specific ailment, or which providers offer the best value. Consumers need advisors to navigate through our healthcare system. In the managed care vocabulary, the advisor is the Primary Care Physician.

MANAGED CARE DESCRIBED: As envisioned by perhaps its foremost proponent Alain Enthoven, Professor Emeritus at Stanford Business School, managed care organizations are integrated entities that include both healthcare delivery systems (providers, labs, etc) and an insurance (financing) function. The critical components are:

1. Multispecialty group practices, comprised of primary care physicians, nurses, specialists, etc;
2. A voluntarily enrolled population that understands the advantages (price and hopefully quality) and disadvantages (reduced provider choice) of membership;
3. Comprehensive care;
4. Per capita prepayment;
5. Accountability by the organization; and
6. A close relationship between the financial and healthcare service delivery arms. [3]

The goal of managed competition, according to Enthoven is 'to divide providers in each community into competing economic units and to use market forces to motivate them to develop efficient delivery systems.' Only through competition can the health plans that do the best job of improving quality, cutting costs and satisfying patients be rewarded.

Competition occurs at the level of integrated financing and delivery plans, not at the individual provider level.

This environment will force competing prepaid group practices to innovate and improve care quality while reducing costs. As such it is far superior to single payer healthcare which has no such competition forcing innovation and cost control. For managed care / managed competition to work, perfect premium price competition among plans must be preserved. Any interference with price competition – including government practices, taxes, employer contributions, union demands or other artificial market imperfections – will modify the competition and reduce its positive effects.

Prepaid group practices originally developed through competition with the traditional fee-for-service / indemnity coverage. To survive, the flagships of the HMO movement had to outperform traditional medical practices. These original groups included Group Health Association in DC (founded in 1935), Group Health Cooperative of Puget Sound (founded in 1945) and Kaiser Permanente (founded in the 1930s) the largest of all. Kaiser is generally regarded as the prime model of a successful prepaid group practice or managed care organization.

A LOOK AT KAISER PERMANENTE: Kaiser Permanente was formed in the 1930s when industrialist Henry Kaiser contracted with physician / entrepreneur Sidney Garfield to provide healthcare to Kaiser employees. Garfield owned a small chain of health clinics. For $.05 per employee per day he offered to cover industrial medical care (workers comp), and for an additional $.05, non-industrial healthcare (major medical) for all Kaiser employees.

As this business grew, Garfield contracted with the Permanente medical group. Kaiser became Permanente's exclusive client, and Permanente, Kaiser's exclusive provider. The organization became known as Kaiser-Permanente.

KP integrated the financial and service provision functions into a single company. It owned its own hospitals to eliminate the conflict between hospitals wanting higher occupancy and carriers wanting lower. It hired physicians on salary to eliminate the potential for moral hazard excess testing and billing. KP emphasized prevention, for it had incentives to keep people healthy and out of the hospital. Remember that it received a fixed payment per subscriber from the Kaiser industrial business, today commonly called capitation. If KP could service its subscriber population for less than $.05 per employee per day, it remained financially solvent. If not, it lost money.

As KP grew, it innovated to maintain quality while reducing costs:

1. Kaiser hospitals in the 1950s reported 25% shorter stays than the US hospital average;
2. Kaiser' ratio of outpatient visits to hospital admissions was 50% higher than the US average in 1969;

3. In the 1960s, Kaiser was among the first to offer home nursing services as a substitute to expensive lengthy hospitalizations;
4. Through the 1970s and 80s, Kaiser continued to emphasize outpatient care, becoming one of the first institutions to offer freestanding surgery and emergency care facilities.[4]

In 1971, Dr. Cecil Cutting, the executive director of the Kaiser Permanente Medical Group in northern California wrote that the 'direct relationship of prepayment to providers become an incentive for the physician to develop economies in spending the medical dollar while maintaining quality'. [5] This differentiated Kaiser Permanente from the more common indemnity form of insurance.

Kaiser Permanente developed a unique institutional culture emphasizing prevention, waste reduction and a constant search for the least expensive / best treatment option.[6] Much of this came from Sidney Garfield. His waste control fanaticism became legendary: employees could only get a new pencil if they turned in a pencil stub of less than 3 inches. 'This period of stringent economy established a pattern of frugal allocation of resources that persisted even into more prosperous years' suggests Harvard Business School's Regina Herzlinger. [7]

The Kaiser culture formed in opposition to – and under attacks from – organized medicine. Garfield established his medical operations in the Mojave Desert in the early 1930s. He battled Great Depression economics and organized medicine that viewed his physicians as an economic threat. (Independent medical practitioners worried that prepayment would motivate physicians to provide fewer services than needed, thus harming both the profession's reputation and pocketbook.)

Garfield hired only true believers in his model, people interested in making the plan work. He claimed that 'if you don't have the [people] who have it in their hearts to make it work and who believe in prepaid practice, it won't work.'[8] His physicians worked 6 days per week. They formed tight social groups. 'We picked people who liked each other – we felt like we were enjoying ourselves.' Garfield worked alongside staff physicians and continually sought their input and new ideas. His clinics were dynamic worksites.

This bonding experience was one factor in the development of KPs' culture. Other factors included its business structure that integrated physicians, hospitals and insurance with each other, long term relations with patients and prepayment / capitation. This set of factors was unique to KP among health insurance companies.

In business terms, KP successfully vertically integrated the provider and financial functions for the overall good of the organization – very difficult to do. (See discussion of vertical integration and transfer prices, below.) KP's evolution and economic incentives allowed financial controllers, for example, to make decisions for the patient's long-term benefit, rather than focus on short term cost control. In part this was because KP had subscribers for life theoretically – or at least as long as they worked for the Kaiser

industrial enterprises. The subscribers' future health had a direct bearing on KP's future success. Also in part, this was because the KP management established a corporate culture that superceded specific division or functional loyalties.

Thus Kaiser Permanente had a very different economic and corporate approach to the business of patient care than did most of its competitors.

NIXON'S HMO ACT OF 1973: Richard Nixon used Kaiser Permanente as the basis of his HMO Act of 1973, because KP was the largest and most successful of the HMO models.

Nixon felt pressured to do something to control rising healthcare costs. [9] National healthcare expenditures almost tripled from $27 billion in 1960 to $73 billion in 1970, creating economic and political problems. Robert Finch, then Secretary of Health, Education and Welfare warned Congress in 1969 that 'the nation is faced with a breakdown in the delivery of health care unless immediate concerted action is taken by government and the private sector'.

Politicians and special interest groups lobbied the Nixon administration to overhaul our healthcare system, though from many different points of view. The Special Committee on Aging wanted Congress to extend Medicare and Medicaid programs to the entire population. The 1969 National Governor's Conference endorsed New York Governor Nelson Rockefeller's (one of Nixon's key rivals for the Republican nomination in 1968) plan for national health insurance. Massachusetts Senator Ted Kennedy and the United Auto Workers led the prestigious Committee of 100 for National Health Insurance in drafting it's own universal healthcare plan.

Even Nixon's own assistant Secretary of Health, Education and Welfare, Lewis Butler, wrote that 'ultimately some kind of national health insurance should be enacted.' And Dr. Vernon Wilson, Nixon's chief of Health Service and Mental Health Administration at HEW said that Kennedy's plan 'was a well-conceived, comprehensive approach to solving the nation's health delivery problems.'

Nixon's problem: he had to do something, but he couldn't support a Democratic healthcare plan sponsored by one of his chief rivals, Ted Kennedy. Nor could support a Republican plan sponsored by another political rival, Nelson Rockefeller – especially a plan that potentially harmed the physicians, hospitals and insurance carriers that supported Nixon politically. He had to develop his own plan.

Dr. Paul Ellwood Jr, sometimes called the father of the HMO came to Nixon's rescue in 1970. Ellwood recommended a prepaid healthcare system that would motivate doctors and hospitals to control costs and keep patients healthy. Assistant Secretary Butler (see above) supported Ellwood's ideas because they fit with the Republican philosophy of support for free markets and competition to reduce costs. Butler also believed that these HMOs would be inexpensive to implement, optional and self regulating. Many conservative politicians and organizations agreed with the HMO idea because it was

flexible, inexpensive, encouraged private investment in profit-making organizations and imposed few mandates or regulations. Nixon's new HEW Secretary, Elliot Richardson predicted in 1970 some 450 HMOs by the end of fiscal 1973 and 1700 by end 1976.

The Republican HMO plan faced opposition from both the left and right between 1970 – 1973. Kennedy and the Left consistently fought for higher levels of guaranteed benefits, community rating, open enrollment periods and significant Federal grants and loans to help HMOs proliferate. Richardson, the AMA and the Right wanted only basic levels of guaranteed benefits, less government funding and individual underwriting. Richardson in particular, feared that community rating would put HMOs at a competitive disadvantage compared to indemnity coverage that routinely rejected people with significant medical needs.

The AMA in particular, lobbied enthusiastically against the HMO idea. Dr. Malcolm Todd, for example, chair of the Physician's Committee to Reelect the President claimed 'We used all the force we could bring to bear against this legislation. As a result, there has been some backtracking on the part of the White House, [which] directed the [HEW] Secretary to slow down this thing.'

As a result of these competing pressures and Nixon's determination to implement his own plan (i.e. not Kennedy's or Rockefeller's), the HMO Act of 1973 was not a particularly close copy of the Kaiser Permanente model. Indeed, the changes to KP's model doomed the entire effort for three main reasons:

First, under Nixon's law, HMO meant simply 'prepayment' – not vertical integration. Healthcare delivery and healthcare finance were separate functions handled by separate companies. This satisfied independent insurance carriers, physician groups and general hospitals - all parts of Nixon's political base. But the key integration feature that made Kaiser-Permanente so successful was lost in the legislation.

Why did carriers, physician groups and general hospitals dislike vertical integration? The short answer: they wanted to compete for revenues with each other.

Carriers hoped to dominate the marketplace and dictate economic terms to providers. The American Medical Association wanted its members to remain free from carrier or hospital meddling so they could protect their incomes. Hospitals wanted to determine patient lengths of stay to protect their own cash flow.

None of these groups trusted the others or the government to protect their interests.

Second, Nixon's law called for a loose physician structure, in which practitioners could opt in or out of any HMO. Again, this satisfied the insurance, physician and hospital groups. But it was the opposite of KPs tight structure in which physicians were fully integrated into both the hospital and financial system. The loose physician structure meant that providers had no particular loyalty to any specific HMO. Another key feature of KP was lost.

Third, Kaiser-Permanente used a capitated financial structure to motivate providers to control costs. Nixon's law allowed providers to bill insurance carriers on a fee-for-service basis. Absent capitation, much of the underlying financial advantage disappeared.

What were the results of Nixon's legislation? 'The HMO Act of 1973 clearly inhibited HMO development' claims Jan Coombs in *The Rise and Fall of HMOs*. Some 124 HMOs developed from 1970 – 1974, but only 40 developed from 1974 – 1978. Also, the enticement of public funding was insufficient to overcome federal legislative and regulatory requirements, so many HMOs turned to Wall Street financing and state approvals. In 1981, 88% of HMOs were nonprofit; by 1986 this had fallen to 41%.

Nixon's act legitimized HMOs and managed care, but so drastically altered the Kaiser Permanente model that insurers and providers had to develop new organizational forms. No longer did managed care equal Kaiser Permanente's closely integrated finance and service provision model. Instead three different types of managed care appeared in the marketplace.

Staff model managed care looked most like KP. Under a staff model, physicians were paid salaries by the integrated carrier/provider, which generally also owned its own hospitals. This allowed the carrier the greatest amount of cost and quality control over providers. Staff models are the most expensive to establish, take the longest time to get up and running, and offer subscribers the most limited networks of providers. They are generally the least attractive model to consumers for this reason.

Group model HMOs look like the original version of Kaiser Permanente. Here a carrier and provider group have mutually exclusive contracts. Carriers still exert cost and quality controls, through perhaps to a lesser degree. Quicker to establish than staff model HMOs, the limited network is still relatively unappealing to consumers.

Independent Practice Associations or Network Models offer the widest provider networks and the least carrier cost and quality control. The American Medical Association favored this form of managed care after Nixon's law – because it allowed AMA members the best opportunity for financial gain.

With IPAs, multiple carriers contract with any willing provider and carriers have the least amount of input and control. This managed care form also has the highest degree of consumer satisfaction as it generally offers the largest provider network and the least restrictions. Some commentators wonder if IPAs are really managed care at all, or instead simply fee-for-service / indemnity healthcare with a price list.

Post Nixon, HMOs grew because managed care premiums were lower than the alternative, indemnity coverage. As a result:

By 1980, 9 million Americans enrolled in HMOs;

By 1990, 33 million enrolled;
By 2000, 60 million enrolled.

However, the majority of subscribers entered IPA or network models:

Group and Staff Market Share [10]

Date	# of subscribers	% of all HMO subs
1980	7.4 million	81%
1990	13.1 million	39%
2002	7.5 million	10%

This raises a key question: Was the US moving toward true managed care or something else?

COST AND QUALITY CONTROLS 1970 – 2000 Nixon's managed care legislation was supposed to use market forces to control healthcare costs and improve quality, just like Kaiser Permanente's experience. Unfortunately, the legislation differed so significantly from KP's model that various government agencies had to step in and devise new cost and quality control mechanisms. These were previously unseen at KP or other managed care organizations. Many of these controls became codified in our healthcare operations and still continue today; they institutionalized a non-Kaiser Permanente type of 'managed care.'

According to Northwestern Professor David Dranove, these cost and quality control programs 'utterly failed on all accounts.'[11] Bureaucrats and administrators – not physicians and medical practitioners – took over and sabotaged the managed care reform movement. They turned it into something that Sidney Garfield would not have recognized.

Hospital Cost Control Programs

New York State had developed the first **rate setting program** in 1970. The New York legislature tried to cap Medicaid hospital payments and included private carriers in the program to avoid hospital cost shifting. This system was already in place when Nixon's HMO legislation passed. It continued since Nixon's plan allowed hospitals to bill carriers fee-for-service.

New York State was the first to try serious Medicaid cost controls since it had such a large Medicaid population. Medicaid costs are split between the federal and each state government. New York officials worried that continued Medicaid inflation might require politically unpopular tax increases. Hence their motivation to control costs.

The New York State Prospective Rate Setting System established a flat fee per patient per day. The fee was set at the beginning of each year so hospitals could budget and

plan, and was approximately equal to the average cost per patient per day the previous year with an inflation factor and regional cost variations applied.

New York officials figured that the patient population would be about the same each year – about the same number of births, broken legs, heart attacks, etc - so on average hospitals would receive the same income year after year, adjusted for inflation. This assumption proved incorrect.

Hospitals quickly learned how to game the system. Since they received the same reimbursement from Medicaid for all patients, they earned more by admitting the healthy and denying care to the sick. Hospital competition quickly switched from providing excellent service to all patients, to denying service to expensive patients. Not a good solution.

New Jersey observed the experience in New York and sought to improve on New York's model by devising its own Prospective Payment System in the late 1970s – a few years after Nixon's HMO legislation. New Jersey modified New York's calculation of average cost/patient/day by introducing some 470 Diagnosis Related Groups (DRGs). This system, designed by Yale Medical School, divided patient costs into diagnostic groups. Cancer surgery now received a higher reimbursement than a simple overnight observation. New Jersey hoped to deny hospitals the ability to game the system as hospitals had in New York.

Under the New Jersey plan, hospitals would receive appropriate payment for medical treatment, but no more; patients would receive necessary care, but no more; and medical cost inflation would be controlled, at least in theory. Again this changed the KP model: there were no DRGs in Garfield's original system because there was no fee-for-service billing. Medicare took the New Jersey system national in the mid-1980s.

How did hospitals control their costs? Many shifted to more outpatient surgeries – not necessarily a bad thing. In 1984 some 28% of all community hospital surgeries were outpatient; by 1996 that percentage had increased to 59%, mirroring KPs' experience.

Other hospitals simply focused on DRG management. Some hired DRG experts to help 'up-classify' patients to receive higher reimbursements. Others began 'dumping' expensive patients who exceeded their DRG reimbursements by transferring them to other hospitals - presumably with less sophisticated admissions procedures. Some hospitals practiced 'skimming', by admitting only potentially profitable patients. Still others engaged in 'unbundling' services, or requiring patients to make more hospital visits at higher reimbursements, often with no additional health benefits. Hospitals, in other words, figured out how to game the DRG reimbursement system just as hospitals had in New York State.

Perhaps the biggest effect of DRG imposition, though, was a change in hospital culture. Hospitals previously were generally non-profits, funded by charitable contributions and cost-plus reimbursement. They were typically run by physicians who were more

interested in providing service to the community than in maximizing revenues. They faced little financial risk. Perhaps they were more inclined to negotiate cooperative financial arrangements with carriers. As Northwestern's David Dranove says

> Until the early 1980s, the managers of nonprofit health care organizations were under little financial pressure. Market conditions enabled even badly managed hospitals to survive. Private insurers either paid whatever price the hospital charged or paid the hospital for its costs plus a predetermined profit margin…(hospitals) that provided unprofitable services or cared for the uninsured covered the expenses by charging higher prices to everyone else.[12]

Physicians had traditionally run hospitals, leaving administrators to manage bookkeeping, purchasing and other defined line functions. These physicians could, perhaps, have worked in vertically integrated operations.
But DRGs changed this. By putting hospitals at financial risk, DRGs put hospitals and carriers on a competitive collision course. If the hospital managed its DRGs better than the carrier, then it received higher reimbursements – and earned more money - at the carrier's expense. Alternately, if the carrier out-managed the hospital, it made money at the hospital's expense. No longer was collaboration even possible – competition ruled.

Hospitals addressed this competition by hiring MBAs to put them on a level playing field against carrier financial expertise. Hospitals at first hoped to continue business as normal, with the MBA folks focusing on their specific DRG and financial areas of expertise. But this model disintegrated as the business school graduates began assuming true management responsibility.

This responsibility shift opened a Pandora's box. Once hospitals began hiring sophisticated MBAs - to fight the DRG battle - and giving them true responsibility, the MBAs learned how to manage hospitals…and then began buying them.

MBAs saw three particularly attractive reasons to own hospitals. First, hospitals had good long term cash flow provided by the government and private carriers. Second, implementing sound business practices could control hospital expenses – something previously insufficiently widespread in non-profit hospitals. And third, hospitals could design sophisticated accounting and billing systems to increase profits.

So attractive were these opportunities that investor-owned systems acquired over 100 hospitals by 1975; 273 hospitals by 1980 and nearly 500 hospitals (plus 200 more under management contract) by 1985.[13] By about 2000, investor-owned hospital networks dominated the landscape, and companies such as Partners Community Health Plan in Boston and the Sutter system in California were 'unabashed about flaunting their power, publicly stating their intention to use their leverage when negotiating rates with managed care purchasers.'[14]

The DRG subtle accounting change altered the mindset of hospital administrators and investors and began our national shift to investor-owned and professionally managed hospitals. Hospitals felt they had to maintain control over their billing function. Though carriers and regulators won some DRG battles, within 25 years hospitals won the DRG war.

The loser: true managed care. Rather than developing a national system of integrated financing / treatment operations like Sidney Garfield developed for the Kaiser industrial workers, we instead became an investor-owned, private hospital based healthcare system skilled at competing with financing organizations. The unintended consequence of Nixon's legislation became a stronger, more ingrained fee-for-service reimbursement system based on hospital vs. HMO competition. This was not at all what Sidney Garfield had originally developed.

Hospital Quality Control Programs

Just as Diagnosis Related Groups were aimed at controlling hospital costs, so various measures were introduced in the 1970s to control hospital quality. These aimed primarily at ensuring that patients received appropriate, high quality hospitalization and care.

They fared no better than DRGs and none supported close cooperation between carriers and hospitals. None, in other words, supported the development of true managed care.

The first Professional Standard Review Organizations (PSROs) began in 1972. These were established by the Social Security Amendments of 1972 to 'promote the effective, efficient, and economical delivery of health care services of proper quality for which payments may be made.'[15] PSROs were local physician organizations designed to monitor the necessity, appropriateness and quality of hospital care. PSROs established standards of care for a wide range of diseases, with a goal of treatment practice uniformity – rather like guilds.

These organizations were quite ineffective. Local physicians, it turned out, were generally reluctant to judge or punish their colleagues. PSROs created dilemmas for physicians who observed questionable quality or potentially excessive treatment in others. Should they report on physicians who unnecessarily bring patients into the hospital - but increase everyone's income? Should they be team players? Or should they fight other physicians and hospital administrators and create political or professional problems for themselves?

Most physicians decided their interests – financial and professional - lay in getting along with their colleagues rather than reporting on them. Hence PSROs failed to have much impact on US medical quality.

Regulators grasped this problem and modified the PSRO concept when creating the next quality control mechanism, the Professional Review Organization (PRO) in 1983. These were private companies, initially contracted by Medicaid. PROs were designed to assure the necessity and appropriateness of Medicaid services by reviewing hospital records for evidence of upcoding, dumping or unbundling of services. PROs established elaborate guidelines and enforcement protocols, again focusing on physicians and hospitals working in a particular locale.

Unfortunately, the process of developing guidelines introduced an even bigger problem - startling variations in medical practice across seemingly similar communities.[16] A famous early study 'Are Hospital Services Rationed in New Haven or Over-Utilized in Boston' reported that rates of certain procedures including coronary artery bypass graft surgery were much higher in New Haven than Boston, but rates of other procedures such as carotid endarterectomy were higher in Boston than New Haven.[17]
Studies such as this[18] suggested the PRO focus was too narrow and that the real hospital quality problem involved treatment variations. These put patients at risk, for some were under-treated while others were over-treated.

Once our medical community realized that treatment variation was a huge healthcare systemic problem, the question arose about how to address it. The medical community decided to continue measuring and controlling treatment inputs – costs, types of procedures, second opinions, etc. (It could, alternatively, have started to measure treatment outcomes – mortality and infection rates for example. The medical community apparently decided these outcome quality measurements were inappropriate, undesirable or too difficult to quantify.)

The exclusive focus on input measurement doomed future quality control programs to failure.

The first such post-PRO program was development of Treatment Guidelines. These had a goal of standardizing medical treatments to control both quality and costs. Treatment guidelines typically provide the medical staff with detailed day-by-day instructions for testing, nursing, surgery, rehabilitation and discharge planning. Guidelines also provide a systemized method of ordering tests.

Unfortunately, contradictory treatment guidelines proliferated. By 1994 the AMA reported over 1600 sets of guidelines designed by potentially competing special interests. Hospital guidelines sometimes said 'treat' (presumably to increase hospital occupancy) while carrier guidelines said 'don't treat' (presumably to control costs). Some guidelines were developed by pharmaceuticals and recommended drug therapy; others by surgical supply manufacturers and recommended surgery. Hospital bureaucracies and physicians often resisted the imposition of guidelines, which ultimately became voluntary and only marginally effective.

Regulators next turned to Utilization Review to overcome the narrow focus of PROs and ambiguity of Treatment Guidelines.

Utilization Review is a screening procedure to determine (a) if the patient should be admitted, (b) surgical second opinions and (c) on-going review of high cost cases.

Independent 'objective' companies perform Utilization Review. These companies have developed best practice criteria. Procedurally, the hospital admissions nurse reports clinical data and a treatment plan to the UR nurse who may agree to hospitalization, recommend outpatient treatment or even refuse the treatment plan. Typically there is also an appeal procedure.

Supporters claim Utilization Review achieves two goals. First, UR companies keep their screening procedures current with the medical literature, something no physician or hospital could possibly do given the hundreds of studies published annually. Second, they claim that UR reduces inpatient costs by reducing unnecessary hospitalizations and treatment.[19]

Detractors see UR as an unwanted intrusion in the physician-patient relationship, with some physicians even lying to get around UR restrictions.[20] Other detractors claim the UR companies have a financial bias to show cost reductions in order to get their contracts renewed. Interestingly this is the opposite of hospitals' financial bias to perform treatments.

Some commentators have concluded that UR has failed to provide the desired level of cost and quality control. The Journal of the American Medical Association reported a 'Retrospective Drug Utilization Review' study in 2003 that concluded 'we were unable to identify an effect of retrospective drug utilization review on…clinical outcomes'.[21] The New England Journal of Medicine reported that a studied utilization review program 'reduced the number of diagnostic and surgical procedures performed that required second opinions…(but) otherwise the program had little effect'.[22] The Canadian Medical Association Journal published a research study 'How valid are utilization review tools in assessing appropriate use of acute care beds?' and found that some UR companies underestimate – while others overestimate – appropriate hospital admission stays.[23] The CMAJ article concluded that

Although utilization review tools are widely accepted, these considerations…raise serious questions about the value of the tools…and whether they should be used at all.

Effects of Cost and Quality Control Programs on Managed Care Development

Some carriers like Utilization Review while others do not. But that misses our point:

None, in other words, mitigate the conflict wrought by DRGs. But all became codified in US healthcare practices post-Nixon. All supported the deviation from true managed care. And all – especially when combined with DRGs - make a return to real 'managed

care' a la Kaiser-Permanente increasingly difficult. The reason: to implement true managed care now, we must first undo all the post-1973 healthcare systemic and bureaucratic evolution based largely on conflict between hospitals and carriers. No small task.

Our 1973 – 2000 experience with managed care did, however, superficially appear somewhat successful. Healthcare spending in 2000 was $300 billion less than had been forecast by the Congressional Budget Office only 7 years earlier.[24] Unfortunately these savings were primarily the result of two features, neither of which appeared in the original managed care plan design:

1. Hospital overcapacity in the 1990s (resulting from overbuilding in the 1980s plus treatment constraints in the 1990s) allowed carriers to gain significant price concessions from providers;
2. Managed care insurance companies controlled costs by service denial: denial of provider payments, denial of specialist referrals, denial of hospital admissions. 'At the peak of managed care's sway, in 1999, far more physicians were financially rewarded for productivity [i.e. number of patients seen] by insurers than for patient satisfaction' claims Harvard Business School's Regina Herzlinger. [25]

Providers hated managed care. Carriers squeezed hospital revenue. Physicians lost control of their incomes and professional independence – in both cases to administrators – largely because of DRGs and Utilization Review. Subscribers hated it for they felt at the mercy of a heartless insurance carrier that denied necessary services for the sake of profit. The popular 2002 film John Q played on these concerns – a father whose insurance company wouldn't pay for his son's medical treatments takes an Emergency Room hostage until doctors agree to operate. John Q could be any American according to the film's marketing; it grossed over $71 million in the first 2 months.

Meanwhile, the US Institute of Medicine in 2001, during the heyday of managed care, released its shattering study 'Crossing the Quality Chasm' claiming

> The US healthcare system does not provide consistent, high quality medical care to all people…between the healthcare that we now have and the healthcare that we could have lies not just a gap, but a chasm…
>
> The nation's healthcare delivery system has fallen far short in it's ability to translate knowledge into practice…

This and other observations led ***The Economist*** to claim that managed care just 'treated the symptoms' – like every other healthcare control strategy. [26]

THE MANAGED CARE PROPONENTS CALL FOUL: The US healthcare system that developed post 1973 was not the healthcare system envisioned or designed by true

managed care proponents. It strayed from their original concept and Kaiser Permanente's model, and thus failed to realize its true potential due to Nixon's political compromises and subsequent market evolution. The proponents called for a return to basics so managed care could finally replicate KP's financial and quality results nationally; they did not want to be blamed for managed care's failure.

Thus Stanford's Alain Enthoven wrote ***The History and Principles of Managed Competition*** and ***Why Managed Care Has Failed to Contain Health Costs*** both in 1993 [27] just as the Clinton administration began considering national healthcare reform…apparently hoping that this time a President would bring his ideas to life. In these back-to-basics pieces Enthoven reminded readers that Nixon had perverted his ideal, creating 'a system dominated by the cost-increasing incentive of fee-for-service payment combined with the cost-unconscious demand of insured patients' whose insurance was paid by employers and subsidized by taxpayers.

US HMOs developed provider networks, Enthoven claimed, simply by cobbling together independent physicians and paying them according to a fee schedule – in other words, IPAs. This was not the Kaiser Permanente model!

Enthoven went on to decry fee-for-service for 11 reasons:

1. Fee-for-service creates an adversarial relationship between doctors and payers;
2. Fee-for-service has little accountability – poor data collection and provider motivations for economy;
3. Fee-for-service 'free choice of provider' leaves patients to make remarkably poorly informed choices;
4. Fee-for-service generates excess hospital capacity, high tech equipment and open-heart surgeries;
5. Fee-for-service generated an excess supply of specialists;
6. Fee-for-service misallocates resources, as no incentive to use the least costly settings for treatment;
7. Fee-for-service has no capacity to plan care processes from diagnosis to treatment to rehabilitation;
8. Fee-for-service has led to a dangerous proliferation of facilities for complex and costly procedures without the volumes necessary to maintain good outcomes;
9. Fee-for-service cannot practice total quality management due to lack of service integration;
10. Fee-for-service cannot organize the rational use of technology
11. Organized systems, unlike fee-for-service, can emphasize prevention, early diagnosis and effective chronic disease management.

He further reiterated how to structure the market by a set of rules 'laid down once and for all.' These include appropriate types of plan sponsors, rules to ensure equity, rules to manage the enrollment process, rules for managing risk selection, rules for

monitoring specialty care and quality, and lots more rules to make the system work. His goal: define a system involving

> Intelligent, active collective purchasing agents contracting with healthcare plans on behalf of a large group of subscribers and continuously structuring and adjusting the market to overcome attempts to avoid price competition.

Any deviation from this ideal system reduces its effectiveness. Groups that dreamt up ways to get around the rules for their own advantage upset Enthoven. He lamented the self centered interests of many involved in healthcare: 'Whatever set of rules one proposes, critics could and did dream up ways for health plans to get around them to their advantage.'

Nixon's HMO Law of 1973 and subsequent healthcare evolution so perverted his managed care ideal that he wrote in *Why Managed Care Has Failed to Contain Health Costs* 'Some say that competition has failed. I say that competition has not yet been tried.'

He described Health Insurance Purchasing Cooperatives as the mechanism of implementing true managed care, just as Hilary Clinton was developing her healthcare plan. Enthoven's *History and Principles* seemed to serve as the intellectual basis to promote true managed care for all.

BILL AND HILARY CLINTON TAKE ON HEALTHCARE

Bill Clinton had campaigned for President on four healthcare platforms:

1. To provide healthcare coverage for all Americans;
2. To slow runaway medical care cost inflation;
3. To minimize governmental intrusion; and
4. To avoid harming most special interest groups. [28]

He delegated responsibility for the specific healthcare plan design to his wife, Hilary. She introduced her plan in mid-September 1993.

The plan itself was broad, ambitious and founded in Enthoven's theories. It would set up one or more large 'healthcare purchasing alliances' in each region. These would restructure the health insurance market by serving as the group purchaser for people not on Medicare, including small and medium sized employers. Large companies with 5000+ employees could act as their own purchaser.

These alliances would manage competition among plans and carriers, along the lines that Enthoven envisioned. They would – theoretically – offer people their choice of health plans and would provide them with competitive information about costs, services and quality. As envisioned by the authors, consumers would have a minimum of 3 plan options, varying by cost-sharing, out of network restrictions and specific services

covered (above the mandated minimums). The alliances' responsibilities would include maintaining competition among plan options so those that operated most efficiently would get rewarded in the marketplace.

The Clinton Plan would require carriers to offer a comprehensive minimum set of benefits including hospital and office care, clinical prevention services, hospice care and home health and long term care. By 2001 it would add mental health and substance abuse services.

The entire healthcare distribution operation would be run by a complex administration including a National Health Board responsible for oversight, budgets and national quality. States would also have responsibility for establishing risk-adjustment procedures, monitoring carrier fiscal stability and monitoring the quality of local care. This combined state and federal administrative effort was deemed necessary to ensure two things:

1. That our healthcare system would function well both during and after the transition to the Clinton Plan; and
2. That Enthoven's dual theories of managed care and managed competition would be made operational.

Hilary Clinton presented her 1000+ page healthcare plan in 1993. For about a year proponents and opponents discussed, debated, analyzed and considered her healthcare plan for America. Articles appeared in learned journals; interest groups spent over $100 million lobbying and campaigning for or against it. Ultimately, in 1994, Congress voted the plan down.

The interesting question from this story is 'why'. Why did the American people – and ultimately Congress – reject Hilary's plan?

Public opinion polling during this period highlighted contradictory and confusing indicators. The American public apparently liked the ideas – while disliking the Clinton plan. Understanding how this can be helps explain the fundamental problem with establishing true managed care in the US.

The Wall Street Journal reported in 1994 that 'Many Don't Realize It's the Clinton Plan They Like'. The article summarized results of a WSJ-NBC news poll asking people their reaction to a health plan that contained the same features as the Clinton plan but without revealing that it actually was the President's. Some 76% found 'some' or 'a great deal' of appeal in Clinton's plan – even while indicating in other polls their opposition to 'the Clinton Healthcare Plan'.

How can people actually like the plans' features while opposing the plan itself? According to former Harvard University President Derek Bok, there are two answers: [29]

First, Americans distrust government imposed solutions to problems;

Second, special interests (intentionally or otherwise) play on popular fears with targeted marketing campaigns.

Bok reports that polls taken during the 1993 – 1994 healthcare debate showed that 80% of the population believed healthcare costs would rise more than the Clintons claimed, including 54% who thought costs would rise 'much more'. Similarly although only 25% of Americans said that they understood what a health alliance actually was, 65% assumed that the President's plan would lead to more bureaucracy. Perhaps the Clintons marketed their plan poorly. But perhaps also, popular distrust of government made their marketing task impossible.

Plan opponents understood this popular sentiment and played on it. The over $100 million spent to lobby the public for or against healthcare reform, according to Bok, 'seemed designed less to inform than to arouse latent fears and anxieties'. He reports on an infamous Harry and Louise TV commercial paid for by the Health Insurance Association of America:

> This plan forces us to buy our insurance through those new mandatory government health alliances,' complained a prototypical wife, Louise... 'Run by tens of thousands of new bureaucrats,' added husband Harry. 'Having choices we don't like is not choice at all,' replied Louise. 'They choose, we lose,' both concluded with evident disapproval.

The University of Pennsylvania's Annenberg School of Communications found that 59% of all TV ads on healthcare reform were misleading, with most attacking rather than advocating one position or the other. Opponents said the Clinton plan was 'involuntary enthanasia' that deprived families of their choice of a doctor. Proponents claimed that 'unless the Clinton plan is passed, million of Americans will have no access to healthcare.' Fearmongering on both sides led less to education and compromise than to rejection amidst a climate of fear and mistrust.

This shows the fundamental problem with the Clinton healthcare plan – the same problem that has plagued every other government attempt to reform healthcare. Government designed, top-down solutions imposed on Americans fail due to the lack of buy-in by participants. Americans, it appears, do not want to be told what kind of healthcare to purchase.

Top-down solutions attempt to impose the values of some group – Stanford academics, Washington liberals, Texas conservatives or whomever – on the rest of Americans. It matters less that the healthcare plan is good or bad; what matters is that it is imposed. Americans need time to evolve solutions to our healthcare problems, to feel comfortable with and to embrace healthcare reform. This is not, as in the Clinton case, a 12 – 15 month process. It is a process in which Americans gain positive experiences necessary to 'buy-in'. (Remember that it took years and years for Garfield to develop the Kaiser-Permanente operation.)

Absent this buy-in, we will, apparently, reject a health plan we like (according to the Wall Street Journal polling data) simply because it is imposed on us.

In short, any attempt to implement reform healthcare need focus at least as strongly on the acceptance process as on the plan itself. At least that appears the major lesson of this story. And popular acceptance is likely a multi-year, long term process.

The Clinton Administration ultimately failed to pass its huge healthcare reform plan. American culture and politics intervened, and for the second time in 20 years an attempt to take Kaiser Permanente national failed. That political debacle led to another 15+ years of fee-for-service healthcare that deviated from the 'true' managed care model, with economic and quality results that harmed Americans.

MANAGED CARE PROPONENTS POST CLINTON REFORMS: The true believers, though, weren't finished yet. In 2002, Enthoven and Laura Tollen edited 'Toward a 21st Century Health System' which again extolled the virtues of Kaiser Permanente. In the Foreword, William Roper, Dean of the University of North Carolina School of Public Health, claimed

> Prepaid group practices have remained the health reform prescription of choice of many in the health policy community…and I proudly put myself among them.

The problem with managed care in the 1980s-1990s, says Roper, was that it was forced on people, which planted the seeds of consumer backlash. Enthoven echoes this in his Preface by stating that 'Patient satisfaction depends a great deal on whether or not the patient became an HMO member voluntarily or involuntarily.' (He apparently had learned from the Clinton's failure.) If only people would want to join prepaid group practices like Kaiser Permanente, then our healthcare system would improve. If only we could diffuse the model, then people would see its successes and want to join.

Chapter 1 of 'Toward a 21st Century…' discusses the two key barriers to diffusion of this model:

1. Lack of a group / corporate culture, and
2. Lack of financial incentives.[30]

Are these surmountable problems? Can the Kaiser Permanente model be successfully replicated? In other words, ***can managed care ever work?***

The Corporate Culture Problem: By the late 1990s, Kaiser Permanente began losing money – some $270 million in 1997 alone. This was due to its rapid growth; some 50% of top managers were new to their positions by the late 1990s, and 20% of them were new to the organization. 'The culture-imbued physicians, the hospitals managed directly by Kaiser, the seasoned insurance officials who worked with the providers to balance healthcare quality and cost, the tense interplay among the three elements of the system

– all were diminished' in this process, suggests Harvard's Herzlinger. Kaiser's membership soared, but it nearly lost its soul in the process. [31]

Remember Sidney Garfield who claimed you need true believers to make prepaid group practices work. He went on to state that 'they aren't going to work unless they get men [and women] who really believe in giving service to the people.' In our market based economy, especially with our post-1973 experiences with DRGs and the like, it's very difficult to hire seasoned, experienced managers, skilled in competition but with the right care-giving, philosophical orientation.

Absent culture, HMOs manage costs by denying claims – not nearly the same as managing health. Even Enthoven agrees that developing a corporate culture takes time, energy and effort – they are 'difficult to develop and slow to grow' [32] - and then still may not succeed. Corporate culture grows from shared experiences and difficulties. You can't recreate Kaiser's culture without its evolutionary past. Absent soul and shared evolution, you're doomed to fail.

This is apparently what happened to Kaiser Permanente during it's failed attempt to expand into North Carolina.[33] KP entered North Carolina in 1984 and exited in 1999, where is operated mainly as a Group Model HMO. It peaked at 134,000 subscribers in 1997. According to the University of North Carolina researchers who studied this expansion, corporate culture problems plagued the enterprise from the beginning:

- KP struggled to find the right balance between giving the North Carolina operation the flexibility and autonomy necessary to respond to local market conditions while maintaining the overall corporate goals and policies. In other words, KP struggled to find the right mix of national corporate culture with local medical culture;
- The original KP – North Carolina leadership was supposed to replicate the California model, not innovate. Managers referred to the 'cookbook formula' imposed from KP headquarters;
- KP – North Carolina managers found it hard enough to build the familiar group model delivery system from scratch under less than hospitable market conditions (i.e. local medical cultural norms and specific state regs) – but found that creating a network model (as demanded by local conditions) so far removed from KP's core competence was impossible;
- Managers reported that KP's flirtation with network models nearly cost the company it's soul;
- KP's expansions into Texas, Kansas City, New York and New England also failed.

The University of North Carolina researchers concluded that this failed expansion case illustrates the difficulties of replicating the vertically integrated model in new geographic markets under different market conditions.

Why Vertical Integration Fails (or the Financial Incentive Problem): In Kaiser Permanente's model the providers and financiers work together for the overall good of patients and the organization. This is vertical integration: the financial and provider functions belong to the same corporation.

Merging these functions together is extraordinarily difficult, especially absent the shared values of a meaningful corporate culture. Hospitals, physicians and financiers have fundamental conflicts:

- Hospitals want high bed occupancy to generate income; carriers want low occupancy to reduce expenses;
- Hospitals want high reimbursements per patient; carriers want low;
- Physicians want high compensation / rewards from hospitals for referrals; hospitals want to pay less
- Hospitals want to make money; carriers want to control premium rates

The financial mechanism that links the insurance function to the provider function is called a transfer price. If the transfer price is too high, then the hospital makes money but the insurance carrier loses – a big problem if the insurance managers are compensated based on profits or if the insurance carrier is publicly traded.

If the transfer price is too low, then the carrier makes money but the hospital loses – and hospital managers face the same problems as carrier managers, above.

If the transfer price is set at market, then why integrate? Remember Enthoven's 11 problems with fee-for-service pricing. At market transfer pricing, there seems little advantage to owning both the financial and delivery systems as you just recreate the problems that you integrated to solve.

Vertical integration, according to McKinsey 'is notoriously difficult to set, easy to get wrong and – when a company does get it wrong – very costly to fix.' [34] Enthoven apparently agrees, claiming that managing true prepaid group practices requires 'wise, if not visionary, leadership, which has been relatively rare in American healthcare in recent years.'[35]

The examples of good vertical integration in Prepaid Group Practices – Kaiser Premanente until the 1980s, Group Health Cooperative in Seattle, HealthPartners in Minneapolis, the Mayo Clinic in Minnesota and others – were formed in a different era. That was before hospitals consolidated, before universities trained students in healthcare administration, before American consumers became accustomed to wide provider choice, before DRGs created billing conflicts between carriers and providers and before the myriad of state and federal healthcare regulations. Senior officials at existing Prepaid Group Practices think that 'without substantial changes to the US financial and regulatory systems, it would be difficult for new PGPs to develop and for many of the current ones to expand' due largely to the difficulty of exporting the entrenched group culture.[36] In this, they are probably correct.

Indeed, the UNC researchers who studied Kaiser Permanente's foray into North Carolina suggest several elements necessary for managed care success.

Key Idea: Elements necessary for managed care success today:

1. Broad choice of health plans, so HMOs can demonstrate their value advantages (financial savings and quality improvements vs. fee-for-service plans);
2. Risk adjustment to mitigate adverse selection;
3. Employer contributions that allow employees to retain any savings resulting from an economical choice;
4. A level playing field among HMOs, insurers and self-funded plans;
5. Reliable, comparable information about plan quality and customer satisfaction.

Unfortunately for managed care, if these are the necessary preconditions, the US healthcare market is far from an appropriate environment. Let's review some of these elements:

First, broad choice of health plans. Our current national trend is for fewer carriers to offer a broader choice of plans with broader provider networks. Many employers (mainly smaller) offer only a limited plan selection, often for reasons of administrative expediency. Subscribers demand wide provider choice, perhaps as reaction to managed care excesses of the 1990s. True managed care options with limited provider access in return for (theoretically) lower premiums and better quality run counter to this national trend.

Second, risk adjustment among health plans. In Enthoven's model carriers will use advanced statistical techniques to determine the likely future health costs of a subscriber, and the managed competition system will make financial arrangements (called risk adjustments) among plans to level the risk playing field. These statistical techniques are not yet available. As Enthoven wrote, not particularly comfortingly, in 1993:

> It turns out to be much harder than one might think to turn available diagnostic information into 'risk adjusters'. For example, among patents diagnosed in one year to have breast cancer or HIV, there will be a very wide variation in medical costs the next year. **But it seems reasonable to suppose that diagnosis-based models eventually will be available** [37]

It may or may not be reasonable to make this supposition – but it is certainly a weak premise upon which to base our healthcare policy.

Third, employer contributions should allow employees to retain savings from choosing a true HMO. Unfortunately a number of factors currently mitigate against this.

Employees generally pay half or less of their premiums on a pre-tax basis. Here's a typical scenario:

Total healthcare monthly premiums = $1000
Employee contribution (33%) = $ 333 to employee
Tax deductibility (at 40% combined state and fed) = $199 net to employee

If the HMO cuts costs by 15% or $150/month versus the competition (quite an outstanding achievement), the employee likely would only see a $30 monthly after tax savings. To take advantage of this small savings, the employee may need to change primary care physician, change benefits and access a smaller provider network. Not very attractive to the employee.

But it creates a huge burden for the managed care organization. Since the employee only pays, effectively, about 20% of the premium after tax, the carrier must generate outstandingly good results to get employees to enroll.

Would the employer allow the employee to keep all the savings as managed care proponents desire? Unclear. Many employers want to reduce their own health insurance burden. One rational response by employers: fix the employee contribution at $199/month, regardless of plan. Then let employees choose among a true managed care option or fee-for-service coverage. The employer would keep any savings generated by the managed care organization.

In sum, our business environment is currently not structured as the managed care proponents require.

Fourth, we need reliable, comparable information about plan quality. This is often called transparency and requires both price and outcome data.

Unfortunately, our healthcare system is extremely poor at collecting and disseminating comprehensible outcome data. We don't, currently, know which providers have the best results, which hospitals have the lowest infection rates or which PCPs have the best diagnostic capabilities. Our healthcare system is evolving in this direction, but we're far from there today.

Thus, the pre-conditions outlined by the UNC researchers do not exist in our healthcare system. They agree by noting two real trends in US health insurance:

- More broad network insurance products divorced from provider systems;
- Policies that emphasize copayments and deductibles at time of purchase rather than cost-conscious choice at time of insurance policy purchase.

Their conclusion: true managed care has structural features – narrow networks and lower premiums – at variance with common employer policies and national trends.

CAN MANAGED CARE WORK IN THE US TODAY? The answer: No, managed care cannot work in the US today. Even supporters see this, as Northwestern's David Dranove wrote in 2002: 'my optimistic view of managed care's potential has wavered. I accept the possibility that managed care will never fulfill its promise.'[37]

We had two major attempts to develop the Kaiser Permanente model as our national healthcare. Nixon and Clinton – both brilliant politicians - failed. If neither of them could do it, then we wonder who could? It's time to move on.

Each attempt to replicate Kaiser Permanente – in North Carolina, for example – led either to failure or to such major changes in the model as to make it unrecognizable.

Furthermore, each political attempt to implement Enthoven's ideas nationally – by Nixon and Clinton – proved disastrous. Special interests force political compromises that drastically alter the ideal model. After 40 years of trying we have clear evidence that our society simply cannot implement true managed care.

Managed care's time has passed. It's now time to move on to other, more fruitful, healthcare reform options.

Review Questions
Answers on next page

1. What is the classic definition of managed care?
    a. Large multispecialty group practices that provide a comprehensive set of healthcare services at a per capita price set in advance
    b. An HMO plan that requires referrals from a primary care provider
    c. A PPO plan that does not require referrals to see a specialist

2. How does managed care differ from indemnity insurance?
    a. Managed care differs from indemnity or fee-for-service health insurance, especially in terms of prevention, cost controls and outcome measurements.
    b. Managed care is far more efficient than indemnity insurance
    c. Indemnity insurance allows more access to specialists than managed care

3. How does managed care differ from single payer healthcare?
    a. Managed care uses competition (i.e. managed competition) to keep prices low and quality high while single payer healthcare generally does not embrace competition.
    b. Managed care is generally less expensive than single payer
    c. Single payer is generally less expensive than managed care

4. How does managed care differ from consumer driven healthcare?
    a. CDHC proponents believe that consumers can make their own healthcare choices. Managed care proponents disagree; they think healthcare is fundamentally unlike other consumer products. They think consumers need help navigating among diagnoses and specialists so require Primary Care Providers to act as advisors and gatekeepers.
    b. Managed care is less expensive than CDHC
    c. CDHC generally has higher deductibles than managed care

5. What is the classic example of a managed care organization?
    a. Massachusetts General Hospital
    b. Blue Cross and Blue Shield
    c. Kaiser Permanente

6. How did Nixon change the Kaiser Permanente model in his HMO Law of 1973?
    a. He did not require vertical integration between finance and service delivery
    b. He required vertical integration between finance and service delivery
    c. He restricted the number of HMOs that any given physician could join

Answers to review questions
Correct answers in bold

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   a. CDHC proponents believe that consumers can make their own healthcare choices. Managed care proponents disagree; they think healthcare is fundamentally unlike other consumer products. They think consumers need help navigating among diagnoses and specialists so require Primary Care Providers to act as advisors and gatekeepers.
   b. Managed care is less expensive than CDHC
   c. CDHC generally has higher deductibles than managed care

5. What is the classic example of a managed care organization?
   a. Massachusetts General Hospital
   b. Blue Cross and Blue Shield
   c. Kaiser Permanente

6. How did Nixon change the Kaiser Permanente model in his HMO Law of 1973?
   a. He did not require vertical integration between finance and service delivery
   b. He required vertical integration between finance and service delivery
   c. He restricted the number of HMOs that any given physician could join

Public Health Insurance

Medicare became law on July 30, 1965, when President Lyndon B. Johnson signed the Social Security Amendments of 1965 into law. The legislation created both the Medicare and Medicaid programs as amendments to the Social Security Act.[78]

Medicare was established to provide health insurance coverage for Americans aged 65 and older, as well as certain younger individuals with disabilities. It was designed to address the growing healthcare needs of older adults and provide them with access to affordable healthcare services. Prior to the establishment of Medicare, many older Americans struggled to afford medical care, leading to significant financial burdens and barriers to accessing necessary healthcare services.

The creation of Medicare was a significant milestone in U.S. healthcare history, marking the federal government's commitment to ensuring access to healthcare for older adults and individuals with disabilities. Since its inception, Medicare has undergone several expansions and reforms to improve coverage and access to care for its beneficiaries, making it one of the most important and widely used healthcare programs in the United States.

Medicare consists of 4 main parts:

1. **Part A (Hospital Insurance)**:
    - Covers inpatient hospital stays, skilled nursing facility care, hospice care, and some home health care services.
    - Most people do not pay a premium for Part A if they or their spouse paid Medicare taxes while working.
2. **Part B (Medical Insurance)**:
    - Covers outpatient care, doctor visits, preventive services, and some medical equipment and supplies.
    - Requires a monthly premium, which can vary depending on income.
3. **Part C (Medicare Advantage)**:
    - Private insurance plans approved by Medicare that provide all Part A and Part B benefits.
    - Often includes additional benefits such as vision, dental, and prescription drug coverage.
    - Plans may have different costs and coverage rules.

[78] Much of this section comes from ChatGPT, written in April 2024.

4. **Part D (Prescription Drug Coverage)**:
    - Helps cover the cost of prescription drugs.
    - Offered by private insurance companies approved by Medicare.
    - Monthly premiums, deductibles, and copayments or coinsurance apply.
5. **Medigap (Medicare Supplement Insurance)**:
    - Sold by private insurance companies to fill "gaps" in Original Medicare coverage, such as copayments, coinsurance, and deductibles.
    - Helps pay for expenses not covered by Original Medicare.
6. **Other Coverage Options**:
    - Some people may qualify for other Medicare programs, such as Medicare Savings Programs or programs for people with specific health conditions.

Overall, Medicare provides essential healthcare coverage for millions of Americans, though it's crucial for individuals to understand the different parts and options available to choose the coverage that best suits their needs.

The Four Components Medicare

Medicare Part A, often referred to as Hospital Insurance, covers a range of inpatient hospital services and certain types of post-hospital care. Here's a more detailed breakdown of what Medicare Part A covers:

1. **Inpatient Hospital Care**:
    - Part A covers semi-private rooms, meals, general nursing, and other hospital services and supplies when you're formally admitted as an inpatient by a doctor.
    - It includes care received in acute care hospitals, critical access hospitals, inpatient rehabilitation facilities, and long-term care hospitals.
2. **Skilled Nursing Facility (SNF) Care**:
    - Part A covers a stay in a skilled nursing facility (SNF) if it's medically necessary following a hospital stay of at least three days.
    - SNF care includes services such as skilled nursing care, rehabilitation services, and other related health services.
3. **Hospice Care**:
    - Part A covers hospice care for individuals with a terminal illness whose life expectancy is six months or less.

- Hospice care includes services like pain relief, symptom management, and emotional and spiritual support for both the individual and their family.

4. **Home Health Care**:
    - Part A covers certain home health services if you're homebound and require skilled nursing care, physical therapy, speech-language pathology services, or continued occupational therapy.
5. **Blood**:
    - Part A covers the cost of the first three pints of blood you receive in a calendar year, or the blood you get as a hospital inpatient during a stay, after you've paid a deductible.

It's important to note that while Medicare Part A covers a significant portion of inpatient hospital services and related care, it doesn't cover everything. For example, it typically doesn't cover private-duty nursing, a private room (unless medically necessary), or personal care items like toothpaste or razors.

Most people don't have to pay a premium for Medicare Part A if they or their spouse paid Medicare taxes while working. However, there are deductibles, coinsurance, and copayments associated with Part A services. It's essential to understand these costs and coverage limitations to make informed decisions about your healthcare needs.

Inpatient hospital care covered by Medicare Part A includes a range of services and supplies necessary for treating acute medical conditions and providing necessary care during a hospital stay. Here are some services that are typically included:

1. **Room and Board**:
    - Coverage for semi-private rooms (unless medically necessary for a private room), meals, and general nursing care.
2. **Nursing Care**:
    - Skilled nursing services provided by registered nurses (RNs) or licensed practical nurses (LPNs) for the management and monitoring of medical conditions.
3. **Medical Services and Supplies**:
    - Physician services, including consultations, exams, and medical procedures performed during the hospital stay.
    - Necessary medical supplies and equipment used during the hospitalization, such as IVs, oxygen, and other medical devices.
4. **Diagnostic Tests and Procedures**:

- Coverage for diagnostic tests, laboratory work, and medical imaging procedures necessary for diagnosing and treating the patient's medical condition.

5. **Surgical Services**:
    - Coverage for medically necessary surgeries performed during the hospital stay, including pre-operative and post-operative care.
6. **Hospital Services**:
    - Coverage for hospital services such as operating rooms, recovery rooms, and emergency room services used during the hospital stay.
7. **Medications**:
    - Coverage for medications administered during the hospitalization, including those administered intravenously or through other means.
8. **Therapies**:
    - Coverage for therapies provided during the hospital stay, such as physical therapy, occupational therapy, and speech-language pathology services.

Services typically excluded from Medicare Part A coverage for inpatient hospital care include:

1. **Personal Comfort Items**:
    - Personal comfort items such as telephone or television services, unless provided as part of the hospital's standard care.
2. **Private Duty Nursing**:
    - Nursing services provided by individuals not employed or contracted by the hospital, unless specifically authorized by Medicare under certain circumstances.
3. **Private Room Charges**:
    - Charges associated with a private room unless medically necessary as determined by the attending physician.
4. **Certain Medical Procedures and Treatments**:
    - Some elective procedures or treatments not deemed medically necessary by Medicare may not be covered.

Medicare Part A covers skilled nursing facility (SNF) care under certain circumstances. A Medicare beneficiary can stay in a skilled nursing facility as long as they meet specific criteria and as long as the care remains medically necessary. Here are the key points regarding Medicare coverage for skilled nursing facility stays:

1. **Qualifying Hospital Stay**:
    - The beneficiary must have a qualifying hospital stay of at least three consecutive days as an inpatient. Observation days do not count toward this requirement.
2. **Medically Necessary Care**:
    - The skilled nursing care must be medically necessary and related to the condition for which the beneficiary was hospitalized.
3. **Skilled Care Requirement**:
    - The care provided in the skilled nursing facility must require skilled nursing or rehabilitation services on a daily basis. This includes services such as physical therapy, occupational therapy, or skilled nursing care.
4. **Coverage Period**:
    - Medicare Part A covers up to 100 days of skilled nursing facility care per benefit period.
    - The first 20 days are covered in full by Medicare.
    - For days 21 through 100, the beneficiary is responsible for a daily coinsurance amount.
5. **Benefit Period**:
    - A benefit period begins the day the beneficiary is admitted to a hospital or skilled nursing facility as an inpatient and ends when they haven't received any inpatient hospital care or skilled nursing care in a skilled nursing facility for 60 consecutive days.
    - If the beneficiary needs skilled nursing care again after the benefit period ends, a new benefit period begins, and they may qualify for another 100 days of coverage.

While Medicare covers skilled nursing facility care for a limited period, it does not cover long-term care services or custodial care (assistance with activities of daily living like bathing, dressing, and eating) in a skilled nursing facility. After Medicare coverage ends, beneficiaries may need to explore other options for long-term care, such as Medicaid or private long-term care insurance, if they require ongoing assistance.

Medicare makes a distinction between skilled nursing care and long-term care based on the level of care required and the specific services provided. Understanding this difference is crucial for Medicare beneficiaries to determine their coverage eligibility. Here's how Medicare distinguishes between skilled nursing care and long-term care:

1. **Skilled Nursing Care**:
    - Skilled nursing care refers to services provided by licensed healthcare professionals, such as registered nurses (RNs) or licensed practical nurses (LPNs), that are necessary for the treatment and management of a medical condition.
    - Skilled nursing care involves services that require the expertise of trained medical professionals and cannot be safely performed by individuals without medical training.
    - Examples of skilled nursing care include wound care, intravenous medication administration, physical therapy, and rehabilitation services following surgery or illness.
2. **Rehabilitation Services**:
    - Medicare covers skilled nursing facility care when it is primarily for skilled nursing or rehabilitation services on a daily basis. This includes services such as physical therapy, occupational therapy, or speech-language pathology services that are needed to improve the beneficiary's condition or help them regain function.
3. **Time-Limited Care**:
    - Skilled nursing care provided under Medicare is typically time-limited and intended to help the beneficiary recover from an acute illness, injury, or surgical procedure.
    - Medicare Part A covers up to 100 days of skilled nursing facility care per benefit period, with the understanding that the care is expected to result in improvement or stabilization of the beneficiary's condition.
4. **Long-Term Care**:
    - Long-term care refers to assistance with activities of daily living (ADLs) and other support services that are needed on an ongoing basis due to chronic illness, disability, or advanced age.
    - Long-term care includes services such as assistance with bathing, dressing, eating, toileting, and mobility, as well as supervision and assistance with medications.

- Medicare does not generally cover long-term care services, as they are considered custodial care and not primarily skilled nursing or rehabilitative services.

Medicare Part B, also known as Medical Insurance, covers a wide range of outpatient services, preventive care, and medically necessary services that are not covered by Medicare Part A. Here's an overview of what Medicare Part B covers:

1. **Doctor Visits and Services**:
    - Coverage for visits to doctors, including primary care physicians, specialists, and other healthcare providers.
    - Services provided during doctor visits, such as physical exams, consultations, and evaluations.
2. **Outpatient Care**:
    - Coverage for outpatient medical services and procedures received outside of a hospital setting.
    - This includes services such as lab tests, X-rays, diagnostic imaging, and outpatient surgeries.
3. **Preventive Care**:
    - Coverage for preventive services to help prevent illness or detect health problems early when they are most treatable.
    - Examples include flu shots, vaccines, screenings for various conditions (e.g., cancer screenings, mammograms, colonoscopies), and counseling services.
4. **Durable Medical Equipment (DME)**:
    - Coverage for durable medical equipment prescribed by a doctor for use at home.
    - Examples include wheelchairs, walkers, oxygen equipment, and hospital beds.
5. **Ambulance Services**:
    - Coverage for emergency and non-emergency ambulance transportation to a hospital or other medical facility when medically necessary.
6. **Outpatient Mental Health Services**:
    - Coverage for outpatient mental health services, including individual and group therapy sessions, counseling, and psychiatric evaluations.

7. **Outpatient Rehabilitation Services**:
    - Coverage for outpatient therapy services, including physical therapy, occupational therapy, and speech-language pathology services.
8. **Some Prescription Drugs**:
    - Limited coverage for certain outpatient prescription drugs that cannot be self-administered and are typically administered by a healthcare provider.
9. **Some Preventive Medications**:
    - Coverage for certain preventive medications, such as certain vaccines (e.g., flu shots) and injectable osteoporosis drugs.
10. **Clinical Research Studies**:
    - Coverage for certain costs associated with participating in approved clinical research studies.

While Medicare Part B covers many services, beneficiaries are generally responsible for paying a monthly premium, an annual deductible, and coinsurance or copayments for covered services. Additionally, not all services are covered at 100%, so beneficiaries may have out-of-pocket costs associated with their care.

> What are some physician or outpatient services that typically are not covered by Medicare?

While Medicare Part B covers a wide range of physician and outpatient services, there are certain services and expenses that are typically not covered by Medicare. These may include:

1. **Routine Dental Care**: Medicare does not cover most routine dental care, including cleanings, fillings, extractions, dentures, and dental plates.
2. **Routine Vision Care**: Medicare does not cover routine eye exams for eyeglasses or contact lenses. However, it does cover some vision-related services if they are deemed medically necessary, such as exams for diabetic retinopathy or glaucoma.
3. **Routine Hearing Care**: Medicare does not cover routine hearing exams or hearing aids. However, it may cover diagnostic hearing and balance exams if they are ordered by a doctor for the evaluation of a suspected medical condition.
4. **Cosmetic Procedures**: Medicare does not cover cosmetic procedures or surgeries performed solely for cosmetic purposes. This includes procedures such as cosmetic surgery, Botox injections for wrinkles, and hair transplants.

5. **Acupuncture**: While acupuncture may be considered an alternative therapy for certain medical conditions, Medicare typically does not cover acupuncture treatments.
6. **Long-Term Care**: Medicare does not cover custodial or long-term care services, such as assistance with activities of daily living (e.g., bathing, dressing, eating) provided in a nursing home or at home.
7. **Over-the-Counter Medications**: Medicare does not cover most over-the-counter medications, vitamins, or supplements, even if they are recommended by a doctor.
8. **Alternative Medicine**: Medicare generally does not cover alternative or complementary medicine services, such as chiropractic care, massage therapy, or herbal supplements.
9. **Medical Services Outside the United States**: Except in certain limited circumstances, Medicare does not cover medical services received outside of the United States.
10. **Experimental or Investigational Procedures**: Medicare typically does not cover services or treatments that are considered experimental or investigational and not proven to be effective.

How can a Medicare beneficiary get access to these services? Specifically, how can a beneficiary get financial coverage for these?

Medicare beneficiaries seeking coverage for services that are not covered by traditional Medicare Part A and Part B have a few options to explore alternative coverage or financial assistance:

1. **Medicare Advantage (Part C) Plans**:
    - Medicare Advantage plans are offered by private insurance companies approved by Medicare. These plans provide all of the benefits covered by Medicare Part A and Part B and often include additional benefits beyond what Original Medicare covers.
    - Many Medicare Advantage plans offer coverage for services such as routine dental care, vision care, and hearing care that are not covered by Original Medicare.
    - Some Medicare Advantage plans also offer coverage for services like acupuncture, chiropractic care, and fitness programs that are not covered by traditional Medicare.
    - Beneficiaries should review the specific benefits and costs associated with each Medicare Advantage plan to determine if it meets their needs.

2. **Medicare Supplement Insurance (Medigap)**:
    - Medigap plans are supplemental insurance policies sold by private insurance companies to help fill the "gaps" in Original Medicare coverage, such as copayments, coinsurance, and deductibles.
    - While Medigap plans do not typically cover services that are not covered by Medicare, they can help beneficiaries pay for out-of-pocket costs associated with covered services.
    - Some Medigap plans may offer additional benefits beyond what Original Medicare covers, such as coverage for foreign travel emergencies.
3. **Other Insurance Coverage**:
    - Some beneficiaries may have access to other insurance coverage through employer-sponsored plans, retiree health plans, or union plans that offer coverage for services not covered by Medicare.
    - Veterans may be eligible for coverage through the Department of Veterans Affairs (VA) for certain healthcare services not covered by Medicare.
4. **State and Local Assistance Programs**:
    - Some states offer assistance programs that provide coverage or financial assistance for services not covered by Medicare, such as prescription drugs, dental care, and vision care.
    - Beneficiaries can contact their State Health Insurance Assistance Program (SHIP) or State Medicaid office to inquire about available assistance programs in their area.
5. **Out-of-Pocket Payment**:
    - In some cases, beneficiaries may need to pay out-of-pocket for services that are not covered by Medicare or other insurance plans.
    - Beneficiaries can explore payment options with healthcare providers, such as setting up payment plans or negotiating discounted rates for services.

Medicare Part C, also known as Medicare Advantage, is an alternative way for Medicare beneficiaries to receive their Medicare benefits through private insurance plans approved by Medicare. Unlike traditional Medicare (Parts A and B), which is administered by the federal government, Medicare Advantage plans are offered by private insurance companies that contract with Medicare to provide all of the beneficiary's Part A and Part B benefits.

Here are some key features of Medicare Part C or Medicare Advantage:

1. **All-in-One Coverage**:

- Medicare Advantage plans provide all of the benefits covered by Medicare Part A (Hospital Insurance) and Part B (Medical Insurance), and often include additional benefits beyond what Original Medicare covers.
- These additional benefits may include coverage for prescription drugs (Part D), routine dental care, vision care, hearing aids, and wellness programs.

2. **Variety of Plan Options**:
    - Medicare Advantage plans come in various types, including Health Maintenance Organizations (HMOs), Preferred Provider Organizations (PPOs), Private Fee-for-Service (PFFS) plans, Special Needs Plans (SNPs), and Medicare Medical Savings Account (MSA) plans.
    - Each plan type has different rules and restrictions regarding network providers, out-of-pocket costs, and coverage limitations.
3. **Managed Care Approach**:
    - Many Medicare Advantage plans use a managed care approach to healthcare delivery, which may involve network restrictions and requirements for referrals to see specialists.
    - HMOs typically require beneficiaries to use network providers and obtain referrals from a primary care physician to see specialists.
    - PPOs offer more flexibility in provider choice but may have higher out-of-pocket costs for services received out of network.
4. **Annual Enrollment Period**:
    - Beneficiaries can enroll in or switch Medicare Advantage plans during the annual Medicare Open Enrollment Period, which runs from October 15 to December 7 each year.
    - Some beneficiaries may also be eligible for special enrollment periods based on certain qualifying events, such as moving to a new area or losing other coverage.
5. **Premiums and Cost-Sharing**:
    - Medicare Advantage plans may have premiums in addition to the standard Medicare Part B premium, although some plans offer $0 premium options.
    - Beneficiaries are still responsible for paying their Medicare Part B premium, as well as any copayments, coinsurance, and deductibles associated with their Medicare Advantage plan.
6. **Coverage Limitations**:

- While Medicare Advantage plans must provide at least the same level of coverage as Original Medicare, they may have different rules, restrictions, and coverage limitations.
- Beneficiaries should carefully review the benefits and costs of each Medicare Advantage plan to ensure it meets their healthcare needs and budget.

Medicare Part C has become increasingly popular among Medicare beneficiaries for several reasons:

1. **All-in-One Coverage**:
    - Medicare Advantage plans often provide comprehensive coverage that includes all the benefits of Original Medicare (Parts A and B), along with additional benefits such as prescription drug coverage (Part D), dental, vision, and hearing benefits, wellness programs, and sometimes even gym memberships.
    - This all-in-one coverage simplifies healthcare management for beneficiaries by consolidating their coverage into a single plan.
2. **Cost Savings**:
    - Medicare Advantage plans may offer lower out-of-pocket costs compared to Original Medicare, including lower deductibles, copayments, and coinsurance.
    - Many Medicare Advantage plans have annual out-of-pocket maximums, providing financial protection for beneficiaries in case of significant medical expenses.
    - Some Medicare Advantage plans offer $0 monthly premiums, providing an affordable option for beneficiaries on a fixed income.
3. **Additional Benefits**:
    - Medicare Advantage plans often offer additional benefits beyond what Original Medicare covers, such as vision, dental, and hearing benefits, which can be particularly appealing to beneficiaries who need these services.
    - Many plans also offer wellness programs, preventive care services, and access to telehealth services, which can help beneficiaries stay healthy and manage chronic conditions more effectively.
4. **Provider Networks**:

- While some Medicare Advantage plans have restrictive provider networks, others offer broader networks or even out-of-network coverage in certain circumstances, providing beneficiaries with flexibility in choosing their healthcare providers.
- Beneficiaries who prefer having a primary care physician to coordinate their care may find the managed care approach of Medicare Advantage appealing.

5. **Value-Added Services**:
    - Some Medicare Advantage plans offer value-added services such as care coordination, disease management programs, transportation assistance, and home health services, which can improve the overall quality of care for beneficiaries.
6. **Annual Enrollment Period**:
    - The annual Medicare Open Enrollment Period provides beneficiaries with an opportunity to review and change their Medicare coverage each year, including switching to a Medicare Advantage plan if it better meets their needs.
7. **Market Competition**:
    - Medicare Advantage plans are offered by private insurance companies competing for beneficiaries' business, leading to innovation, improved benefits, and enhanced customer service.
    - The availability of a wide range of plan options allows beneficiaries to choose a plan that best suits their individual healthcare needs and preferences.

Still, some 35% of Medicare beneficiaries remain in traditional Medicare for several reasons.

1. **Freedom of Provider Choice**:
    - Original Medicare allows beneficiaries to see any healthcare provider who accepts Medicare, without the need for referrals or obtaining permission from a primary care physician.
    - Some beneficiaries prefer the flexibility of choosing their healthcare providers, including specialists and hospitals, without restrictions imposed by network limitations.
2. **Predictable Coverage**:

- Original Medicare provides standardized coverage, making it easier for beneficiaries to understand their benefits and costs.
- While copayments, coinsurance, and deductibles still apply, beneficiaries may appreciate the transparency and predictability of costs associated with Original Medicare.

3. **Consistency of Coverage**:
    - Original Medicare coverage remains consistent regardless of where beneficiaries live or travel within the United States.
    - Beneficiaries who frequently travel or live in multiple states may find Original Medicare more convenient than Medicare Advantage plans, which may have limited provider networks or coverage areas.
4. **Access to Specialists**:
    - Some beneficiaries with complex medical conditions or specialized healthcare needs may prefer Original Medicare because it allows them to see specialists without requiring referrals or network restrictions.
    - Original Medicare generally offers more flexibility in accessing specialized care, which can be important for individuals with chronic or serious health conditions.
5. **Supplemental Coverage Options**:
    - Beneficiaries who choose Original Medicare can supplement their coverage with a Medicare Supplement Insurance (Medigap) policy to help cover out-of-pocket costs, such as deductibles, copayments, and coinsurance.
    - Medigap plans offer standardized benefits across different insurance companies, providing beneficiaries with additional financial protection and peace of mind.
6. **Preference for Fee-for-Service Model**:
    - Some beneficiaries prefer the fee-for-service model of Original Medicare, where healthcare providers are paid for each service rendered, rather than the managed care approach of Medicare Advantage plans.
    - Fee-for-service Medicare allows beneficiaries to have more control over their healthcare decisions and treatment options.
7. **Concerns About Plan Stability**:

- Medicare Advantage plans may change their benefits, provider networks, premiums, and formularies annually, which can be a concern for beneficiaries who prefer the stability and consistency of Original Medicare.

8. **Lack of Availability**:
    - In some areas, particularly rural or underserved areas, there may be limited availability of Medicare Advantage plans, making Original Medicare the only viable option for beneficiaries.

Some beneficiaries may prefer the flexibility, consistency, and freedom of choice provided by Original Medicare. The decision to remain in traditional Medicare versus enrolling in Medicare Advantage is highly individual and depends on each beneficiary's healthcare needs, preferences, and priorities.

Medicare Part D is the prescription drug coverage component of Medicare. It was introduced as part of the Medicare Modernization Act of 2003 and became effective in 2006. Part D is designed to help Medicare beneficiaries afford the costs of prescription drugs, whether they are taken at home or administered in a clinical setting. Here are the key features of Medicare Part D:

1. **Coverage through Private Insurance Plans**:
    - Medicare Part D is provided through private insurance plans approved by Medicare. These plans are offered by insurance companies and other private companies that contract with Medicare.
    - Beneficiaries can choose from a variety of Part D plans available in their area, each offering a different list of covered drugs (formulary), premiums, deductibles, and copayments or coinsurance.
2. **Prescription Drug Formulary**:
    - Each Medicare Part D plan maintains a formulary, which is a list of covered prescription drugs. Formularies vary between plans and can change from year to year.
    - Part D plans are required to cover at least two drugs in each therapeutic category and class, ensuring beneficiaries have access to a range of treatment options.
3. **Annual Enrollment Period**:
    - Beneficiaries can enroll in or make changes to their Medicare Part D coverage during the annual Medicare Open Enrollment Period, which runs from October 15 to December 7 each year.

- Outside of this period, beneficiaries may be eligible for a Special Enrollment Period if they experience certain qualifying events, such as losing other prescription drug coverage.

4. **Premiums and Cost-Sharing**:
    - Beneficiaries typically pay a monthly premium for Medicare Part D coverage, in addition to any premiums they pay for Medicare Part A (if applicable) and Part B.
    - Part D plans also have an annual deductible, which beneficiaries must pay out-of-pocket before their plan begins to cover prescription drug costs.
    - After meeting the deductible, beneficiaries typically pay a copayment or coinsurance for each prescription filled, and the plan covers the remaining cost.
5. **Coverage Gap (Donut Hole)**:
    - Until recently, Medicare Part D included a coverage gap, often referred to as the "donut hole," where beneficiaries had to pay a larger share of their prescription drug costs.
    - However, due to changes in the Affordable Care Act, the coverage gap has been gradually closing. As of 2021, beneficiaries only pay 25% of the cost of their brand-name drugs and 25% of the cost of generic drugs while in the coverage gap.
    - The coverage gap will be fully phased out by 2024, at which point beneficiaries will pay no more than 25% of the cost of their drugs, both generic and brand-name, until they reach catastrophic coverage.
6. **Catastrophic Coverage**:
    - Once a beneficiary's out-of-pocket spending on prescription drugs reaches a certain threshold, they qualify for catastrophic coverage. At this point, they pay a reduced copayment or coinsurance for covered drugs for the remainder of the year.

Medicare Part D provides essential prescription drug coverage for millions of Medicare beneficiaries, helping them afford the medications they need to manage chronic conditions, prevent illness, and improve their overall health and well-being.

The George W. Bush administration proposed and championed Medicare Part C (Medicare Advantage) and Part D (Prescription Drug Coverage) as part of the Medicare Modernization Act of 2003. There were several reasons behind the decision to propose these additions to Medicare:

1. **Addressing Rising Prescription Drug Costs**:

- One of the primary motivations for introducing Medicare Part D was to address the rising costs of prescription drugs for Medicare beneficiaries.
- Prescription drug coverage was seen as a critical component of comprehensive healthcare coverage, particularly as prescription drug costs were becoming increasingly burdensome for seniors and individuals with disabilities.

2. **Expanding Medicare Coverage Options**:
    - Medicare Part C (Medicare Advantage) was introduced to provide beneficiaries with more choices and flexibility in how they receive their Medicare benefits.
    - Medicare Advantage plans, offered by private insurance companies, were intended to offer additional benefits and services beyond what Original Medicare covers, such as prescription drug coverage, dental, vision, and wellness programs.
3. **Promoting Competition and Market-Based Solutions**:
    - The Bush administration favored market-based solutions and competition to improve efficiency and drive down costs in healthcare.
    - By introducing Medicare Advantage and Part D, the administration aimed to encourage competition among private insurance plans, leading to innovation, improved benefits, and better value for beneficiaries.
4. **Political and Legislative Priorities**:
    - The proposal for Medicare Part D and Medicare Advantage was part of the broader legislative agenda of the Bush administration, which sought to enact significant reforms in healthcare and social policy.
    - Medicare Part D and Medicare Advantage were ultimately included in the Medicare Modernization Act of 2003, which was passed by Congress and signed into law by President Bush in December 2003.

Overall, the introduction of Medicare Part C (Medicare Advantage) and Part D (Prescription Drug Coverage) was driven by a combination of factors, including the need to address rising prescription drug costs, expand coverage options for beneficiaries, promote market competition, and advance the administration's legislative priorities in healthcare reform.

Medicare is generally quite popular among its beneficiaries. Surveys and polls consistently show high levels of satisfaction with Medicare among older adults and individuals with disabilities who are enrolled in the program. According to data from the

Centers for Medicare & Medicaid Services (CMS), the vast majority of Medicare beneficiaries express satisfaction with their coverage and access to care.

Here are some key factors contributing to the popularity of Medicare among beneficiaries:

1. **Comprehensive Coverage**:
    - Medicare provides comprehensive healthcare coverage, including hospital insurance (Part A), medical insurance (Part B), and prescription drug coverage (Part D), as well as options for supplemental coverage through Medicare Advantage (Part C) and Medigap plans.
    - The breadth of coverage offered by Medicare helps ensure that beneficiaries have access to essential healthcare services without facing significant financial barriers.
2. **Provider Choice**:
    - Medicare beneficiaries have the freedom to choose their healthcare providers, including doctors, specialists, hospitals, and other healthcare facilities.
    - The ability to see the providers of their choice without needing referrals or obtaining permission from a primary care physician is highly valued by many beneficiaries.
3. **Affordability**:
    - While beneficiaries may still have out-of-pocket costs such as premiums, deductibles, and coinsurance, Medicare generally offers more affordable coverage options compared to private insurance plans, particularly for older adults and individuals with pre-existing health conditions.
4. **Stability and Reliability**:
    - Medicare is a longstanding and well-established program with a strong track record of providing healthcare coverage to millions of Americans.
    - The stability and reliability of Medicare contribute to its popularity and trustworthiness among beneficiaries.

Comparatively, private insurance plans vary widely in popularity among subscribers, depending on factors such as plan features, network coverage, cost, and individual preferences. While some individuals may prefer the flexibility and additional benefits offered by private insurance plans, others may find that Medicare provides more comprehensive coverage and greater peace of mind, particularly as they age and their healthcare needs become more complex.

How Medicare is Funded

Medicare is funded through a combination of general revenue contributions, payroll taxes, beneficiary premiums, and other sources. Here's an overview of how Medicare is funded:

1. **Payroll Taxes**:
    - The largest source of funding for Medicare comes from payroll taxes paid by employees and employers under the Federal Insurance Contributions Act (FICA).
    - The Medicare payroll tax is composed of two parts: the Hospital Insurance (HI) tax and the Supplementary Medical Insurance (SMI) tax.
    - The HI tax funds Medicare Part A (Hospital Insurance), while the SMI tax funds Medicare Part B (Medical Insurance) and Medicare Part D (Prescription Drug Coverage).
2. **General Revenue Contributions**:
    - Medicare Part A (Hospital Insurance) is primarily funded through payroll taxes, but it also receives contributions from general revenues to cover any shortfalls in funding.
    - General revenue contributions help ensure that Medicare Part A remains adequately funded to cover the costs of hospital and inpatient care for beneficiaries.
3. **Beneficiary Premiums**:
    - Medicare beneficiaries also contribute to the funding of Medicare through premiums for certain parts of the program.
    - Most beneficiaries do not pay premiums for Medicare Part A if they or their spouse paid Medicare taxes while working. However, beneficiaries may be required to pay premiums for Medicare Part B (Medical Insurance) and Medicare Part D (Prescription Drug Coverage).
    - Premiums for Medicare Part B and Part D are set annually and may vary depending on factors such as income level and enrollment status.
4. **Medicare Advantage Payments**:
    - Medicare Advantage plans receive payments from the federal government to provide Medicare-covered benefits to beneficiaries enrolled in their plans.

- These payments are based on a complex formula known as the Medicare Advantage capitated payment system, which takes into account factors such as beneficiary demographics, health status, and regional costs.

5. **Other Sources**:
    - In addition to payroll taxes, general revenue contributions, and beneficiary premiums, Medicare may receive funding from other sources, such as interest earned on the Medicare trust funds, state contributions to the Medicaid program (which helps cover some Medicare costs for dually eligible beneficiaries), and certain taxes on high-income individuals.

Medicare cost about $929 billion in 2021, or about $13,000 per beneficiary. The cost per beneficiary has been increasing at a slower rate than overall inflation and private insurance costs over the past 5-8 years. Here are some key points:

- According to data from the Centers for Medicare & Medicaid Services (CMS), Medicare costs per beneficiary grew by about 2-3% annually from 2015 to 2022. This is well below the overall inflation rate during this period.
- Specifically, Medicare spending per beneficiary increased 2.3% in 2021 and 2.9% in 2022, while overall inflation was around 7-9% those years.
- In comparison, private health insurance premiums for employer-sponsored family coverage increased around 4-6% annually from 2015-2022 according to the Kaiser Family Foundation.
- The slower growth in Medicare costs is attributed to payment reforms, increased use of cheaper generic drugs, and delivery system reforms encouraging more cost-effective care.
- However, Medicare costs are expected to rise more rapidly in the coming years due to an aging population and rising healthcare costs overall.

Medicare's funding situation has been a longstanding issue of concern. The program currently gets funding from three main sources:

- Payroll taxes
- Premiums paid by beneficiaries
- General revenues from the federal government

There are two separate trust funds - one for Hospital Insurance (Part A, covering inpatient hospital care) and one for Supplementary Medical Insurance (Parts B and D, covering outpatient care and prescription drugs).

The often-cited projection that the Medicare Hospital Insurance Trust Fund will be depleted or "run out of money" in around 7 years (specifically 2028 according to the

latest Medicare Trustees report) does not mean Medicare itself is going bankrupt or will cease operating altogether.

What it means is that the Hospital Insurance Trust Fund's reserves will be depleted by 2028 based on current income and expenditure projections. After 2028, income to the fund from payroll taxes and other revenue would cover only 90% of projected Part A costs.

The Supplementary Medical Insurance Trust Fund is expected to remain adequately financed into the indefinite future because its funding can be adjusted through changes in premiums and general revenue contributions.

However, shoring up the financial condition of the Hospital Insurance Trust Fund will likely require significant legislative reforms by Congress, such as increasing payroll taxes allocated to Medicare, reducing expenditures through further cost-saving measures, or supplementing the fund with general revenues.

Here are some key points to consider:

1. **Trust Fund Depletion**:
    - The Medicare Trustees issue annual reports that project the financial status of the HI Trust Fund based on revenue and expenditure projections. These reports include estimates of when the trust fund will be depleted if current trends continue.
    - The projected depletion date has fluctuated over time due to various factors such as changes in healthcare costs, enrollment trends, economic conditions, and legislative changes.
2. **Impact on Benefits**:
    - If the HI Trust Fund were to be depleted, it would not mean that Medicare benefits would disappear entirely. Instead, it would mean that the trust fund would no longer have sufficient funds to cover all of its obligations fully.
    - In the event of trust fund depletion, Medicare Part A would still be able to pay a portion of its costs through ongoing revenue from payroll taxes and other sources, but benefits might need to be reduced, or additional funding sources might need to be allocated to cover the shortfall.
3. **Need for Policy Changes**:
    - The projected depletion of the HI Trust Fund underscores the need for policy changes to address the long-term financial sustainability of the Medicare program.

- Potential policy solutions to address trust fund depletion include increasing revenue through payroll taxes or other sources, reducing expenditures through benefit reforms or cost-saving measures, improving the efficiency of healthcare delivery, and implementing measures to address the underlying drivers of healthcare costs.

Measuring Medicare's Outcomes

The easiest way to measure a healthcare system's outcomes or quality is by measuring life expectancy. I like this admittedly imperfect metric for a couple of reasons:

- The data are relatively easy to access.
- Life expectancy generally improves in lock-step with a healthcare system. A well functioning system generally will generate longer life expectancies than a poorly functioning one.
- Life expectancy data also include variables that a narrowly defined medical care system might miss. Access to healthy foods, for example, probably play a life expectancy role. This suggests that a well functioning healthcare system should address the population's nutritional needs, not just their acute care needs.

Let's compare American life expectancies at age 65 to other countries.[79]

- For American men who survived to age 65 in 2021, their remaining life expectancy was around 18.1 years.
- For American women at age 65, remaining life expectancy was around 20.6 years in 2021.
- This places the U.S. below the average among OECD countries for life expectancy at age 65. For example, a 65-year-old man in Switzerland could expect to live around 19.8 more years on average.

Some key comparisons on life expectancy at birth and age 65 from 2021 OECD data:

- Switzerland: 81.1 years at birth, 21.1 remaining at age 65
- Norway: 82.7 years at birth, 20.3 remaining at 65
- Australia: 83.3 years at birth, 21.1 remaining at 65
- Canada: 82.2 years at birth, 21.3 remaining at 65
- United States: 77.0 years at birth, 18.5 remaining at 65

The correlation between life expectancy and overall healthcare system quality is complex, as life expectancy can be influenced by many socioeconomic and

[79] This section comes from Claude.ai, April 2024

environmental factors beyond just the healthcare system itself. However, most research suggests there is a meaningful but moderate correlation.

- Access to high-quality healthcare is undoubtedly a key determinant of life expectancy, especially through prevention and effective management of chronic diseases that affect mortality.
- Countries that rank highly on measures of healthcare access, affordability, and clinical outcomes tend to have higher life expectancies on average.

However, factors like poverty, education levels, diet, rates of smoking/obesity, air pollution, and income inequality also significantly impact life expectancy independently of healthcare.

Statistical analysis estimates that differences in healthcare system performance may account for around 25-40% of the life expectancy gap between the U.S. and other wealthy nations.

The remaining gap is attributed to the socioeconomic, environmental, and behavioral factors prevalent in the U.S. population.

Within countries, individuals with higher incomes and better healthy behaviors tend to experience longer life expectancies, even with similar healthcare access.

That's why I suggest that life expectancy is a good but definitely imperfect measure of Medicare's quality.

Summary

Medicare has been one of the most significant and impactful social programs in American history since its establishment in 1965.

What Medicare Accomplished:

- Provided access to health insurance for millions of elderly Americans age 65+ who previously could not afford or qualify for private coverage.
- Helped dramatically reduce elderly poverty and financial insecurity by covering major hospital and medical expenses.
- Improved access to preventive services and treatment for the elderly population.
- Along with Medicaid, helped desegregate some hospitals that previously refused Black patients.
- Established a national health insurance model and system that other programs like Medicaid and CHIP were built upon.

How Medicare Changed the World:

- Served as a model for other nations to establish universal healthcare programs for their citizens.
- Shifted the physician reimbursement system and expanded the role of private health insurance companies as contractors.
- Created a massive new sector of the economy around the administration of government-funded health insurance.
- Facilitated the integration of new medical technologies and drugs by covering them nationwide.
- Demonstrated how a large social insurance program could be successfully implemented and administered.

Overall Quality and Impact:

- While not perfect, Medicare has been incredibly successful in providing essential health coverage to the elderly.
- It remains one of the most popular and solidly supported government programs in American public opinion.
- Medicare has greatly improved quality of life and financial security for tens of millions of American seniors.
- However, its long-term financial sustainability remains an ongoing challenge that may require reforms.

Overall, Medicare drastically improved access to healthcare for America's senior citizens, served as a model for other countries, fundamentally changed the healthcare system's economics, and continues to provide vital health security today despite future financing concerns.

A word about Medicaid

Medicaid fills critical gaps in health coverage for tens of millions of America's most vulnerable low-income populations.[80] It is a joint federal and state program that provides health coverage to low-income Americans. Here's an overview of this major government health insurance program:

Purpose & Eligibility:

- Medicaid's main purpose is to provide health coverage for low-income adults, children, pregnant women, elderly adults, and people with disabilities.
- Eligibility is based on income level, which must be below a certain federal poverty line threshold. This threshold varies by state.

[80] Much of this section comes from Claude ai.

- As of 2022, over 83 million Americans were enrolled in Medicaid and the related Children's Health Insurance Program (CHIP).

Benefits Covered:

- Mandatory benefits covered by all state programs include inpatient/outpatient hospital services, physician services, laboratory/x-ray services, and early and periodic screening for children.
- States can choose to provide additional optional benefits like prescription drug coverage, physical therapy, dental, vision, and others.

Funding:

- Medicaid is funded jointly by the states and the federal government.
- The federal government pays states a matching rate (averaged 64% in 2020) based on the state's per capita income.
- Total Medicaid spending was over $670 billion in 2020.

Program Administration:

- Medicaid is a federal-state partnership program. The states administer their own Medicaid programs while following federal guidelines.
- This allows for state flexibility in program rules, benefits, eligibility, and provider payments.

Impact:

- Medicaid covers a large share of low-income children, pregnant women, seniors in nursing homes, and people with disabilities.
- It helps provide services that promote care in home/community settings rather than institutions.
- Critics argue for more uniformity across state programs and better cost control measures.

Medicaid generally provides more comprehensive benefits particularly for long-term care services. Here’s a brief summary of benefits in both programs:

Medicare Benefits:

- Hospital Insurance (Part A) - Inpatient hospital care, skilled nursing facility care, hospice, home health services
- Medical Insurance (Part B) - Physician services, outpatient care, preventive services, durable medical equipment

- Prescription Drug Coverage (Part D) - Outpatient prescription drugs
- Medicare Advantage (Part C) - Managed care plans that provide Parts A, B and usually D

Medicaid Benefits:

- Inpatient/outpatient hospital services
- Physician/certified nurse practitioner services
- Lab/x-ray services
- Nursing facility/home health care services for over 21
- Early periodic screening, diagnosis and treatment for under 21
- Family planning services
- Rural health clinic/FQHC services
- Transportation to medical care

Additionally, states can choose to provide optional Medicaid benefits like:

- Prescription drugs
- Rehabilitation services
- Personal care services
- Dental, vision, physical therapy and other therapies

Key Differences:

- Medicaid provides more comprehensive long-term care coverage
- Medicaid covers a broader range of benefits like dental, vision, therapies that Medicare does not
- But Medicaid varies significantly by state, while Medicare benefits are nationally uniform
- Lower-income Medicare beneficiaries can have Medicaid as a supplement

Medicaid generally provides more comprehensive benefits particularly for long-term care services and non-medical benefits that promote overall health for low-income populations.

Medicaid’s financial strength and sustainability are an ongoing issue of concern, though its funding outlook is somewhat better than Medicare's in the near-term.

Funding Sources:

- Medicaid is jointly funded by the federal government and states.
- The federal share is around 64% on average, though this federal matching rate varies by state based on per capita income.
- Total Medicaid spending was over $670 billion in fiscal year 2020.

Cost Growth:

- Medicaid costs have been growing faster than the overall economy, driven by enrollment growth, rising healthcare costs, and expansion of benefits.
- Total Medicaid spending increased by around 6% annually from 2017-2020.
- This growth rate is projected to continue in the range of 5-6% per year over the next decade.

Future Outlook:

- Medicaid's funding is not facing the same insolvency projections as Medicare's Hospital Insurance Trust Fund in the short-term.
- As an entitlement, federal/state funding is obligated to match enrollment and costs.
- However, the program's growing expense poses significant budgetary pressures long-term.
- Cost-controls and potential delivery system reforms may be needed to rein in spending growth.

Challenges:

- Economic downturns increase Medicaid enrollment as more people qualify due to low incomes.
- An aging population will increase Medicaid long-term care costs substantially in coming decades.
- State budgets can be strained during recessions, making their matching funding requirements difficult.

Medicaid accounts for a significant portion of state budgets across the country. According to data from the Kaiser Family Foundation:

- In fiscal year 2021, Medicaid made up 16.8% of total state spending on average across all 50 states and D.C.
- However, there is considerable variation between states in terms of how much of their budget goes to Medicaid:

High Percentages:

- New York (34.8%)
- Missouri (33.4%)
- Pennsylvania (31.3%)
- New Mexico (30.9%)
- West Virginia (30.8%)

Low Percentages:

- Wyoming (7.9%)
- Nevada (8.9%)
- Utah (9.9%)
- Idaho (10.6%)
- Hawaii (11.1%)
- The 10 states with the highest percentage of spending on Medicaid averaged 28.9% in 2021.
- The 10 states with the lowest percentage averaged 13.3%.

This high degree of variation is due to factors like:

- A state's Medicaid enrollment and eligible population
- The state's Federal Medical Assistance Percentage (FMAP) match rate
- Decisions to expand Medicaid eligibility under the ACA
- Cost of living and healthcare costs in each state

So while Medicaid does not face the same short-term funding crisis as Medicare, its long-term cost trajectory and pressure on state/federal budgets remain major fiscal policy concerns that could necessitate cost-saving reforms or measures to raise more program revenue over time.

An Eye on the Future
Medicare for All

"Medicare for All" is a healthcare policy proposal that advocates for a single-payer, government-funded healthcare system in which all residents of a country are covered

for medical services.[81] While opinions on this approach may vary, proponents highlight several potential advantages:

1. **Universal Coverage:**
    - One of the primary advantages is the achievement of universal healthcare coverage. Under Medicare for All, everyone would have access to necessary medical services, regardless of income or employment status.
2. **Simplified Administration:**
    - A single-payer system could reduce administrative complexity by streamlining billing and paperwork. This simplification might lead to cost savings and more efficient healthcare delivery.
3. **Cost Control:**
    - Proponents argue that a single-payer system could potentially control healthcare costs more effectively through negotiation with providers, bulk purchasing of medications, and overall cost management.
4. **Preventive Care Emphasis:**
    - With a focus on preventive care, Medicare for All could encourage early intervention and wellness programs, potentially reducing the overall burden of disease and the associated costs.
5. **Elimination of Health Disparities:**
    - Advocates claim that a single-payer system could help address health disparities by ensuring that everyone, regardless of socioeconomic status, has equal access to healthcare services.
6. **Financial Security:**
    - With universal coverage, individuals would not face financial ruin due to medical expenses. This could provide greater financial security and reduce the fear of bankruptcy related to healthcare costs.
7. **Improved Health Outcomes:**
    - By providing access to healthcare services for everyone, proponents argue that Medicare for All could lead to improved health outcomes on a population level.
8. **Simplified Choice of Providers:**

[81] Much of this section comes from ChatGPT

- A single-payer system could simplify the choice of healthcare providers for individuals, as everyone would be covered under the same system.

9. **Reduced Administrative Costs:**
    - Streamlining administrative processes and reducing the complexity of dealing with multiple insurers could lead to significant cost savings.

It's important to note that while these advantages are highlighted by proponents, there are also concerns and criticisms related to the potential costs, the impact on the healthcare industry, and the role of government in healthcare. The debate over healthcare policy is complex, and different stakeholders may have varied perspectives on the best approach.

How Medicare for All Achieves Universal Coverage

Medicare for All aims to achieve universal coverage by implementing a single-payer healthcare system, where the government serves as the sole payer for healthcare services. This means that all residents of a country would be covered under a single, comprehensive healthcare plan. Here are key features of how Medicare for All achieves universal coverage:

1. **Single-Payer System:**
    - In a single-payer system, the government is the primary entity responsible for paying healthcare providers for medical services. This eliminates the need for multiple private insurance plans.
2. **Comprehensive Benefits:**
    - Medicare for All typically proposes comprehensive coverage, including hospital services, preventive care, mental health services, prescription drugs, and other necessary medical treatments. This ensures that all essential healthcare needs are covered.
3. **No Exclusions for Pre-Existing Conditions:**
    - Unlike some private insurance plans that may deny coverage or charge higher premiums based on pre-existing conditions, Medicare for All is designed to provide coverage without such exclusions or discriminatory practices.
4. **Automatic Enrollment:**
    - The system may involve automatic enrollment for all residents, ensuring that everyone is covered by default. This eliminates the need for individuals to navigate complex insurance markets or worry about being uninsured.

5. **No Out-of-Pocket Costs for Essential Services:**
    - Medicare for All proposals often aim to eliminate or significantly reduce out-of-pocket costs for essential healthcare services, making healthcare more affordable and accessible.
6. **Standardized Benefits:**
    - The system typically establishes standardized benefits, ensuring that everyone receives the same level of coverage for basic healthcare needs. This promotes equity in access to medical services.
7. **Public Funding:**
    - Medicare for All relies on public funding, usually through taxation. This ensures that the financial burden is distributed across the population, and everyone contributes to the healthcare system based on their ability to pay.
8. **Negotiation with Healthcare Providers:**
    - The government, as the single payer, can negotiate directly with healthcare providers, pharmaceutical companies, and other stakeholders to control costs and ensure fair pricing for medical services and medications.
9. **Preventive and Primary Care Focus:**
    - By emphasizing preventive and primary care, Medicare for All aims to address health issues at an early stage, reducing the overall burden of disease and potentially lowering long-term healthcare costs.

It's important to note that the specific details of Medicare for All proposals can vary, and the implementation process may involve significant legislative and administrative changes. The concept of achieving universal coverage through a single-payer system is a central tenet of these proposals. The success of such a system depends on effective planning, funding mechanisms, and public support.

How Medicare for All Simplifies Healthcare Administration

Medicare for All simplifies healthcare administration in several ways:

1. **Elimination of Multiple Payers:**
    - Medicare for All envisions a single-payer system, where the government becomes the sole payer for healthcare services. This eliminates the need for multiple private insurance companies, each with its own set of policies, forms, and administrative processes.
2. **Streamlined Billing and Claims Processing:**

- With a single-payer system, healthcare providers would submit claims to the government payer. This simplifies billing and claims processing, reducing the complexity and paperwork associated with dealing with numerous private insurers.

3. **Standardized Benefits and Reimbursement:**
    - Medicare for All proposals often include standardized benefits and reimbursement rates for healthcare services. This standardization simplifies the process for both healthcare providers and payers, reducing the need for negotiations and complex contracts.
4. **Automatic Enrollment:**
    - The system may involve automatic enrollment for all residents, eliminating the need for individuals to navigate private insurance markets or apply for coverage. This reduces administrative overhead associated with enrollment processes.
5. **Reduced Administrative Costs:**
    - By consolidating the administration under a single-payer, Medicare for All aims to reduce administrative costs related to marketing, underwriting, and managing multiple insurance plans. This can lead to overall cost savings within the healthcare system.
6. **Simplified Provider Networks:**
    - Healthcare providers would deal with a single payer, simplifying their interactions with payers and reducing the need to navigate and contract with multiple insurance networks.
7. **Unified Electronic Health Records (EHR):**
    - A single-payer system could facilitate the development of a unified electronic health records (EHR) system, making it easier to share patient information among healthcare providers and reduce the need for disparate systems.
8. **Consistent Coverage Rules:**
    - With standardized benefits and coverage rules, Medicare for All seeks to create consistency in healthcare coverage. This reduces confusion for both patients and healthcare providers regarding what is covered under the plan.
9. **Efficient Negotiation and Drug Pricing:**

- The government, as the single payer, would have more bargaining power to negotiate with pharmaceutical companies for drug prices. This could lead to more efficient negotiations and potentially lower drug costs.

While the simplification of healthcare administration is a significant goal, it's important to acknowledge that the transition to a single-payer system involves complex challenges and considerations. Critics argue that the potential benefits should be carefully weighed against the potential disruptions and changes to the existing healthcare infrastructure.

How Medicare for All Controls Healthcare Spending

Proponent of Medicare for All argue that it helps control healthcare spending through various mechanisms. While there are different proposals and variations, here are common ways in which Medicare for All aims to control healthcare spending:

1. **Negotiating Power:**
    - A single-payer system consolidates the negotiating power of the government, allowing it to negotiate directly with healthcare providers, pharmaceutical companies, and other stakeholders. This can lead to lower prices for medical services, drugs, and other healthcare-related expenses.
2. **Bulk Purchasing of Medications:**
    - With a single-payer system, the government can engage in bulk purchasing of medications, negotiating lower prices for prescription drugs. This can result in significant cost savings and contribute to controlling overall healthcare spending.
3. **Administrative Efficiency:**
    - By eliminating the administrative complexity associated with multiple private insurance plans, Medicare for All aims to increase administrative efficiency. Streamlining billing, claims processing, and administrative tasks can reduce overhead costs within the healthcare system.
4. **Preventive Care Emphasis:**
    - Medicare for All often emphasizes preventive care and early intervention. By addressing health issues at an early stage, the system aims to reduce the overall burden of disease, potentially lowering long-term healthcare costs.
5. **Standardized Benefits and Reimbursement:**
    - Standardizing benefits and reimbursement rates across the healthcare system can contribute to cost control. Healthcare providers and payers operate under consistent rules, reducing the need for complex negotiations and individual contracts.

6. **Global Budgeting:**
    - Some Medicare for All proposals consider implementing global budgeting for healthcare spending. This involves setting a predetermined budget for healthcare expenditures, which can encourage efficiency and resource allocation within the system.
7. **Reduced Administrative Costs:**
    - The consolidation of administrative functions under a single-payer system is expected to reduce administrative costs associated with marketing, underwriting, and managing multiple private insurance plans.
8. **Preventing Price Gouging:**
    - Advocates argue that a single-payer system can prevent price gouging by setting reasonable reimbursement rates for healthcare services. This can prevent excessive charges from healthcare providers.
9. **Addressing Overutilization:**
    - Some Medicare for All proposals include measures to address overutilization of healthcare services. By promoting evidence-based practices and discouraging unnecessary procedures, the system aims to control costs associated with unnecessary medical interventions.

It's important to note that the effectiveness of these cost-control measures depends on the specific details of the Medicare for All proposal and its implementation. Critics argue that potential savings may be offset by increased demand for healthcare services, and the overall impact on healthcare spending is a subject of ongoing debate.

How Medicare for All Emphasizes Preventive Care

Medicare for All emphasizes preventive care as a key component of its healthcare approach. The goal is to shift the focus from treating illnesses and conditions after they occur to preventing them in the first place. Here are ways in which Medicare for All aims to prioritize and promote preventive care:

1. **Comprehensive Coverage:**
    - Medicare for All proposals typically include comprehensive coverage for preventive services. This can include routine check-ups, vaccinations, screenings, and other preventive measures without cost-sharing for patients.
2. **Early Detection and Screening:**
    - The emphasis is placed on early detection and screening for common diseases and conditions. Regular screenings, such as mammograms,

colonoscopies, and vaccinations, are included in the covered services to detect potential health issues early when they may be more treatable.

3. **Immunizations:**
    - Medicare for All supports and promotes access to immunizations for preventable diseases. By ensuring that vaccinations are readily available and covered, the goal is to protect individuals and communities from vaccine-preventable illnesses.
4. **Health Education and Promotion:**
    - The system may include health education and promotion efforts to inform individuals about healthy lifestyles, nutrition, exercise, and other factors that contribute to overall well-being. Educating the public about healthy choices can help prevent various health issues.
5. **Chronic Disease Management:**
    - Medicare for All aims to address chronic diseases through preventive measures and management strategies. By providing ongoing care and support for individuals with chronic conditions, the system seeks to prevent complications and improve overall health outcomes.
6. **Access to Primary Care:**
    - Ensuring access to primary care is a fundamental aspect of preventive care. Medicare for All aims to provide individuals with consistent access to primary care physicians, promoting regular check-ups and health maintenance.
7. **Community-Based Health Initiatives:**
    - Some proposals may allocate resources for community-based health initiatives. These initiatives can include programs that promote healthy living, provide education on preventive measures, and engage communities in activities that support overall well-being.
8. **Incentives for Providers:**
    - Medicare for All proposals may include incentives for healthcare providers to prioritize preventive care. This can involve reimbursement models that reward healthcare professionals for delivering preventive services and promoting patient health.
9. **Integration of Behavioral Health Services:**
    - Addressing mental health is often part of preventive care. By integrating behavioral health services into the healthcare system, Medicare for All

aims to identify and address mental health concerns early on, preventing more serious issues.

By incorporating these elements into the healthcare system, Medicare for All seeks to create a proactive and preventive approach that not only improves health outcomes for individuals but also contributes to the overall health of the population.

How Medicare for All Eliminates Health Disparities

Medicare for All aims to address and reduce health disparities through various mechanisms designed to ensure equitable access to healthcare services. Here are ways in which Medicare for All seeks to eliminate health disparities:

1. **Universal Coverage:**
    - By providing universal coverage, Medicare for All ensures that everyone, regardless of socioeconomic status, has access to necessary healthcare services. Universal coverage is a fundamental step toward reducing disparities in healthcare access.
2. **Equal Access to Services:**
    - Medicare for All seeks to provide equal access to a comprehensive set of healthcare services for all individuals. This includes preventive care, primary care, specialty services, mental health services, and other essential healthcare components.
3. **Elimination of Cost Barriers:**
    - By eliminating or significantly reducing out-of-pocket costs for essential services, Medicare for All aims to remove financial barriers that can disproportionately affect individuals with lower incomes. This can help ensure that cost is not a barrier to receiving necessary medical care.
4. **Standardized Benefits:**
    - Standardizing benefits across the healthcare system helps ensure that all individuals receive the same level of coverage for basic healthcare needs. This consistency can contribute to reducing disparities in access to specific services.
5. **Culturally Competent Care:**
    - Medicare for All proposals often emphasize the importance of culturally competent care. This involves recognizing and addressing the unique cultural, linguistic, and social factors that can impact healthcare outcomes, particularly for marginalized communities.
6. **Community-Based Health Initiatives:**

- Some proposals may allocate resources for community-based health initiatives. These initiatives can address social determinants of health and focus on improving health outcomes in specific communities facing disparities.

7. **Focus on Preventive Care:**
    - Preventive care is a key aspect of Medicare for All, and promoting early detection and intervention can help address health issues before they become more severe. This approach is crucial for reducing disparities in health outcomes.
8. **Health Education and Outreach:**
    - Medicare for All may include initiatives to provide health education and outreach to underserved communities. Informing individuals about preventive measures, healthy lifestyles, and available healthcare resources can empower communities to make informed decisions about their health.
9. **Investment in Underserved Areas:**
    - Some proposals may prioritize investments in healthcare infrastructure in underserved areas. This can involve increasing the number of healthcare facilities, ensuring an adequate healthcare workforce, and addressing geographic disparities in healthcare access.
10. **Data Collection and Monitoring:**
    - Implementing robust data collection and monitoring systems can help identify and address disparities in healthcare outcomes. By understanding the specific challenges faced by different populations, policymakers can tailor interventions to reduce disparities.

It's important to note that while Medicare for All aims to address health disparities, the effectiveness of these measures depends on the specific details of the proposal, its implementation, and ongoing efforts to monitor and adapt strategies to evolving needs. Reducing health disparities requires a comprehensive and sustained approach across multiple dimensions of healthcare delivery and social determinants of health.

How Medicare for All Improves the Financial Security of All Americans

Medicare for All proponents argue that implementing a single-payer healthcare system could improve the financial security of all Americans through several mechanisms. Here are ways in which Medicare for All aims to enhance financial security:

1. **Elimination of Out-of-Pocket Costs:**

- Medicare for All typically envisions reducing or eliminating out-of-pocket costs for essential healthcare services. By doing so, individuals would be less likely to face financial hardship due to medical expenses.

2. **Universal Coverage:**
    - The provision of universal healthcare coverage ensures that all Americans have access to necessary medical services. With everyone covered, individuals are less likely to face financial ruin due to medical emergencies or untreated health conditions.
3. **No Medical Bankruptcy:**
    - By removing the financial burden associated with high healthcare costs, Medicare for All aims to reduce the incidence of medical bankruptcies. Individuals and families would not face the prospect of financial devastation due to overwhelming medical bills.
4. **Preventive Care Emphasis:**
    - Medicare for All emphasizes preventive care, which can help identify and address health issues before they become more severe and costly. Preventive measures can contribute to long-term financial savings by avoiding expensive treatments for advanced illnesses.
5. **Stable Premiums and Deductibles:**
    - A single-payer system could lead to more stable premiums and deductibles. With a government-administered healthcare plan, the pricing structure may be more predictable, providing individuals with a clearer understanding of their healthcare expenses.
6. **Income-Linked Financing:**
    - Financing Medicare for All through progressive taxation ensures that individuals contribute based on their ability to pay. This approach aims to distribute the financial burden more equitably, reducing the strain on lower-income individuals and families.
7. **Negotiation for Lower Drug Prices:**
    - The government, as the single payer, would have more negotiating power over drug prices. This could lead to lower prescription drug costs, contributing to financial relief for individuals who rely on medications.
8. **Financial Predictability:**
    - Knowing that essential healthcare services are covered without significant out-of-pocket costs provides individuals with greater financial predictability.

This stability allows for better financial planning and reduces the anxiety associated with unexpected medical expenses.

9. **Freed-up Disposable Income:**
    - With reduced or eliminated healthcare costs, individuals and families may have more disposable income. This can be used for other essential needs, contributing to overall economic well-being.
10. **Job Flexibility:**
    - Individuals may experience increased job flexibility as they are not tied to employer-sponsored health insurance. This can facilitate career changes, entrepreneurship, and other professional pursuits without the concern of losing healthcare coverage.

While proponents argue that Medicare for All could enhance financial security, critics raise concerns about potential tax implications, the overall cost of implementing such a system, and potential trade-offs. The debate over the financial implications of Medicare for All is complex and involves considerations of both costs and benefits.

How Does Medicare for All Improve Health Outcomes

Proponents of Medicare for All argue that implementing a single-payer healthcare system could lead to improved health outcomes for the population. Here are ways in which Medicare for All aims to enhance health outcomes:

1. **Universal Access to Healthcare:**
    - Medicare for All provides universal access to healthcare services, ensuring that all residents have coverage for essential medical treatments, preventive care, and health services. This universal access is intended to reduce disparities in healthcare utilization and outcomes.
2. **Early Detection and Prevention:**
    - The emphasis on preventive care and regular check-ups in Medicare for All aims to detect health issues at an early stage. Early detection allows for timely intervention and preventive measures, reducing the severity of illnesses and improving overall health outcomes.
3. **Comprehensive Coverage:**
    - Medicare for All typically offers comprehensive coverage, including preventive services, primary care, specialty care, mental health services, and prescription drugs. Comprehensive coverage addresses a wide range of health needs and contributes to holistic healthcare.
4. **Elimination of Financial Barriers:**

- By reducing or eliminating out-of-pocket costs for essential healthcare services, Medicare for All aims to remove financial barriers that may prevent individuals from seeking necessary medical care. Financial accessibility is crucial for timely and appropriate healthcare utilization.

5. **Focus on Social Determinants of Health:**
    - Medicare for All may incorporate initiatives addressing social determinants of health, such as housing, education, and nutrition. Addressing these broader factors can positively impact health outcomes and contribute to overall well-being.
6. **Health Education and Promotion:**
    - Initiatives promoting health education and prevention can be integrated into the healthcare system. Educating the public about healthy lifestyles, nutrition, and disease prevention contributes to better health awareness and outcomes.
7. **Reduced Delayed Care:**
    - With universal coverage, individuals are less likely to delay seeking medical care due to concerns about affordability. Timely access to healthcare services can prevent the progression of illnesses and improve outcomes.
8. **Coordination of Care:**
    - A single-payer system can facilitate better coordination of care among healthcare providers. Improved communication and collaboration can enhance the management of chronic conditions and complex medical cases, leading to better health outcomes.
9. **Mental Health Integration:**
    - Integrating mental health services into the overall healthcare system addresses the importance of mental health in overall well-being. Comprehensive mental health support can positively impact mental health outcomes.
10. **Evidence-Based Medicine:**
    - Medicare for All may emphasize evidence-based medicine, encouraging healthcare providers to follow established guidelines and practices supported by scientific evidence. This approach can lead to more effective and standardized care.

It's important to note that the effectiveness of Medicare for All in improving health outcomes depends on various factors, including the specific design of the program,

implementation strategies, and ongoing efforts to address challenges in the healthcare system. The debate around the impact of Medicare for All on health outcomes is multifaceted and involves considerations of access, quality of care, and overall public health.

Simplified Choice of Providers

Medicare for All simplifies the choice of healthcare providers by streamlining the healthcare system and offering a single, comprehensive coverage plan. Here are ways in which it aims to simplify the choice of providers:

1. **Universal Coverage:**
    - Medicare for All provides universal coverage, ensuring that everyone has access to the same set of healthcare providers. This eliminates the need to navigate complex networks associated with multiple private insurance plans.
2. **No Network Restrictions:**
    - Unlike many private insurance plans that may have specific networks of providers, Medicare for All aims to eliminate network restrictions. Individuals can choose healthcare providers based on their preferences, without concerns about in-network or out-of-network distinctions.
3. **Freedom to Choose Any Doctor or Hospital:**
    - With Medicare for All, individuals have the freedom to choose any doctor, specialist, or hospital that accepts the coverage. This flexibility simplifies the process of selecting healthcare providers and allows individuals to maintain existing relationships with their preferred providers.
4. **Consistent Benefits Across Providers:**
    - Standardized benefits across the healthcare system mean that individuals receive the same level of coverage regardless of the healthcare provider they choose. This consistency simplifies the decision-making process for individuals seeking medical care.
5. **No Referral Requirements:**
    - Some insurance plans require referrals from primary care physicians to see specialists. Medicare for All typically eliminates the need for referrals, allowing individuals to directly access the healthcare providers they need without additional administrative steps.
6. **Simplified Billing and Administration:**

- Medicare for All streamlines billing and administrative processes. Healthcare providers deal with a single payer, reducing the administrative burden associated with managing multiple insurance plans with varying reimbursement rules.

7. **Access to Primary Care:**
    - The system emphasizes access to primary care, ensuring that individuals can easily find and choose a primary care physician. Access to primary care is crucial for preventive services and managing overall health.
8. **Continuity of Care:**
    - Medicare for All supports continuity of care, allowing individuals to maintain relationships with their healthcare providers over time. This can contribute to better-coordinated and personalized care.
9. **Elimination of Employer-Based Networks:**
    - With Medicare for All, individuals are not bound by employer-based networks. This flexibility is particularly beneficial for those who change jobs or pursue self-employment, as their choice of providers is not tied to employer-sponsored plans.
10. **Reduced Administrative Complexity for Providers:**
    - Healthcare providers experience reduced administrative complexity by dealing with a single payer. This simplification can contribute to more efficient and streamlined interactions between providers and the healthcare system.

While the aim is to simplify the choice of providers, it's important to consider that the actual implementation and the specifics of the Medicare for All plan can vary. Additionally, ongoing efforts are needed to monitor and address any challenges that may arise in the transition to a single-payer system.

How Does Medicare for All Reduce Healthcare Administration Costs

Medicare for All is designed to reduce healthcare administration costs through the implementation of a single-payer system. Here are ways in which it aims to achieve this:

1. **Simplified Billing and Claims Processing:**
    - With Medicare for All, healthcare providers would submit claims to a single payer (the government), streamlining billing and claims processing. This simplification reduces the administrative burden associated with dealing with multiple private insurers, each with its own billing processes and requirements.

2. **Reduced Administrative Overhead for Providers:**
    - Healthcare providers would experience reduced administrative overhead as they interact with a single, standardized system. This includes fewer resources dedicated to managing billing, claims, and administrative tasks associated with multiple insurers.
3. **Elimination of Private Insurance Administrative Costs:**
    - Medicare for All aims to eliminate the administrative costs associated with managing private insurance plans. This includes marketing, underwriting, and administrative overhead specific to each private insurer, leading to overall cost savings.
4. **Standardized Benefits and Reimbursement:**
    - Standardizing benefits and reimbursement rates across the healthcare system simplifies the negotiation process for healthcare providers. This reduces the need for complex negotiations and individual contracts, contributing to administrative efficiency.
5. **Reduced Marketing and Advertising Expenses:**
    - Private insurers currently spend significant resources on marketing and advertising to attract and retain customers. With a single-payer system, the need for such marketing efforts diminishes, leading to cost savings.
6. **Efficient Allocation of Resources:**
    - Medicare for All eliminates the need for insurance companies to allocate resources for tasks such as profit margins, shareholder returns, and executive compensation. This allows for a more efficient allocation of resources directly to healthcare services.
7. **Consolidated Administrative Functions:**
    - Administrative functions related to insurance coverage, claims processing, and other tasks are consolidated under a single-payer system. This consolidation reduces redundancy, simplifies processes, and minimizes administrative complexity.
8. **Savings on Fraud Prevention:**
    - A single-payer system can result in more effective fraud prevention measures. With a unified system, it becomes easier to implement standardized fraud detection and prevention practices, reducing the resources required for individual insurers to combat fraud.
9. **Streamlined Enrollment Processes:**

- Medicare for All typically involves simplified enrollment processes. With universal coverage and potentially automatic enrollment, the need for complex enrollment procedures and paperwork is reduced, leading to administrative efficiency.

10. **Lower Administrative Costs per Beneficiary:**
    - The administrative costs per beneficiary can be lower in a single-payer system due to economies of scale. The efficiency gained from serving a larger population under a unified system can contribute to lower administrative costs per individual covered.

It's important to note that while proponents argue that Medicare for All can lead to significant administrative cost savings, critics raise concerns about potential challenges in implementing and managing such a system. The actual impact on administrative costs may depend on the specific design and implementation of the single-payer system.

Why Medicare for All is a Bad Idea

Critics of Medicare for All typically raise several concerns and potential drawbacks, including:

1. **Cost:**
    - Critics argue that implementing Medicare for All could result in substantial increases in government spending. Financing such a program might require higher taxes, which could impact the economy and individual incomes.
2. **Impact on Quality of Care:**
    - Some opponents express concerns about potential reductions in the quality of healthcare. They argue that a single-payer system may lead to longer wait times for medical services and less innovation in the healthcare sector.
3. **Disruption to Existing Systems:**
    - Transitioning to a single-payer system could involve significant disruptions to existing healthcare systems, including the private insurance industry. Critics worry about the potential negative impact on jobs and the overall economy during the transition.
4. **Loss of Choice:**
    - Critics argue that a single-payer system may limit individuals' choices by eliminating private insurance options. Some people value the ability to

choose their healthcare plans and providers, and they fear that a government-controlled system could restrict those choices.

5. **Bureaucracy and Administrative Challenges:**
    - Concerns are raised about potential bureaucratic challenges and administrative inefficiencies in a government-run healthcare system. Critics worry that a single-payer system might lead to increased red tape, delays in care, and administrative complexities.
6. **Incentives for Innovation:**
    - Opponents argue that a competitive healthcare market fosters innovation and technological advancements. They express concerns that a government-dominated system might reduce the incentives for medical research and innovation.
7. **Potential Tax Burden:**
    - Implementing Medicare for All could require substantial tax increases to fund the program. Critics are concerned about the potential burden on taxpayers and the economic consequences of higher taxes.
8. **Resistance to Change:**
    - Some individuals may resist the idea of a major overhaul of the healthcare system, especially if they are satisfied with their current insurance arrangements. Opposition may come from those who fear uncertainty or perceive a loss of control over their healthcare choices.
9. **Variability in Healthcare Needs:**
    - Critics argue that a one-size-fits-all approach may not adequately address the diverse healthcare needs of different populations and demographics. Tailoring healthcare plans to individual preferences and needs may be more challenging in a single-payer system.
10. **Political and Ideological Divisions:**
    - The debate over Medicare for All is often influenced by political and ideological divisions. Opposition may stem from differing views on the role of government in healthcare and the balance between individual freedom and collective responsibility.

It's important to note that these concerns are raised by critics, and supporters of Medicare for All contend that the proposed system would address current shortcomings in the healthcare system, provide universal access to care, and reduce overall healthcare costs. The ongoing debate revolves around finding a balance that addresses

the needs of the population while considering the potential drawbacks and challenges associated with a significant healthcare system overhaul.

How Will Medicare for All Raise Healthcare Costs

Some potential ways Medicare for All might increase healthcare spending:

1. **Increased Demand for Services:**
    - Critics suggest that the elimination of out-of-pocket costs and the provision of universal coverage could lead to an increase in the demand for healthcare services. A surge in demand, especially for elective or non-urgent procedures, could strain the healthcare system and potentially lead to higher costs.
2. **Reduced Incentives for Cost Containment:**
    - Some critics argue that a government-run, single-payer system may reduce incentives for cost containment and efficiency. In a competitive market, providers and insurers have an incentive to control costs to remain competitive. In a single-payer system, critics express concerns that such market forces may be diminished.
3. **Potential for Overutilization:**
    - Critics worry that the absence of cost-sharing measures could lead to overutilization of healthcare services. Without financial barriers, individuals might be more inclined to seek unnecessary or excessive medical care, contributing to increased healthcare costs.
4. **Challenges in Controlling Drug Prices:**
    - While proponents argue that a single-payer system could negotiate lower drug prices, critics express concerns about the potential challenges in effectively controlling pharmaceutical costs. Negotiating with drug manufacturers may not guarantee significant reductions in drug prices.
5. **Transition Costs:**
    - Critics point out that the transition to a Medicare for All system may involve significant upfront costs. The process of implementing the new system, including changes to administrative structures, workforce training, and infrastructure development, could lead to temporary increases in overall healthcare spending.
6. **Potential for Bureaucratic Inefficiencies:**
    - Concerns are raised about the potential for bureaucratic inefficiencies in a government-administered system. Critics argue that a single-payer system

might introduce administrative complexities, red tape, and delays in decision-making, which could impact overall healthcare costs.

7. **Impact on Provider Reimbursement:**
    - Critics express concerns that a government-run system might result in lower reimbursement rates for healthcare providers. If reimbursement rates are set too low, there could be challenges in maintaining an adequate supply of healthcare professionals and facilities, potentially affecting the quality of care.
8. **Resistance from Healthcare Industry:**
    - Some critics argue that the healthcare industry, including pharmaceutical companies, insurers, and certain healthcare providers, may resist cost containment efforts associated with a single-payer system. This resistance could pose challenges in achieving cost savings.
9. **Economic Impact of Tax Increases:**
    - Financing Medicare for All could require substantial tax increases to fund the program. Critics argue that higher taxes could have broader economic consequences, potentially impacting economic growth, individual incomes, and job creation.

It's important to recognize that the potential impact on healthcare costs is a complex and debated aspect of Medicare for All. Proponents argue that the system could lead to overall cost savings through administrative efficiencies, negotiation of lower prices, and a focus on preventive care. The ongoing discussion revolves around finding a balance that addresses cost concerns while ensuring access to quality healthcare for all.

How Medicare for All Will Reduce Medicare Care Quality

Medicare for All critics raise concerns about potential challenges that could affect the quality of care. Here are some arguments made by critics:

1. **Provider Reimbursement Rates:**
    - Critics express concerns that Medicare for All might lead to lower reimbursement rates for healthcare providers. If reimbursement rates are set too low, there could be challenges in attracting and retaining skilled healthcare professionals. This, in turn, could potentially impact the quality of care provided.
2. **Reduced Incentives for Innovation:**
    - Some opponents argue that a single-payer system might reduce incentives for innovation in healthcare. In a competitive market, providers and pharmaceutical companies have incentives to invest in research and

development to stay ahead. Critics worry that a government-dominated system may result in fewer innovations in medical treatments and technologies.

3. **Impact on Access to Specialized Care:**
    - Critics express concerns about the potential impact on access to specialized and advanced medical treatments. If reimbursement rates are not sufficient, healthcare providers may limit certain services or technologies, potentially affecting the availability of specialized care options.
4. **Bureaucratic Inefficiencies:**
    - Concerns are raised about the potential for bureaucratic inefficiencies in a government-run healthcare system. Critics argue that increased bureaucracy, red tape, and administrative complexities could slow down decision-making processes, potentially affecting the efficiency and quality of care.
5. **Difficulty in Addressing Regional Variances:**
    - Critics worry that a single-payer system might face challenges in addressing regional variances in healthcare needs and costs. Healthcare requirements can vary significantly across different regions, and critics argue that a one-size-fits-all approach may not adequately address these variations.
6. **Possible Impact on Provider Networks:**
    - The restructuring associated with Medicare for All could potentially impact existing provider networks. If healthcare providers face challenges in adapting to the new system, it may lead to disruptions in established patient-provider relationships, potentially affecting the continuity and quality of care.
7. **Potential for Longer Wait Times:**
    - Critics express concerns that increased demand for healthcare services, especially in the absence of cost-sharing measures, could lead to longer wait times for medical treatments. Longer wait times may impact patient outcomes and satisfaction.
8. **Resistance to Change:**
    - Some individuals and healthcare professionals may resist the significant changes associated with transitioning to a single-payer system.

Resistance to change could pose challenges in adapting to new care delivery models and may affect the overall quality of healthcare services.

It's important to note that these concerns are raised by critics, and proponents of Medicare for All argue that the system could lead to improved quality through better coordination of care, emphasis on preventive services, and standardized benefits. The debate over the impact on healthcare quality involves considerations of access, efficiency, and the overall healthcare delivery model. The effectiveness of Medicare for All in maintaining or enhancing healthcare quality would depend on the specific design and implementation of the program.

How Medicare for All Will Negatively Disrupt the Existing Healthcare System

The transition to Medicare for All could potentially lead to disruptions in the existing healthcare system, and critics often raise concerns about various aspects of this transformation. While proponents argue that a single-payer system could bring about positive changes, opponents highlight potential negative impacts. Here are some concerns raised by critics:

1. **Job Displacement:**
    - Critics worry that the shift to Medicare for All could result in job displacement, particularly in the private health insurance sector. Employees working in administrative roles related to private insurance may face challenges during the transition.
2. **Impact on Private Insurance Industry:**
    - The implementation of Medicare for All could have a significant impact on the private health insurance industry. Critics argue that the elimination or reduction of private insurance options could disrupt the existing market and lead to economic challenges for companies in this sector.
3. **Transition Costs:**
    - The transition to a single-payer system may involve significant upfront costs. Critics express concerns about the financial implications of the transition, including the costs associated with restructuring administrative systems, implementing new technology, and retraining healthcare professionals.
4. **Potential for Provider Disruptions:**
    - Healthcare providers may experience disruptions during the transition, especially if there are changes in reimbursement rates or adjustments to administrative processes. Critics worry that these disruptions could impact the stability of healthcare delivery.

5. **Resistance from Stakeholders:**
    - Various stakeholders in the healthcare system, including healthcare providers, pharmaceutical companies, and insurers, may resist the changes associated with Medicare for All. Resistance from these stakeholders could pose challenges in the implementation of the new system.
6. **Uncertainty for Healthcare Professionals:**
    - Healthcare professionals may face uncertainties about the impact of Medicare for All on their practices, reimbursement rates, and overall job stability. This uncertainty could potentially affect the morale and job satisfaction of healthcare professionals.
7. **Potential for Reduced Innovation:**
    - Critics argue that a government-run system might reduce incentives for innovation in healthcare. In a competitive market, providers and pharmaceutical companies have incentives to invest in research and development. The shift to a single-payer system may impact these incentives.
8. **Challenges in Managing Increased Demand:**
    - The elimination of out-of-pocket costs and the provision of universal coverage could potentially lead to increased demand for healthcare services. Critics express concerns about the healthcare system's ability to effectively manage and respond to this surge in demand.
9. **Regional Variations in Healthcare Needs:**
    - Healthcare needs can vary significantly across different regions. Critics worry that a one-size-fits-all approach may not adequately address regional variations in healthcare requirements, potentially leading to disparities in access and quality of care.
10. **Political and Public Resistance:**
    - The implementation of Medicare for All may face political and public resistance. Some individuals may be resistant to major changes in the healthcare system, and opposition could pose challenges in achieving widespread acceptance and support.

It's important to note that these concerns are raised by critics, and proponents of Medicare for All argue that the system could address current shortcomings in the healthcare system, provide universal access to care, and reduce overall healthcare

costs. The ongoing debate involves finding a balance that considers the potential disruptions while aiming to achieve the goals of improved access and affordability.

How Medicare for All Will Reduce Patient Choices and Options

Medicare for All could potentially impact patient choices and options in the healthcare system. While proponents argue that a single-payer system may enhance access to care for all individuals, critics express concerns about potential limitations on patient choices. Here are some arguments made by critics regarding how Medicare for All might reduce patient choices:

1. **Limitation of Private Insurance Options:**
    - Medicare for All proposals often involve the elimination or significant reduction of private health insurance options. Critics argue that this could limit individuals' ability to choose from a variety of plans with different coverage options and provider networks.
2. **Restrictions on Provider Choices:**
    - In a single-payer system, the government may negotiate reimbursement rates with healthcare providers, potentially leading to limitations on the number of providers willing to accept those rates. Critics express concerns that this could restrict patients' choices of healthcare providers.
3. **Standardized Benefits:**
    - Medicare for All typically involves standardizing benefits across the healthcare system. While this simplifies the process, critics argue that it may limit the ability of individuals to choose plans tailored to their specific healthcare needs and preferences.
4. **Impact on Specialty Care Access:**
    - Critics worry that the emphasis on cost containment in a single-payer system might lead to limitations in access to specialized or elective medical services. Patients may have fewer options for seeking specialized care or choosing specific healthcare facilities.
5. **Reduced Flexibility in Plan Selection:**
    - The elimination of private insurance options could result in reduced flexibility for individuals to choose plans that align with their preferences, including factors such as deductibles, co-pays, and coverage for specific medical services.
6. **Potential for Longer Wait Times:**

- Increased demand for healthcare services, coupled with potential cost-containment measures, could lead to longer wait times for medical treatments. Critics argue that this may limit patients' ability to promptly access the care they need.

7. **Impact on Provider Networks:**
    - The restructuring associated with Medicare for All might impact existing provider networks. Critics express concerns that changes in reimbursement rates or administrative processes may lead to disruptions in established patient-provider relationships.
8. **Limited Control Over Healthcare Decisions:**
    - Critics argue that a government-administered system may limit individuals' control over their healthcare decisions. The standardization of benefits and potential restrictions on certain medical services could reduce patient autonomy in choosing the care that best suits their needs.
9. **Potential for Reduced Innovation in Care Models:**
    - In a single-payer system, critics express concerns about potential reductions in innovation in healthcare delivery models. A more centralized system may be less conducive to experimentation with new care models and approaches.
10. **Resistance to Change:**
    - Patients and healthcare professionals may resist major changes in the healthcare system. The transition to Medicare for All could face opposition from those who value their current insurance arrangements and fear a loss of control over their healthcare choices.

It's important to note that these concerns are raised by critics, and the actual impact on patient choices and options would depend on the specific design and implementation of Medicare for All. Proponents argue that the system could increase overall access to care and simplify the healthcare process, while opponents highlight potential trade-offs in terms of choice and flexibility.

Medicare for All Raises Bureaucratic and Administrative Challenges

Here are some of the bureaucratic and administrative challenges that some critics have been raised:

1. **System Overhaul and Implementation:**
    - The shift to a single-payer system involves a comprehensive overhaul of the existing healthcare infrastructure. Implementing new administrative

structures, technology systems, and processes on a national scale can be a complex and resource-intensive task.

2. **Transition Costs:**
    - The transition to Medicare for All may come with significant upfront costs. Adapting to new administrative requirements, retraining healthcare professionals, and updating technology systems could require substantial financial investments.
3. **Workforce Training:**
    - Healthcare professionals and administrative staff may require training to adapt to the new system. Training a large workforce to navigate changes in billing, claims processing, and administrative procedures is a logistical challenge.
4. **Data Integration and Standardization:**
    - Achieving seamless data integration and standardization across the healthcare system is crucial for the efficient operation of a single-payer system. This involves addressing interoperability issues and ensuring that diverse healthcare entities can effectively share information.
5. **Provider Reimbursement:**
    - Establishing fair and effective provider reimbursement rates is a complex task. Determining rates that are acceptable to healthcare providers while maintaining cost control requires careful negotiation and administrative coordination.
6. **Coordination with State Programs:**
    - Coordination with existing state-level healthcare programs and Medicaid systems may present challenges. Ensuring a smooth transition and integration with state-specific programs requires effective collaboration and administrative planning.
7. **Claims Processing and Billing:**
    - Streamlining claims processing and billing is a key aspect of administrative efficiency. The implementation of a single-payer system requires the development of standardized processes to handle claims and billing on a national scale.
8. **Technology Infrastructure:**
    - Upgrading and modernizing the technology infrastructure to support a national healthcare system is a significant undertaking. Ensuring the

security, interoperability, and efficiency of healthcare information systems is a complex administrative task.

9. **Resistance from Stakeholders:**
    - Stakeholders, including healthcare providers, insurers, and pharmaceutical companies, may resist administrative changes associated with Medicare for All. Overcoming potential resistance and ensuring buy-in from diverse stakeholders is a challenge.
10. **Public Education and Communication:**
    - Effectively communicating changes to the public and educating individuals about the new system is crucial. Public awareness campaigns and communication strategies are necessary to inform individuals about their rights, benefits, and changes in healthcare procedures.
11. **Addressing Regional Variations:**
    - The administrative challenges include addressing regional variations in healthcare needs, costs, and delivery. Tailoring administrative processes to accommodate these variations while maintaining national standards requires careful consideration.
12. **Ensuring Adequate Healthcare Workforce:**
    - The transition to a single-payer system may require adjustments in the healthcare workforce to meet increased demand. Ensuring an adequate number of healthcare professionals and support staff is an administrative challenge.

It's important to note that while critics highlight these administrative challenges, proponents argue that the long-term benefits of Medicare for All, such as improved access, simplified billing, and overall cost savings, could outweigh these initial complexities. The effectiveness of addressing administrative challenges would depend on the planning, implementation, and ongoing management of the transition to a single-payer system.

How Medicare for All Might Reduce Healthcare Innovation

Critics of Medicare for All express concerns that a transition to a single-payer healthcare system could potentially reduce incentives for healthcare innovation. While proponents argue that a single-payer system could lead to cost savings and increased access to care, opponents highlight potential challenges related to innovation. Here are some arguments made by critics regarding how Medicare for All might impact healthcare innovation:

1. **Reduced Financial Incentives for Research and Development:**

- Critics argue that a single-payer system might reduce financial incentives for pharmaceutical companies and healthcare providers to invest in research and development. In a competitive market, the potential for high profits can drive innovation. A more centralized system may alter these financial dynamics.

2. **Risk Aversion in a Government-Run System:**
    - Some critics express concerns that a government-administered healthcare system may be more risk-averse when it comes to adopting new and innovative medical technologies. Bureaucratic processes and decision-making may prioritize cost containment over embracing novel, yet potentially more expensive, treatments.
3. **Impact on Biotechnology and Life Sciences:**
    - The biotechnology and life sciences sectors heavily rely on private investments for innovation. Critics argue that a reduction in private investment resulting from changes in the market dynamics under a single-payer system could impede progress in these fields.
4. **Potential for Limited Choice of Treatments:**
    - A single-payer system may negotiate prices and coverage for medical treatments on a national level. Critics worry that centralized decision-making could limit the variety of available treatments and reduce options for patients seeking innovative therapies.
5. **Slower Adoption of New Technologies:**
    - Critics express concerns that a more centralized healthcare system may lead to slower adoption of new medical technologies. The bureaucracy associated with decision-making and budgetary constraints may result in delays in incorporating innovative treatments into standard medical practice.
6. **Impact on Academic Medical Centers:**
    - Academic medical centers often play a crucial role in medical research and innovation. Critics argue that changes in funding mechanisms and reimbursement rates under a single-payer system may affect the ability of academic institutions to invest in groundbreaking research.
7. **Potential Brain Drain in Healthcare Professions:**
    - Some critics suggest that the potential for lower earning potential and reduced financial rewards for innovation could lead to a "brain drain" in

healthcare professions. Skilled professionals may be drawn to sectors or countries that offer more favorable incentives for innovation.

8. **Incentives for Cost Control Over Innovation:**
    - In a system that prioritizes cost control, critics argue that healthcare providers may face pressure to focus on cost-effective treatments rather than invest in cutting-edge, albeit more expensive, medical innovations.
9. **Impact on Startups and Small Biotech Companies:**
    - Critics express concerns about the potential challenges faced by startups and small biotech companies in securing funding under a single-payer system. Reduced profitability and increased regulatory hurdles could impact the ability of these entities to contribute to innovation.
10. **Potential Disincentives for Entrepreneurship:**
    - A shift to a single-payer system may alter the incentives for entrepreneurship in the healthcare sector. Critics worry that reduced profit margins and increased regulation may discourage entrepreneurs from entering the healthcare industry.

It's important to note that these concerns are raised by critics, and the impact on healthcare innovation would depend on various factors, including the specific design of the single-payer system, ongoing policy adjustments, and efforts to balance cost containment with support for innovation. Proponents argue that a single-payer system could foster a more efficient and equitable healthcare system, but the potential trade-offs with innovation remain a part of the broader debate.

How Might Medicare for All Affect Individual and Corporate Taxes

While specific policy details can vary, here are general considerations regarding how Medicare for All might affect taxes:

Individual Taxes:

1. **Potential for Increased Taxes:**
    - Financing a comprehensive healthcare system like Medicare for All would likely require additional government revenue. Proponents often discuss funding sources such as progressive income taxes, payroll taxes, and other measures. Consequently, some individuals, particularly those with higher incomes, could see an increase in their tax burden.
2. **Offset by Elimination of Premiums and Out-of-Pocket Costs:**
    - Supporters argue that while taxes may increase, individuals and families would no longer be required to pay premiums, deductibles, or copayments

associated with private health insurance. This could offset the impact of higher taxes, especially for those who currently face significant healthcare-related costs.

3. **Progressive Taxation Approach:**
    - Proponents often advocate for a progressive taxation approach, where higher-income individuals contribute a larger percentage of their income toward funding Medicare for All. This is seen as a way to distribute the financial burden more equitably.
4. **Potential for Savings:**
    - Supporters argue that the overall cost of healthcare for individuals and families would decrease under Medicare for All. While taxes may go up, the elimination of private insurance premiums and reduced out-of-pocket expenses could result in net savings for many households.

Corporate Taxes:

1. **Impact on Employers:**
    - Under Medicare for All, employers may see changes in their financial responsibilities related to employee healthcare. While some proponents argue that businesses could experience cost savings by no longer providing private health insurance plans, critics suggest that increased corporate taxes may offset these potential savings.
2. **Potential for Employer Payroll Taxes:**
    - One proposed funding mechanism for Medicare for All involves implementing payroll taxes on employers. This could be a way to shift the financial responsibility for healthcare from businesses to the broader tax base.
3. **Reduced Administrative Costs for Employers:**
    - Supporters argue that employers could benefit from reduced administrative costs associated with managing private health insurance plans for their employees. A single-payer system may simplify administrative processes for businesses.
4. **Economic Impact:**
    - Critics express concerns that increased corporate taxes could have broader economic consequences, potentially affecting job creation, business investment, and economic growth. Proponents argue that the overall reduction in healthcare costs could positively impact the economy.

5. **Potential for Redistribution of Costs:**
    - The shift to Medicare for All could redistribute the costs of healthcare from employers to the government. This could lead to changes in corporate financial strategies and impact industries differently based on their current healthcare spending.
6. **Sector-Specific Considerations:**
    - Different industries may be affected in varying ways. Some sectors that currently provide generous health benefits may face higher taxes, while others with lower healthcare costs may benefit from a more level playing field.

It's important to note that the specific impact on taxes would depend on the details of the Medicare for All proposal, including the chosen funding mechanisms and how the transition is structured. The debate over the financial aspects of Medicare for All involves considerations of both the costs and potential savings for individuals, employers, and the government.

Can Medicare for All Address the Healthcare Needs of Americans?

While proponents argue that a single-payer system can provide more equitable access to care, critics raise concerns about potential challenges in addressing the diverse healthcare needs of the population. Here are considerations on both sides of the debate:

Proponents' Arguments:

1. **Universal Access to Basic Healthcare:**
    - Proponents contend that Medicare for All aims to ensure universal access to basic healthcare services for all Americans. By providing a baseline level of coverage, the system seeks to address fundamental healthcare needs across the population.
2. **Standardized Benefits:**
    - Medicare for All proposals often include standardized benefits, eliminating variations in coverage between different insurance plans. This standardization is intended to ensure that individuals receive consistent and comprehensive healthcare services regardless of their specific circumstances.
3. **Preventive Care Emphasis:**
    - Supporters argue that a single-payer system can emphasize preventive care, addressing health needs at an earlier stage and potentially reducing

the overall burden on the healthcare system. By focusing on preventive measures, the system aims to improve population health.

4. **Elimination of Disparities in Access:**
    - Proponents suggest that Medicare for All can help eliminate disparities in access to healthcare. By providing coverage to all individuals, regardless of factors such as income or employment status, the system seeks to reduce variations in healthcare access.
5. **Efficient Resource Allocation:**
    - A single-payer system could streamline administrative processes and resource allocation, ensuring that healthcare resources are distributed more efficiently. This efficiency may contribute to a more equitable distribution of healthcare services.

Critics' Concerns:

1. **One-Size-Fits-All Approach:**
    - Critics argue that a single-payer system may adopt a one-size-fits-all approach that does not adequately address the diverse healthcare needs of individuals and communities. Different populations may have unique health requirements that may not be fully accommodated.
2. **Regional Variations:**
    - Healthcare needs can vary significantly across regions due to factors such as demographics, prevalence of certain health conditions, and local healthcare infrastructure. Critics express concerns that a nationalized system may struggle to address these regional variations effectively.
3. **Limited Choice of Providers:**
    - Critics worry that a single-payer system might limit individuals' choices of healthcare providers. While proponents argue for cost containment, critics express concerns that reduced provider options could impact the ability of individuals to access specialized or preferred care.
4. **Inadequate Addressing of Specific Conditions:**
    - Some critics suggest that certain specialized or rare health conditions may not receive sufficient attention or resources in a more centralized healthcare system. Tailoring care to specific conditions or demographic groups could be challenging.
5. **Resistance to Innovations in Care Models:**

- Critics argue that a government-dominated system may be less conducive to experimenting with innovative care models and approaches. The potential for bureaucratic hurdles and resistance to change could impede the adoption of new and effective healthcare solutions.

6. **Potential for Longer Wait Times:**
    - Increased demand for healthcare services, combined with potential resource constraints, could lead to longer wait times for medical treatments. Critics express concerns that longer wait times may negatively impact patient outcomes.

The debate over whether Medicare for All can effectively address variations in healthcare needs revolves around finding a balance between providing universal access and accommodating the diverse health requirements of the population. The effectiveness of the system would depend on the specific design, implementation, and ongoing adjustments made to address these considerations.

How Will Our Divisive Political Environment Affect Medicare for All?

The divisive political environment in the United States has a significant impact on discussions and potential implementations of policies, including Medicare for All. The perspectives and stances of political actors, policymakers, and the general public contribute to the challenges and opportunities for advancing such proposals. Here are key considerations regarding how the divisive political environment may affect Medicare for All:

Challenges:

1. **Partisan Divisions:**
    - Healthcare policy, including proposals like Medicare for All, has become deeply polarized along party lines. Divisions between Democrats and Republicans can hinder bipartisan support for comprehensive healthcare reform, making it challenging to pass legislation.
2. **Ideological Differences:**
    - Ideological differences regarding the role of government in healthcare and the balance between individual choice and collective responsibility contribute to the political divide. Finding common ground on the fundamental principles of healthcare policy is a significant hurdle.
3. **Interest Group Opposition:**
    - Powerful interest groups, including those representing insurance companies, pharmaceuticals, and healthcare providers, may actively oppose or lobby against significant changes to the healthcare system. The

influence of these groups can create obstacles for transformative healthcare proposals.

4. **Public Opinion Variability:**
    - Public opinion on healthcare reform, including Medicare for All, varies across political affiliations. Bridging the gap in public support and addressing concerns from different ideological perspectives is a complex task.
5. **Fiscal Concerns:**
    - Discussions around how to fund Medicare for All often involve debates on tax increases and government spending. Fiscal conservatives may express concerns about the potential economic impact and sustainability of such a large-scale healthcare program.

Opportunities:

1. **Public Demand for Change:**
    - Despite political divisions, there is public demand for improvements in the healthcare system. The impact of the COVID-19 pandemic has further highlighted the importance of accessible and affordable healthcare. Public pressure may create opportunities for policymakers to revisit healthcare reform proposals.
2. **Evolving Policy Discourse:**
    - The political landscape is dynamic, and policy priorities can evolve over time. Shifting public attitudes, changes in leadership, and external factors may contribute to a reevaluation of healthcare policies, potentially creating openings for new proposals.
3. **State-Level Initiatives:**
    - Some states have explored or implemented their own healthcare reforms. State-level initiatives, even if limited in scope, could serve as test cases for certain aspects of healthcare reform and inform national discussions.
4. **Incremental Changes:**
    - Given the challenges of passing comprehensive reform, there may be opportunities for incremental changes to the healthcare system. Policymakers may explore targeted measures that address specific issues, gradually building towards broader reforms.
5. **Coalitions and Compromise:**

- Building coalitions and finding areas of compromise can be crucial for advancing healthcare policy. While comprehensive reform may face hurdles, targeted measures that garner bipartisan support could lay the groundwork for broader changes.

6. **External Events Shaping Priorities:**
    - Unforeseen events, such as public health crises or economic challenges, can reshape political priorities. External factors may create windows of opportunity for reexamining and reforming healthcare policy.

The future of Medicare for All is intricately tied to the dynamics of the political environment. Achieving consensus and overcoming political divisions will require strategic policymaking, effective communication, and a willingness to find common ground on the complex issues surrounding healthcare reform. The interplay of political, economic, and societal factors will continue to shape the trajectory of healthcare policy discussions in the United States.

Rationing and treatment rejection in Medicare

Medicare typically does not cover certain services, treatments, or items that are considered elective, cosmetic, or not medically necessary. Here are some examples:

1. **Cosmetic Surgery**: Procedures performed solely for cosmetic purposes, such as facelifts, breast augmentation, and liposuction, are generally not covered.
2. **Acupuncture**: While some private Medicare Advantage plans may offer coverage for acupuncture, traditional Medicare typically does not cover this service.
3. **Long-Term Care**: Medicare does not cover most long-term care services, including assisted living facilities, custodial care, and nursing home care.
4. **Dental Care**: Routine dental care, such as cleanings, fillings, and extractions, is generally not covered by Medicare. Some Medicare Advantage plans may offer limited dental coverage.
5. **Vision Care**: Routine eye exams, eyeglasses, and contact lenses are typically not covered by Medicare, though there are exceptions for certain eye diseases and conditions.
6. **Hearing Aids**: Medicare does not cover hearing aids or routine hearing exams, though some Medicare Advantage plans may offer coverage for these services.
7. **Foot Care**: Routine foot care, including podiatry services, is generally not covered unless it's related to a medical condition such as diabetes.

8. **Acupressure, Massage Therapy, and Chiropractic Services**: These services are typically not covered by traditional Medicare, though coverage may be available through certain Medicare Advantage plans.
9. **Experimental or Investigational Treatments**: Medicare does not cover treatments that are considered experimental or not proven to be effective.

How does Medicare decide which services to fund and which to reject?

Medicare determines which services to cover based on several factors, including:

1. **Medical Necessity**: Medicare covers services and treatments that are deemed medically necessary to diagnose or treat a medical condition. This means the service must be considered reasonable and necessary for the diagnosis or treatment of an illness or injury.
2. **Evidence-Based Medicine**: Medicare evaluates medical treatments and services based on scientific evidence of their effectiveness. Services that have been proven through clinical studies to improve health outcomes or quality of life are more likely to be covered.
3. **National Coverage Determinations (NCDs)**: The Centers for Medicare & Medicaid Services (CMS) establishes National Coverage Determinations (NCDs) to specify whether Medicare will cover a particular item or service. These determinations are based on factors such as clinical evidence, expert opinions, and public comments.
4. **Local Coverage Determinations (LCDs)**: Medicare Administrative Contractors (MACs) develop Local Coverage Determinations (LCDs) that provide additional guidance on coverage for specific services within their geographic jurisdictions. LCDs may vary by region and can provide more detailed criteria for coverage.
5. **Cost-Effectiveness**: Medicare considers the cost-effectiveness of services when making coverage decisions. While Medicare aims to provide access to necessary healthcare services, it also seeks to manage costs and ensure the sustainability of the program.
6. **Statutory Exclusions**: Some services are explicitly excluded from Medicare coverage by law. For example, Medicare cannot cover most dental care, eyeglasses, and hearing aids under the original Medicare program.
7. **Public Input and Stakeholder Feedback**: Medicare may consider input from healthcare providers, beneficiary advocacy groups, medical societies, and other stakeholders when making coverage decisions. Public comments and feedback are often solicited during the decision-making process for NCDs and LCDs.

Overall, Medicare aims to strike a balance between providing access to essential healthcare services while managing costs and ensuring the quality and effectiveness of

care. Coverage decisions are based on a combination of medical evidence, clinical judgment, statutory requirements, and input from stakeholders.

Medicare's coverage policies evolve over time, and they may update their coverage decisions periodically to reflect advancements in medical technology and changes in clinical evidence. However, there are certain technology-based treatments or services that Medicare historically has been cautious about covering due to various factors such as limited evidence of effectiveness, high costs, or ongoing research. Here are some examples:

1. **Virtual Reality Therapy**: While virtual reality (VR) therapy shows promise in various healthcare applications, including pain management and mental health treatment, Medicare's coverage for VR therapy may be limited due to a lack of extensive clinical evidence supporting its effectiveness in specific medical conditions.
2. **Telehealth Services**: While Medicare has expanded coverage for telehealth services in response to the COVID-19 pandemic, coverage for certain telehealth modalities and services may still be limited. For example, coverage for remote patient monitoring devices or certain telehealth platforms may vary based on specific criteria.
3. **Genetic Testing and Personalized Medicine**: Medicare may cover certain genetic tests for specific medical conditions or hereditary diseases. However, coverage for more comprehensive genetic testing panels or personalized medicine approaches may be limited due to concerns about cost-effectiveness and the need for additional evidence of clinical utility.
4. **Robotic Surgery**: While robotic-assisted surgical procedures have become more common in recent years, Medicare's coverage for robotic surgery may be limited to specific indications and procedures. Coverage decisions may depend on factors such as the availability of clinical evidence demonstrating improved outcomes compared to traditional surgical approaches.
5. **Stem Cell Therapy**: Medicare's coverage for stem cell therapy may be limited due to concerns about the safety, efficacy, and regulation of stem cell treatments. Coverage decisions may vary depending on whether the stem cell therapy is considered standard of care for a specific medical condition or is part of an approved clinical trial.
6. **Artificial Intelligence (AI) Applications**: Medicare's coverage for AI-based diagnostic tools or decision support systems may be limited to specific applications with robust clinical evidence supporting their accuracy and clinical utility. Coverage decisions may also depend on regulatory approval and compliance with Medicare billing requirements.

It's essential to note that Medicare's coverage decisions are subject to change, and coverage for specific technology-based treatments or services may evolve over time as new evidence emerges and healthcare practices evolve. Individuals should consult with healthcare providers and Medicare representatives to understand the current coverage policies and options available to them.

Medicare aims to provide coverage for medically necessary treatments that are proven to be effective and appropriate for the patient's condition. However, there may be instances where Medicare does not cover certain treatments that could be considered potentially life-saving. Here are some reasons why this might occur:

1. **Lack of Sufficient Evidence**: Medicare typically requires strong evidence of a treatment's effectiveness before providing coverage. If there is insufficient clinical evidence to support the effectiveness of a particular treatment for a specific condition, Medicare may not cover it, even if it has the potential to be life-saving.
2. **Experimental or Investigational Treatments**: Medicare generally does not cover treatments that are considered experimental or investigational, meaning they have not yet been proven through rigorous clinical trials to be safe and effective for the intended use.
3. **Off-Label Use of Drugs**: Medicare may not cover the off-label use of drugs, meaning the use of a medication for a condition or indication not approved by the Food and Drug Administration (FDA). While off-label use is common in medical practice, Medicare may only cover medications for FDA-approved indications.
4. **Cost Considerations**: In some cases, the cost of a treatment may be prohibitively high, and Medicare may determine that the cost outweighs the potential benefit, especially if there are other, more cost-effective treatments available.
5. **Statutory Exclusions**: Certain treatments or services may be explicitly excluded from Medicare coverage by law. For example, Medicare cannot cover most dental care, hearing aids, or cosmetic surgery under the original Medicare program.

It's important to note that Medicare's coverage policies may vary depending on factors such as the specific medical condition, the individual's health status, and the availability of alternative treatments. In some cases, individuals may have the option to appeal Medicare's coverage decision or seek coverage through other avenues, such as clinical trials, private insurance, or financial assistance programs.

Medicare typically covers a wide range of cancer treatments that are considered medically necessary and proven to be effective. However, there may be certain cancer treatments or related services that Medicare does not cover or has limitations on coverage. Here are some examples:

1. **Off-Label Use of Drugs**: Medicare may not cover the off-label use of drugs for cancer treatment, meaning the use of a medication for a purpose other than its FDA-approved indication. Coverage for off-label use is evaluated on a case-by-case basis and may depend on the availability of strong clinical evidence supporting the treatment's effectiveness.
2. **Experimental or Investigational Treatments**: Medicare generally does not cover treatments that are considered experimental or investigational for cancer, meaning they have not yet been proven through rigorous clinical trials to be safe and effective. Coverage for experimental treatments may be available through clinical trials or other research studies but is not typically covered by Medicare outside of these contexts.
3. **Alternative or Complementary Therapies**: Medicare typically does not cover alternative or complementary therapies for cancer treatment that have not been proven to be effective through scientific research. This may include treatments such as acupuncture, herbal remedies, and dietary supplements.
4. **High-Cost Drugs or Therapies**: Medicare may have limitations on coverage for certain high-cost cancer drugs or therapies, particularly if the cost exceeds Medicare's established payment limits or if the treatment is considered to be of limited clinical benefit.
5. **Non-Medically Necessary Services**: Medicare generally does not cover cancer treatments that are not considered medically necessary or appropriate for the patient's condition. This may include treatments that are considered to be primarily palliative or supportive in nature and do not directly target the underlying cancer.

It's important for individuals with cancer and their caregivers to work closely with healthcare providers and Medicare representatives to understand the coverage options available and any potential limitations or restrictions on coverage for specific treatments. In some cases, individuals may have the option to appeal Medicare's coverage decision or explore alternative sources of coverage or financial assistance for cancer treatment costs.

Some coronary treatments that Medicare rejects as an example

Medicare generally provides coverage for a wide range of treatments for coronary artery disease and related conditions, particularly those that are considered medically necessary and proven to be effective. However, there may be certain coronary treatments or related services that Medicare does not cover or has limitations on coverage. Here are some examples:

1. **Elective Angioplasty or Stenting**: Medicare may not cover elective coronary angioplasty or stenting procedures if they are not deemed medically necessary.

Coverage is typically provided for these procedures when they are performed to alleviate symptoms of coronary artery disease or to treat acute coronary syndromes.

2. **High-Risk or Investigational Procedures**: Medicare may not cover certain high-risk or investigational coronary procedures that have not been proven through rigorous clinical trials to be safe and effective. This may include emerging techniques or devices for treating coronary artery disease that are still undergoing evaluation.
3. **Preventive Screening Tests**: Medicare generally does not cover routine screening tests for coronary artery disease in asymptomatic individuals who do not have risk factors. Coverage for screening tests such as coronary calcium scoring or coronary CT angiography may be limited to certain high-risk populations or individuals with specific indications.
4. **Alternative or Complementary Therapies**: Medicare typically does not cover alternative or complementary therapies for coronary artery disease that have not been proven to be effective through scientific research. This may include treatments such as chelation therapy, acupuncture, or herbal remedies.
5. **Non-Medically Necessary Services**: Medicare generally does not cover coronary treatments or procedures that are not considered medically necessary or appropriate for the patient's condition. This may include treatments that are considered to be primarily preventive in nature or that do not directly address the underlying coronary artery disease.

It's important for individuals with coronary artery disease and their healthcare providers to carefully review Medicare's coverage policies and guidelines to understand the options available and any potential limitations or restrictions on coverage for specific treatments. In some cases, individuals may have the option to appeal Medicare's coverage decision or explore alternative sources of coverage or financial assistance for coronary treatment costs.

How Medicare’s treatment approval / rejection protocols compare to NICE’s protocols in the UK's National Health Service

Medicare in the United States and the National Health Service (NHS) in the United Kingdom operate under different healthcare systems and have different protocols for determining coverage and treatment approval. While both systems aim to provide access to high-quality healthcare services, there are some key differences in their approaches to treatment approval and rejection:

1. **Medicare in the United States**:
    - Medicare is a federal health insurance program primarily for people aged 65 and older, as well as some younger individuals with disabilities.

- Coverage decisions are made by the Centers for Medicare & Medicaid Services (CMS), which sets coverage policies based on factors such as medical necessity, clinical evidence, cost-effectiveness, and statutory requirements.
- Medicare coverage decisions may vary by region and may be influenced by input from stakeholders, including healthcare providers, beneficiary advocacy groups, and medical societies.
- Medicare generally provides coverage for treatments that are deemed medically necessary and proven to be effective, although coverage for certain treatments may be limited or subject to specific criteria.

2. **National Institute for Health and Care Excellence (NICE) in the United Kingdom**:
    - NICE is an independent organization responsible for providing national guidance and recommendations on health technologies and clinical practices in England and Wales.
    - NICE evaluates the clinical and cost-effectiveness of treatments and interventions through its technology appraisal and clinical guideline programs.
    - NICE assesses the evidence base for treatments and issues guidance on whether they should be recommended for use within the NHS based on considerations such as clinical effectiveness, cost-effectiveness, and impact on patient outcomes.
    - NICE's recommendations are influential in determining access to treatments within the NHS, and healthcare providers are generally expected to follow NICE guidance in their clinical practice.

In terms of stringency, it's challenging to make a direct comparison between Medicare's coverage protocols and NICE's protocols, as they operate within different healthcare systems with unique priorities and constraints. Both systems strive to ensure that patients have access to effective and appropriate treatments while managing costs and promoting high-quality care. However, the specific criteria and processes for treatment approval and rejection may differ between the two systems based on their respective healthcare delivery models and organizational structures.

A brief description of NICE’s rationing protocol

The National Institute for Health and Care Excellence (NICE) in the United Kingdom does not operate under a formal "rationing" protocol per se, but it does employ a rigorous system to assess the clinical and cost-effectiveness of healthcare interventions. Here's an overview of NICE's approach:

1. **Health Technology Assessment (HTA)**: NICE conducts health technology assessments to evaluate the clinical and cost-effectiveness of healthcare interventions, including drugs, medical devices, procedures, and public health programs. These assessments are based on systematic reviews of available evidence, economic analyses, and consultation with clinical experts.
2. **Evidence Review and Appraisal**: NICE reviews the available evidence on the effectiveness and safety of the intervention in question, considering data from clinical trials, observational studies, and other sources. The quality and reliability of the evidence are carefully assessed to ensure robustness.
3. **Cost-Effectiveness Analysis**: NICE evaluates the cost-effectiveness of the intervention by comparing its clinical benefits with its costs. Economic analyses are conducted to assess factors such as the cost per quality-adjusted life year (QALY) gained. NICE uses a cost-effectiveness threshold to determine whether an intervention represents value for money within the context of the NHS budget.
4. **Guidance Development**: Based on its assessment, NICE develops guidance recommending whether the intervention should be adopted within the NHS. This guidance is published in the form of technology appraisals, clinical guidelines, diagnostics guidance, and public health guidance. Recommendations may include advice on which patient groups are most likely to benefit from the intervention, dosage and administration details, and any conditions or criteria for use.
5. **Consultation and Stakeholder Involvement**: NICE involves various stakeholders, including patient representatives, healthcare professionals, industry stakeholders, and the public, throughout the guidance development process. Stakeholder input is sought during scoping, evidence review, and consultation phases to ensure that multiple perspectives are considered.
6. **Implementation**: NICE guidance is intended to inform clinical practice and decision-making within the NHS. While NICE recommendations are not legally binding, healthcare providers and commissioners are generally expected to adhere to NICE guidance in their decision-making processes, subject to local variation and individual patient circumstances.

Overall, NICE's approach aims to ensure that NHS resources are allocated efficiently and that patients have access to effective, evidence-based healthcare interventions that represent value for money. While difficult decisions may arise regarding the funding and provision of certain interventions, NICE's transparent and evidence-based approach seeks to balance clinical need, patient benefit, and affordability within the context of finite healthcare resources.

NICE uses QALYs to determine treatment cost effectiveness

The National Institute for Health and Care Excellence (NICE) in the United Kingdom uses Quality-Adjusted Life Years (QALYs) as a measure of health outcomes to assess the cost-effectiveness of healthcare interventions. QALYs combine both the quantity and quality of life gained from a healthcare intervention into a single measure. Here's how NICE uses QALYs to determine treatment cost-effectiveness:

1. **Definition of QALY**: A QALY is a measure of health outcome that combines both the length of life (quantity) and the quality of life (utility or health-related quality of life) experienced during that time. One QALY is equivalent to one year of life lived in perfect health. Health states considered less desirable than perfect health have QALY values less than 1.
2. **Utility Values**: Utility values represent the quality of life associated with different health states. These values are typically obtained through preference-based measures such as the EuroQol 5-Dimension (EQ-5D) questionnaire, which assesses health-related quality of life across five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression). Utility values range from 0 (representing death) to 1 (representing perfect health), with negative values indicating health states worse than death.
3. **Assessment of Health Benefits**: When evaluating a healthcare intervention, NICE considers the impact of the intervention on patients' health-related quality of life over time. This is done by estimating the number of QALYs gained or lost as a result of the intervention compared to the relevant comparator or standard of care.
4. **Cost per QALY**: NICE assesses the cost-effectiveness of a healthcare intervention by calculating the incremental cost per QALY gained compared to the next best alternative or comparator. This involves comparing the additional costs of the intervention (e.g., drug costs, administration costs, monitoring costs) with the additional health benefits in terms of QALYs gained. Interventions with lower incremental cost per QALY gained are generally considered more cost-effective.
5. **Cost-Effectiveness Threshold**: NICE uses a cost-effectiveness threshold to determine whether an intervention represents value for money within the context of the National Health Service (NHS) budget. This threshold represents the maximum amount that the NHS is willing to pay for each additional QALY gained. While the exact threshold may vary over time, it is typically set at around £20,000 to £30,000 per QALY gained.
6. **Decision Making**: Based on its assessment of cost-effectiveness, NICE provides recommendations on whether the intervention should be funded and adopted within the NHS. Interventions with incremental cost-effectiveness ratios below the cost-effectiveness threshold are generally recommended for adoption, while

those above the threshold may face greater scrutiny or may not be recommended for routine use.

Overall, QALYs provide a standardized and quantitative measure of health outcomes that allows NICE to compare the costs and benefits of different healthcare interventions in a consistent and transparent manner. By considering both the costs and health benefits of interventions in terms of QALYs, NICE aims to ensure that NHS resources are allocated efficiently and that patients have access to cost-effective treatments that provide meaningful improvements in health-related quality of life.

What is the EuroQol 5-Dimension (EQ-5D) questionnaire?

The EuroQol 5-Dimension (EQ-5D) questionnaire is a widely used instrument for measuring health-related quality of life (HRQoL) across five dimensions. It is a standardized, generic measure designed to provide a simple, generic measure of health for clinical and economic appraisal. The EQ-5D is used in a variety of healthcare settings, including clinical trials, health technology assessments, and population health surveys. Here's an overview of the EQ-5D questionnaire:

1. **Dimensions**: The EQ-5D assesses health-related quality of life across five dimensions:
    - Mobility: Assessing the respondent's ability to move around.
    - Self-care: Assessing the respondent's ability to perform self-care activities (e.g., bathing, dressing).
    - Usual activities: Assessing the respondent's ability to perform usual activities (e.g., work, study, housework, family or leisure activities).
    - Pain/discomfort: Assessing the respondent's level of pain or discomfort.
    - Anxiety/depression: Assessing the respondent's level of anxiety or depression.
2. **Levels**: Within each dimension, respondents indicate their current health state by selecting one of three levels:
    - No problems
    - Some problems
    - Extreme problems
3. **Scoring**: The EQ-5D descriptive system can be converted into a health utility index by applying country-specific value sets. These value sets are based on preferences elicited from general population surveys using methods such as time trade-off (TTO) or visual analogue scale (VAS). Health utility index scores typically range from 0 (representing death or a health state equivalent to death)

to 1 (representing full health or perfect health). Negative scores are possible, indicating health states considered worse than death.

4. **EQ VAS**: In addition to the EQ-5D descriptive system, the EQ-5D questionnaire includes a visual analogue scale (EQ VAS) where respondents rate their current health status on a vertical scale ranging from 0 (worst imaginable health state) to 100 (best imaginable health state).
5. **Versions**: The EQ-5D questionnaire is available in several versions, including the EQ-5D-3L (3-level version) and the EQ-5D-5L (5-level version), which offers greater sensitivity by providing five response levels for each dimension.

The EQ-5D questionnaire is used to assess and quantify health-related quality of life from the patient's perspective, allowing for comparisons of health outcomes across different populations, interventions, and healthcare settings. Its simplicity and ease of administration make it a valuable tool for health outcome measurement in both research and clinical practice.

QALY value in US dollars, 2024

The value of a Quality-Adjusted Life Year (QALY) in US dollars in 2024 is not a fixed or standard figure. The concept of a QALY is used primarily in health economics and healthcare decision-making to assess the cost-effectiveness of medical interventions. The value of a QALY can vary depending on several factors, including the perspective of the analysis, the healthcare system context, the specific intervention being evaluated, and the willingness-to-pay threshold used by decision-makers.

In the United States, there isn't a universally accepted value for a QALY as there is in some other countries with government-funded healthcare systems. Instead, decision-makers such as insurers, healthcare providers, and policymakers may use different methods or criteria to determine the value of a QALY within their specific contexts.

Some economic evaluations in the US healthcare system may use a willingness-to-pay threshold, which represents the maximum amount that society is willing to pay for a QALY gained. This threshold can vary but is often cited to be in the range of $50,000 to $150,000 per QALY gained. However, it's important to note that these values are not fixed and can vary depending on the context and the preferences of decision-makers.

In summary, the value of a QALY in US dollars in 2024 is not a set figure and would depend on the specific analysis, context, and willingness-to-pay threshold used in the evaluation.

How the dollar value of 1 QALY is determined

The dollar value of 1 Quality-Adjusted Life Year (QALY) is not determined based on an individual's income or earnings. Instead, it is typically assessed in health economics

studies and healthcare decision-making processes using a willingness-to-pay (WTP) threshold or cost-effectiveness threshold.

The willingness-to-pay threshold represents the maximum amount that society is willing to pay for one additional QALY gained from a healthcare intervention. This threshold is often determined based on various factors, including societal preferences, budget constraints, opportunity costs, and the value of health improvements relative to other goods and services.

Decision-makers such as government agencies, insurers, and healthcare providers may use different methods to establish a willingness-to-pay threshold within their specific contexts. Some countries with government-funded healthcare systems have established explicit thresholds for cost-effectiveness analysis. For example, in the United Kingdom, the National Institute for Health and Care Excellence (NICE) has historically used a threshold range of £20,000 to £30,000 per QALY gained as a reference point for assessing the cost-effectiveness of healthcare interventions within the National Health Service (NHS).

In the United States, willingness-to-pay thresholds may vary depending on the payer, the specific healthcare intervention being evaluated, and other contextual factors. While there is no universally accepted threshold, some studies have suggested thresholds in the range of $50,000 to $150,000 per QALY gained based on empirical analyses and surveys of societal preferences.

It's important to note that the dollar value of a QALY is not directly tied to an individual's income or earnings. Instead, it reflects societal preferences and the value placed on health improvements relative to other goods and services. Therefore, 1 QALY gained from a healthcare intervention would generally be considered equally valuable regardless of the individual's income level.

The difference in estimated values of a Quality-Adjusted Life Year (QALY) between Harvard Professor David Cutler's estimation in 2003, in his book Your Money or Your Life, and current estimations can be attributed to several factors:

1. **Methodological Differences**: Different researchers may use different methods and assumptions to estimate the value of a QALY, leading to variation in results. David Cutler's estimation in 2003 may have relied on different data sources, economic models, or approaches compared to more recent estimations.
2. **Changes in Healthcare Costs**: Healthcare costs and the cost-effectiveness of medical interventions can change over time due to factors such as advances in medical technology, changes in treatment patterns, and shifts in healthcare delivery models. These changes can affect the perceived value of health improvements and may contribute to differences in estimated values of a QALY over time.

3. **Changes in Societal Preferences**: Societal preferences regarding the value of health improvements and the allocation of healthcare resources may evolve over time. Attitudes towards healthcare spending, willingness to pay for health benefits, and ethical considerations can influence the perceived value of a QALY and may vary across different time periods and contexts.
4. **Inflation Adjustments**: While inflation is a factor to consider when comparing economic values over time, it's important to note that the value of a QALY is not solely determined by inflation. Changes in healthcare costs, healthcare utilization patterns, and societal preferences can also influence the estimated value of a QALY, independent of inflation.
5. **Data Availability and Quality**: The availability and quality of data used to estimate the value of a QALY may have improved over time, leading to more accurate and reliable estimates in recent years. Advances in data collection methods, health outcomes research, and economic modeling techniques can contribute to more robust estimations of the value of health outcomes.

Overall, the discrepancy in estimated values of a QALY between David Cutler's estimation in 2003 and current estimations may reflect differences in methodology, changes in healthcare costs and societal preferences, and improvements in data availability and quality over time. It's essential to interpret estimates of the value of a QALY within the specific context of the analysis and to consider the underlying assumptions and limitations of the methods used to generate these estimates.

Quality-Adjusted Life Years (QALYs) have been widely used in health economics and healthcare decision-making for several decades, and the theory and methodology behind QALYs are generally accepted within the healthcare research and administration community. Here are some reasons why QALYs are widely accepted:

1. **Standardized Measure**: QALYs provide a standardized and quantitative measure of health outcomes that allows for comparisons across different health interventions, populations, and healthcare settings. This makes QALYs a valuable tool for assessing the effectiveness and value of healthcare interventions in a consistent and transparent manner.
2. **Incorporation of Patient Preferences**: QALYs incorporate patient preferences for health states, as measured through preference-based instruments such as the EuroQol 5-Dimension (EQ-5D) questionnaire or the Health Utilities Index (HUI). By capturing individuals' subjective valuations of health-related quality of life, QALYs provide a patient-centered perspective on health outcomes.
3. **Cost-Effectiveness Analysis**: QALYs are commonly used in cost-effectiveness analysis to assess the value for money of healthcare interventions. By comparing the costs of interventions with the health benefits in terms of QALYs gained,

decision-makers can prioritize resource allocation and identify interventions that offer the greatest health improvements for a given budget.

4. **Regulatory and Reimbursement Decisions**: QALYs are used by government agencies, insurers, and healthcare providers to inform regulatory decisions, reimbursement policies, and coverage determinations. For example, agencies such as the National Institute for Health and Care Excellence (NICE) in the United Kingdom use QALYs to assess the cost-effectiveness of healthcare interventions and provide guidance on their adoption within the healthcare system.
5. **Transparency and Accountability**: QALYs promote transparency and accountability in healthcare decision-making by providing a clear and quantifiable measure of health outcomes. By explicitly considering both the costs and benefits of healthcare interventions in terms of QALYs, decision-makers can justify resource allocation decisions and prioritize interventions that offer the greatest health gains per dollar spent.

While QALYs are widely accepted and commonly used in healthcare research and administration, it's important to acknowledge that they are not without limitations. Criticisms of QALYs include concerns about equity, cultural differences in valuing health states, and challenges in measuring complex health outcomes comprehensively. Despite these limitations, QALYs remain a valuable tool for evaluating health outcomes and informing resource allocation decisions in healthcare.

QALYs and Medicare for All

The inclusion of Quality-Adjusted Life Years (QALYs) in a Medicare for All system would depend on various factors, including the specific design of the healthcare system, policy priorities, and political considerations. Here are some points to consider:

1. **Cost-Effectiveness Analysis**: Medicare for All would likely aim to provide comprehensive healthcare coverage to all residents of the United States. While cost containment measures would be necessary to ensure the sustainability of the healthcare system, the extent to which cost-effectiveness analysis, including the use of QALYs, would be incorporated into decision-making could vary.
2. **Political Considerations**: The use of QALYs in healthcare decision-making is a topic of debate, and opinions on their appropriateness and ethical implications vary. Some stakeholders argue that QALYs can help ensure efficient resource allocation and promote value-based healthcare delivery, while others raise concerns about equity, fairness, and the potential for discriminatory practices.
3. **Patient-Centered Care**: Medicare for All would likely prioritize patient-centered care and equitable access to healthcare services. While QALYs provide a standardized measure of health outcomes, they may not fully capture individual

preferences, values, and priorities. As such, there may be a need to balance the use of QALYs with other considerations, such as patient-reported outcomes and shared decision-making.

4. **Regulatory and Reimbursement Policies**: If QALYs were to be incorporated into a Medicare for All system, they could potentially inform regulatory decisions, reimbursement policies, and coverage determinations. Government agencies responsible for healthcare oversight and administration, such as the Centers for Medicare & Medicaid Services (CMS), could use QALYs to assess the cost-effectiveness of healthcare interventions and guide resource allocation decisions.
5. **Public Perception and Acceptance**: The inclusion of QALYs in a Medicare for All system would likely be subject to public scrutiny and debate. Stakeholder engagement, transparency, and accountability would be important considerations in shaping healthcare policy and ensuring that decision-making processes are perceived as fair and equitable.

Ultimately, the inclusion of QALYs in a Medicare for All system would require careful consideration of the benefits, challenges, and implications for healthcare delivery, patient outcomes, and healthcare spending. Policymakers would need to weigh the potential advantages of using QALYs to inform resource allocation decisions against concerns about equity, access, and patient-centered care.

In Canada, the healthcare system is publicly funded and administered at the provincial and territorial level, with each province and territory responsible for delivering healthcare services to its residents. While Canada's healthcare system, often referred to as Medicare, provides universal coverage for medically necessary healthcare services, the use of Quality-Adjusted Life Years (QALYs) to determine treatment approval or rejection varies across jurisdictions.

Generally, Canadian healthcare decision-making processes prioritize evidence-based medicine, clinical effectiveness, and cost-effectiveness in treatment decisions. Health technology assessment (HTA) agencies, such as the Canadian Agency for Drugs and Technologies in Health (CADTH) and the Institut national d'excellence en santé et en services sociaux (INESSS) in Quebec, play a significant role in evaluating the clinical and economic evidence for healthcare interventions.

While QALYs are commonly used in health economics and healthcare decision-making worldwide, including in countries with government-funded healthcare systems such as the United Kingdom, their use in Canada may vary. Some HTA agencies in Canada may incorporate QALYs or similar measures of health-related quality of life into their assessments of healthcare interventions to assess their cost-effectiveness and value for money.

However, the extent to which QALYs are used to inform treatment approval or rejection decisions in Canada can depend on several factors, including jurisdictional differences,

institutional practices, stakeholder preferences, and public policy priorities. Other considerations, such as patient preferences, equity, and feasibility, may also influence healthcare decision-making in Canada.

In summary, while QALYs may be used as part of health technology assessment processes in Canada, their use and influence on treatment approval or rejection decisions may vary across provinces and territories. Decision-makers in Canada typically consider a range of factors, including clinical effectiveness, cost-effectiveness, patient preferences, and equity, when making decisions about the allocation of healthcare resources and coverage of healthcare interventions.

In France, healthcare decision-making is guided by the principles of solidarity, universality, and equity, with a strong emphasis on ensuring access to high-quality healthcare for all citizens. The French healthcare system, known as "l'Assurance Maladie" or "la Sécurité Sociale," is based on a mix of public and private financing and delivery of healthcare services.

While Quality-Adjusted Life Years (QALYs) are commonly used in health economics and healthcare decision-making in some countries, such as the United Kingdom, their use in France may be less prevalent. Instead, the French healthcare system relies on a combination of clinical effectiveness, evidence-based medicine, and economic evaluation to inform treatment approval or rejection decisions.

The French National Authority for Health (Haute Autorité de Santé, HAS) plays a key role in evaluating the clinical and economic evidence for healthcare interventions and providing recommendations to inform healthcare policy and practice. HAS conducts health technology assessments (HTAs) to assess the clinical benefits, safety, and cost-effectiveness of new drugs, medical devices, procedures, and healthcare technologies.

While HAS may consider measures of health-related quality of life, such as QALYs, as part of its HTA processes, the specific methods and criteria used to evaluate healthcare interventions in France may vary. HAS takes into account a range of factors, including clinical effectiveness, patient safety, public health impact, and economic considerations, when making recommendations about the adoption and reimbursement of healthcare interventions.

Decision-making in France typically emphasizes evidence-based medicine, clinical effectiveness, and patient-centered care to ensure the delivery of high-quality healthcare services to the population.

While the British National Health Service (NHS) incorporates Quality-Adjusted Life Years (QALYs) into its health technology assessment processes to assess the cost-effectiveness of healthcare interventions, and to provide guidance on treatment decisions, it's not accurate to characterize the French system as allowing for more subjective decisions made solely by individual doctors.

Both the NHS in the UK and the French healthcare system (l'Assurance Maladie) rely on evidence-based medicine, clinical guidelines, and health technology assessment to inform treatment decisions. Here's a nuanced view:

1. **British National Health Service (NHS)**:
    - The NHS uses QALYs and other measures of health outcomes as part of its health technology assessment processes conducted by organizations like the National Institute for Health and Care Excellence (NICE). These assessments inform recommendations about which healthcare interventions should be funded and provided within the NHS.
    - While NICE provides guidance on the cost-effectiveness of healthcare interventions, individual treatment decisions are typically made by healthcare professionals in consultation with patients, taking into account clinical considerations, patient preferences, and other factors.
2. **French Healthcare System (l'Assurance Maladie)**:
    - In France, the Haute Autorité de Santé (HAS) conducts health technology assessments to evaluate the clinical and economic evidence for healthcare interventions. HAS provides recommendations to inform healthcare policy and practice, including reimbursement decisions.
    - Like in the UK, individual treatment decisions in France involve healthcare professionals (including doctors) working with patients to make decisions based on clinical evidence, patient preferences, and other relevant factors.

In both systems, treatment decisions are guided by a combination of clinical evidence, patient preferences, and healthcare professionals' expertise. While QALYs and health technology assessment may play a more prominent role in decision-making within the NHS, and individual doctors in France may have more autonomy, both systems aim to ensure access to high-quality, evidence-based healthcare for their populations. Ultimately, treatment decisions are made collaboratively between healthcare professionals and patients, taking into account the best available evidence and the individual needs and preferences of the patient.

Review Questions

Some Key Utilization Drivers

Chronic disease treatments consume about 85% of all healthcare spending with about half of Americans – that's roughly 160 million folks - having one or more chronic diseases. The number of chronic disease patients grows by 7 – 8 million every 5 years.[82]

The ten most common chronic conditions are arthritis, cancer, chronic obstructive pulmonary disease, coronary heart disease, asthma, diabetes, hepatitis, hypertension, stroke and weak or failing kidneys. These often – not always – have a lifestyle cause, a combination of excess body weight, suboptimal nutrition and insufficient exercise.

We have known about these chronic diseases, their costs and their causes for years, yet they continue and increase. Why? This chapter will suggest answers and focus on diabetes as a prime example of a lifestyle-caused chronic condition.

Diabetes occurs when your body produces too little insulin and results in you having too much sugar in your bloodstream. The disease comes in 2 basic forms: Type 1, an autoimmune disorder typically identified in kids for which there is no cure and Type 2, largely behaviorally based, in which your body doesn't use insulin well and can't regulate sugar in blood stream. About 95% of diabetic population has Type 2. It is largely preventable and potentially reversable. (Type 1 is neither.) We'll focus on Type 2 in this chapter.

Diabetes increases your risk of developing many of the chronic conditions listed above, perhaps most notably hypertension, failing kidney and heart disease. We might consider it a common cause of and link among America's epidemic of chronic diseases. That's admittedly an overstatement, though not a huge one.

Diabetes is defined by your number on one of 4 medical tests:

- Your A1C (aka hemoglobin A1C or HbA1c) above 6.5%
- Your fasting blood sugar above 126 mg/dL
- Your glucose tolerance above 200 mg/dL 2 hours after drinking a liquid. You need to fast the night before.
- Your random blood sugar above 200 mg/dL

About 37 million Americans have diabetes. It is the 7th leading cause of death and the #1 cause of kidney failure, lower limb amputations and blindness in the US. The number of diabetics has doubled in the past 20 years.

[82] The Relation of the Chronic Disease Epidemic to the Healthcare Crisis, Holman, American College of Rheumatology, Feb 19, 2020

Two syndromes / conditions predict a patient becoming diagnosed with diabetes: 'prediabetes' and 'metabolic syndrome'. Though overlapping in some ways, these are distinct. Both provide a warning to patients about their likely diabetes diagnosis future.

Prediabetes is a narrowly defined condition in which you have too much sugar in your bloodstream though not enough to have full blown diabetes. By the CDC's definition, you have prediabetes if tests determine the following about your blood sugar:

- Your A1C or hemoglobin A1C or HbA1c test is 5.7 and 6.4%.
    - Full blown diabetes is defined 6.5% or greater.
- Your fasting blood sugar test is 100 – 125 mg/dL.
    - Full blown diabetes is defined as 126 mg/dL or greater.
- Your glucose tolerance test is 140 – 199 mg/dL.
    - Full blown diabetes is defined as above 200 mg/dL.

Here's a summary chart.[83]

Result*	A1C Test	Fasting Blood Sugar Test	Glucose Tolerance Test	Random Blood Sugar Test
Diabetes	6.5% or above	126 mg/dL or above	200 mg/dL or above	200 mg/dL or above
Prediabetes	5.7 – 6.4%	100 – 125 mg/dL	140 – 199 mg/dL	N/A
Normal	Below 5.7%	99 mg/dL or below	140 mg/dL or below	N/A

About 96 million Americans have prediabetes including, according to Dr. Dariush Mozaffarian, dean of the Tufts Friedman School of Nutrition Science and Policy, about 1 in 4 American teenagers.[84] The condition increases your risk of developing Type 2 diabetes and suffering from all the problems associated with and resulting from it.

Metabolic syndrome, the other common precursor to full blown diabetes, is defined more broadly, again by the results of medical tests. It is a cluster of medical conditions occurring together, first identified in 1998. Though some researchers quibble about the exact numbers that define it, here is a generally accepted definition. [85]

- Obesity or having a BMI > 30.
    - Alternatively, males have a waist circumference >40 inches, females > 35.

[83] CDC Diabetes Basics https://www.cdc.gov/diabetes/basics/getting-tested.html

[84] Boston Globe, Nov 22, 2021 'The Obesity Pandemic Has Made Covid Much More Deadly'
[85] This definition comes from Harvard Health, Shmerling, Metabolic Syndrome is On the Rise, Oct 2, 2020 and AARP, Levine, Metabolic Syndrome

- Blood triglyceride levels above 150 mg/dL
- Low HDL (good) cholesterol, levels below 40 mg/dL in men or 50 in women
- High blood pressure, greater than 130/85 or on blood pressure medications.
    - For people over 60 years old, the American Heart Association suggests levels above 150/90
- Elevated blood sugar, having a fasting blood glucose level above 100 mg/dL, an A1C above 5.7 or taking diabetes medications.

Researchers seem to suggest that having 3 or more of these indicators defines someone has having metabolic syndrome.

Some 37% of Americans suffer from metabolic syndrome with the risk increasing as you age; some 50% of 60-year-olds have it including almost 60% of Hispanics over 60. [86]

People with metabolic syndrome are about 4x more likely to develop diabetes than healthy folks, 3x more likely to suffer a heart attack or have a stroke, and 55% more likely to develop kidney disease. In addition, according to the National Heart, Lung and Blood Institute[87], the syndrome increases your risk of developing

- Coronary heart disease
- Erectile disfunction
- Heart failure
- Inflammation and immune system problems – raise risks of complications from infections and Covid
- Organ damage esp pancreas, liver, gall bladder, kidneys
- Polycystic ovary syndrome (PCOS)
- Pregnancy complications such as preeclamsia, eclampsia, and gestational diabetes
- Problems with thinking and memory
- Sleep apnea and
- Certain cancers.

Metabolic syndrome, like prediabetes and diabetes itself, is largely preventable by maintaining a healthy weight, eating a healthy diet, exercising regularly and avoiding smoking.[88]

[86] AARP, Metabolic Syndrome, Levine

[87] National Heart, Lung and Blood Institute https://www.nhlbi.nih.gov/health/metabolic-syndrome/living-with

[88] Ibid.

This link between obesity, defined as having a Body Mass Index greater than 30, and diabetes is so strong that some researchers invented a new word for it: diabesity.[89] As the Cleveland Clinic put it in 2021:

> The pancreas creates insulin, which is a hormone that moves glucose out of your blood. Normally, insulin transports glucose to your muscles to use right away for energy or to the liver, where it's stored for later.
>
> But when you have diabesity, your cells resist letting insulin move glucose into them. To make matters worse, the area of your liver where excess glucose is usually stored is filled with fat. It's like trying to put furniture in a room that's already packed. With nowhere to be stored, the glucose remains in the bloodstream.
>
> Your pancreas becomes overworked, and as a result, it wears out. It starts producing less insulin. Diabetes develops and then quickly worsens if the fat resistance remains

The CDC calls diabetes the most expensive medical condition in the US, though no one knows for sure how much it costs because it affects so many other medical conditions. Should we include leg amputations as diabetes costs? The associated prosthetics? Unclear.

The CDC estimated direct diabetes costs and related reduced productivity at the lower end, $327 billion in 2017. That's about $500 billion today give a take a few dozen billion, about 14% of healthcare spending. That's the low estimate.

On the higher end, the American Diabetes Association claims that 25% of all US healthcare spending goes to diabetes and related treatments.[90] I don't know who's right here, but under either estimate, diabetes is a big deal and very expensive.

We know a lot about it, understand its causes and estimate its costs as high under any reasonable assumptions. Why can't we prevent it?

Why We Don't Prevent Diabetes
and cut healthcare spending while improving American's health

The classic advice for treating metabolic syndrome or pre-diabetes, the two typical precursors of full blown diabetes, is lifestyle modification. This traditionally has 2 components: dietary improvement and exercise increase. In short, eat a bit less of primarily healthier foods, and exercise a bit more.

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[89] Cleveland Clinic, November 2021 'Diabesity: How Obesity is Related to Diabetes', slightly edited in the following quote.

[90] American Diabetes Association. Economic costs of diabetes in the US in 2017. *Diabetes Care.* 2018;41:917–928.

Easier said than done.

Let's put some numbers and costs into this advice. We'll use American males as our case study here simply to present an analytic framework. This will help us understand our dismal failure to prevent diabetes.

> We could have used American females instead of males – same methodology, just different numbers. Ditto for other socio-economic groups: Latino women, Appalachian residents, Appalachian single parent families, elderly urban men, etc. Same methodology, different numbers.

We'll first address the dietary part of that old 'diet and exercise' mantra and consider calorie **quantity** and **quality**.

In 2022, the average American male – we'll call him Joe - was 5 foot 9 inches tall, 38 years old, exercised 1 – 3 times per week and weighed 198 lbs.[91] He had a BMI of 29.2, almost obese. He gained about 1.5 pounds per year. According to online calorie consumption estimates[92], he needs to eat about 2650 calories per day; that's the amount necessary to maintain his 1.5 pound / year weight increase.

We'll assume that Joe is single for analytic ease.

Joe needs to reduce his daily calorie intake to 2237 to lose ½ a pound per week. That would get him down to 172 pounds in a year for a BMI of 25.4, slightly overweight but not nearly obese. It would probably get him out of the prediabetic or metabolic syndrome condition and help him avoid diabetes.

> I choose the ½ pound per week weight loss as a moderate amount; I didn't want to bias this analysis with a more aggressive number. Some research suggests that a faster weight loss, with the associated greater degree of daily discomfort /

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[91] Average weight American male adult from healthline.com https://www.healthline.com/health/mens-health/average-weight-for-men

Average height American male adult from World Population Review https://worldpopulationreview.com/state-rankings/average-height-by-state

Average age Americans in 2022 from World Population Review https://worldpopulationreview.com/state-rankings/median-age-by-state

How Much Do Americans Exercise, Romero, Washingtonian, May 12, 2012

Daily calories to lose ½ lb / week from www.Calculator.net

Daily calories to gain 1.5 lbs / year from www.Calculators.net

Average American annual weight gain from Washington Post, 'Look How Much Weight You're Going to Gain' 1/29/2016

[92] In this case I used www.calculator.net.

hunger, leads to a quicker termination of this dietary program with the associated relatively fast rebound back to the original weight.

In other words, I want to stack the odds in Joe's favor.

We'll assume here that Joe spends 10% of his income on food. That comes from the US Department of Agriculture's 2021 estimate. [93]

We know that Joe earns $1,144 / week – that's $59,488 per year - thanks to various Bureau of Labor Statistics studies.[94] That means he has $16.34 available for food each day, 7 days / week, a combination of eating in and eating out. The BLS says we split this about 50/50.

If Joe was a Black or Hispanic male – an example of some specific socio-economic groups – he would only earn $820 / week ($42,640 per year) [95] meaning $11.71 available for food.

Or if Joe were a woman, a different socio-economic group, he would earn, on average, about 15% less and need about 10% fewer calories, than an average American male.[96]

Quick quantitative summary:

- Joe currently eats about 2650 calories per day. He gains about 1.5 pounds per year.
- He needs to reduce his daily caloric intake to 2237 to lose ½ pound per week or 26 pounds / year. That's 13% of his body weight.
- He has $16.34 available for food daily.

Let's turn now from calorie quantity to calorie **quality**. The most recent government recommendation is that our food plate consist of 50% fruits and vegetables, 25% grains – mainly whole grains – and 25% protein and dairy. That's a rough approximation of the

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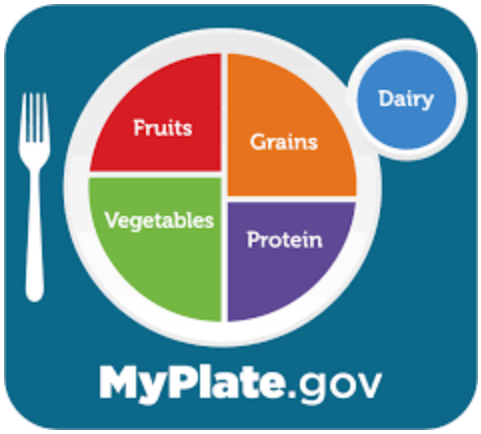
[93] US Dept of Agriculture estimate 2021, https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=76967#:~:text=In%202021%2C%20U.S.%20consumers%20spent,from%20home%20(5.1%20percent).

[94] Overall Median weekly earnings from BLS, wkyeng (5).pdf, July 29, 2022, 'Usual Weekly Earnings of Wage and Salary Workers Second Quarter 2022'

[95] Black and Hispanic male earnings from BLS, 'TED, The Economics Daily', Oct 25, 2021, https://www.bls.gov/opub/ted/2021/median-weekly-earnings-were-916-for-women-in-third-quarter-2021-83-3-percent-of-mens-earnings.htm#:~:text=Source%3A%20U.S.%20Bureau%20of%20Labor,End%20of%20interactive%20chart.&text=In%20the%20third%20quarter%20of%202021%2C%20median%20weekly%20earnings%20for,the%20median%20for%20White%20men.

[96] Earning estimates from various BLS studies. Calorie estimates from calculator.net; I simply substituted 'female' for 'male' using Joe's numbers. The calculator estimated 2008 calories / day for a woman instead of 2237 for Joe.

US Department of Agriculture's MyPlate, image below. You can google MyPlate.gov for more.



I don't like this graphic though. It's too cartoonish in my opinion and not detailed enough as a guide. I prefer the Canadian version, below. It's essentially the same – see the small dairy dish in the protein section as opposed to the small dairy circle in the American MyPlate version - but with more impactful graphics in my opinion. The Canadian version shows specific foods in each category. We'll use it in this chapter rather than the MyPlate image, again, only for presentation reasons. Feel free to disagree with my artistic taste.

The Canadian Food Plate

Water is the recommended drink.

You can quickly see the breadth and types of foods in each category and the approximate serving size of each.

> Proteins, for example, include nuts, beans, legumes and eggs, not just chicken, beef, pork, and fish and take up a quarter of your meal plate.
>
> Fruits and vegetables come in lots of different colors and flavors, with that variety apparently providing nutritional benefits.

This version seems to suggest that we eat lots of different vegetables, not just potatoes and tomatoes, the most commonly consumed vegetables in the US, which together dwarf all the others combined.[97]

Ditto lots of different fruits, not just apples and oranges, the most commonly consumed fruits in the US, which, along with bananas, dwarf the others.[98]

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[97] Potatoes and tomatoes most commonly consumed vegetables, US Economic Research Service, Department of Agriculture, 2019 https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=58340

[98] Apples and oranges are top US fruit choices, US Economic Research Service, Department of Agriculture, 2019 https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=58322

That's why I like this graphic: it's impactful and suggests what to eat simply and comprehensibly.

It also tells you what to avoid. Look at what's not on this plate:

- Corn
- Sugar
- Sweeteners
- Oils, salad dressing
- Refined, bleached flour
- Processed foods and snacks like chips, cookies & baked goods
- Sugary drinks
- Beer, wine & alcohol

We eat lots of these foods. Consider these summaries from a 2016 Pew study of American food and nutrition practices:[99]

> Baked goods, a $35 billion / year market segment not on the Food Plate, includes refined flour and sugar.
>
> Sweeteners, about 15% of daily calories for the average American, include sugar and corn based products (in addition to non-caloric options like aspartame). A can of regular Coke contains 140 calories for example. Americans consume about 40 gallons of soft drinks per person annually, 72% non-diet.[100] Soft drink sales run about $318 billion per year. Not on the Food Plate.
>
> Snacks, about 27% of children's daily caloric intake (remember Tufts School of Nutrition Dean Dr. Mozaffarian's estimate that 1 in 4 American teenagers is pre-diabetic?), mainly salty snacks, candy, cookies, and sugary drinks. Salty snacks, ice cream, candy and cookies are a $70 billion / year industry segment. Not on the Food Plate.
>
> Oils for cooking, flavoring, and salad dressing, about 23% of our daily calories. On average. Americans eat about 36 pounds of these per year. Not on the Food Plate.
>
> Processed foods including hydrogenated oils, HFCS, flavoring agents and emulsifiers used in foods like potato chips, sugary drinks & processed meat, not on the Food Plate. Processed foods tend to lead to higher weight gain than unprocessed.[101]

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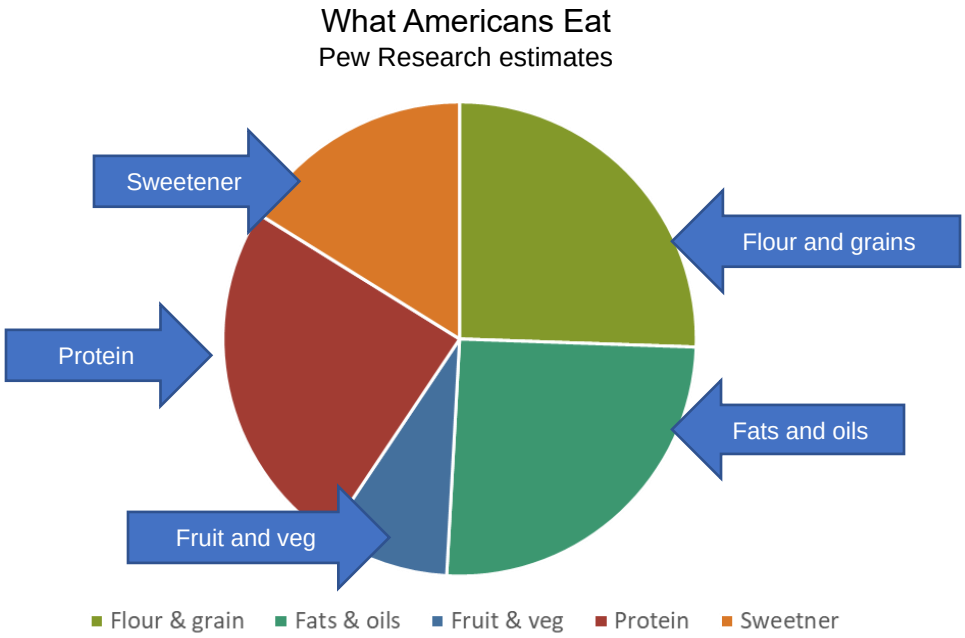
[99] What's On Your Table: How America's Diet Has Changed Over the Decades, Drew Desilver, Dec 13, 2016

[100] Diet vs regular soda percent estimates from statistica.com https://www.statista.com/statistics/1133019/carbonated-soft-drinks-regular-vs-diet-volume-us/

[101] First randomized, controlled study finds ultra processed diet leads to weight gain, Clinical Center News from NIH, 2019 https://clinicalcenter.nih.gov/about/news/newsletter/2019/summer/story-01.html

Instead of eating the high quality calories shown on the Food Plate above, here, according to the Pew Research folks, is what we really eat:



I find this estimate credible based on supermarket shelf space allocations and restaurant menus.

> Supermarkets allocate shelf space according to food sales, more to foods that sell the best. See, for example, the space allocated to salad dressing, cookies and sweetened breakfast cereal.
>
> Restaurants offer meals that people request the most. See, for example, in moderate priced, popular restaurants - the large chains for example – the frequency of 'burger and fries' or 'chicken, potato and small vegetable of the day' or 'salad' generally consisting only of lettuce, tomato and carrot shavings doused in dressing (many restaurants offer more dressing options than vegetable variety). Compare to the frequency of fruit offerings.

Joe, our typical American male, thus faces 3 tasks in the attempt to improve his diet and thus avoid diabetes.

- Eat fewer calories.
- Eat higher quality calories.
- Stay within his $16.34/day food budget.

How might he accomplish all this?

Composite Daily Menus

Let's compare the daily costs of Joe's current diet and a healthier one designed to prevent diabetes. I've developed two sample day's meals – one called Food Plate based on the Canadian Food Plate above and the other called Typical based on the Pew analysis. I used food prices at my local Shaw's supermarket in Easton, Massachusetts in October 2022.

These diets are composites of what people *should* eat and what they often *in fact* eat. In designing these menus – particularly the typical one - I considered supermarket shelf space. I choose popular items meaning lots of people buy and eat them.

We have, of course, endless food options and combinations in this country. I present this analysis in part to show calorie and cost data and in part to show a methodology. Do a similar analysis yourself and see your own results. I suspect they will be close to mine below.

The healthier diet below comes to 2239 calories for a day (very close to our theoretical goal of 2237); the typical diet comes to 2648 calories (very close to our daily estimate of 2650). Some minor rounding issues, a calorie or penny here or there. But look at the cost difference.

Breakfast, Food Plate

- 2 jumbo eggs @ 90 calories each = 180 calories, $1.33
- 2 pieces multigrain toast @ 100 calories each = 220 calories, $.66
- Butter @ 50 calories / serving = 50 calories, $.16
- 1 banana = 100 calories, $.23
- Black coffee = 2 calories, $.20
- 552 calories
- $2.58 at Shaw's, Easton

Breakfast, typical diet

- Shaw's honey bran muffin = 420 calories, $1.25
- Coffee = 2 calories, $.20
- Cream @ 35 calories per serving of Coffeemate = 35 calories, $.07
- Sugar @ 30 calories per serving of granular sugar = 30 calories, $.04
- 487 calories
- $1.56 at Shaw's, Easton

Lunch, Food Plate

- Spinach salad w/ tomato, carrots, yellow pepper, beets (130 cal total, $5.02)
    - 1 serving of fresh spinach = 20 calories, $1.71
    - Half a tomato = 45 calories, $1.50
    - Half a serving of carrots = 15 calories, $.16
    - Half a yellow pepper = 25 calories, $.85
    - Half a serving of beets = 25 calories, $.80
- Oil & vinegar dressing = 84 calories, $.22

- .3 lb chicken breast @ 748 calories per pound = 224 calories, $1.20
- 1 pita = 90 calories, $.37
- Apple = 95 calories, $.66
- 623 calories
- $7.47 at Shaw's, Easton

Lunch, typical diet

- Ham & cheese on sub roll with mustard & iceberg lettuce (538 cal total, $3.20)
    - Ham,.25 pound @ 885 calories per pound = 221 calories, $2.00
    - Cheese, 1 slice = 100 calories, $.30
    - Sub roll = 200 calories, $.50
    - French's mustard, 1 serving = 1 calorie, $.03
    - Iceberg lettuce .15 of a head = 16 calories, $.37
- Bag of chips from multi-bag box = 150 calories, $.52
- 3 Oreos = 160 calories, $.26
- Apple = 95 calories, $.66
- Coca Cola, can = 140 calories, $.23
- 1083 calories
- $4.88 at Shaw's, Easton

Dinner, Food Plate

- Basmati rice bowl with broccoli, summer squash, snap peas, green beans, .4 lb salmon, soy (872 calorie total, $8.48)
    - 2 cups Basmati rice @ 170 calories per cup = 340 calories, $.38
    - 1/3 pound of broccoli = 51 calories, $.66
    - 1/3 pound of summer squash = 24 calories, $.66
    - 1 serving of sugar snap peas = 35 calories, $1.00
    - ¼ pound of green beans = 25 calories, $.82
    - .4 pounds of salmon = 378 calories, $4.80
    - 1 tablespoon low salt soy sauce = 20 calories, $.16
- Blueberries (.5 pint) = 115 calories, $1.00
- Strawberries (.5 lb.) = 74 calories, $2.50
- 1061 calories
- $11.97 at Shaw's, Easton

Dinner, typical diet

- Pasta with sauce, ground beef, grated cheese (578 calories,$2.55 total)
    - Barilla pasta, 1 serving = 200 calories, $.37
    - Prego traditional pasta sauce, 1 serving = 70 calories, $.80
    - 80% ground beef, .25 pounds = 288 calories, $1.25
    - Grated Kraft parmesan cheese, 1 serving = 20 calories, $.13
- Green salad with dressing (150 calories)
    - Dole American salad bag, 2 servings = 30 calories, $1.50
    - Ken's House Italian dressing, 1 serving = 120 calories. $.25
- Canned peaches, 1 serving = 100 calories, $.50
- Friendly's vanilla ice cream, ½ serving = 105 calories, $.28

- Bottle of Budweiser beer = 145 calories, $1.38
- 1078 calories
- $6.46 total, food from Shaw's, Easton, beer from Walmart

You can see my spreadsheets at the end of this chapter for additional details.

> I encourage you to use this methodology with your dietary decisions. You can adjust the daily calorie targets to fit your own needs, then insert your foods of choice.

We learn from this process that 2237 healthier Canadian Food Plate calories cost $22.02 / day. Those are the foods Joe is supposed to eat, with meals designed to lose ½ pound per week. If Joe spends 10% of his salary on food as the Bureau of Labor Statistics suggests, then he needs to earn at least $80,000 per year to afford this menu.

But Joe only earns $59,488 per year. We learned that earlier in this chapter. He can't afford the healthy Food Plate!

> Imagine that Joe is a Black or Hispanic male. He'd only earn $42,640 per year making the Food Plate even more unaffordable.
>
> Try this with your socio-economic demographic of interest and see what you learn.

Now let's consider the 2648 calorie typical diet. It only costs $12.90 / day, making it affordable to people earning at least $47,000 per year. Joe earns that much. It is tasty and satisfying.

But he gains 1.5 pounds per year on it and risks prediabetes, metabolic syndrome and diabetes.

We're beginning to learn why we don't prevent diabetes by following the 'eat more fruits, vegetables and whole grains, less processed food, fat and sugar' mantra. It's too expensive.

This analysis only addressed foods prepared at home using one particular supermarket's prices. I ran a similar analysis on restaurants, comparing healthier and typical meals at Cheesecake Factory and D'Angelo's. It's methodologically easy; simply look up your items of choice on the restaurant's menu and nutritional guide – sometimes they're listed together on the menu - then divide.

Here's what I found, again all in October 2022.

> At the Cheesecake Factory, 'The Club' sandwich with turkey, bacon, bread, French Fries, lettuce, tomato and mayonnaise contains 1740 calories and costs $17.95. That's 1.0¢ per calorie.

The Cheesecake Factory's Skinnylicious Factory Chopped Salad including dressing contains 530 calories and costs $15.95. That's 3.0¢ per calorie, 3x more per calorie than the Club sandwich.

At D'Angelo's, the medium Italian sub contains 790 calories and costs $10.29. That's 1.3¢ per calorie.

The D'Angelo's Garden Salad with small Pokket (pita bread) but without dressing contains 180 calories and costs 4.6¢ per calorie, about 3.5x more per calorie than the Italian sub.

As with our supermarket example above, eating the Food Plate healthier calories costs more. The oft-recommended 'fruits, vegetables and whole grains, not processed food, fat and sugar' diet is still too expensive.

How much more expensive? According to my supermarket food data above, eating healthier – meaning eating according to the Food Plate – costs about $9.12 more per person per day. That's $3320 per year or, for the US average 2.6-person household, over $8300.

A *single person* would need to earn $33,000 more annually to afford the Food Plate meals above. That's using the US Department of Agriculture's '10% of your income on food' estimate discussed above.

An *average American household* would need to earn $83,000 more.

That's not the cost of eating but the *additional* cost of eating a healthy diet, the one designed to avoid or exit from, metabolic syndrome.

That's a significant economic disincentive to eat healthy foods and a significant economic incentive to stay the course.

Why do healthier foods cost more?

This chapter is not a discussion of food subsidies but the question often arises from astute readers. Here's a very short explanation:

Congress and various states subsidize food production.[102] In 2016, for example, the feds provided $13.9 billion in crop subsidies and insurance payments, equivalent to 25% of farmers income. Those subsidies generally went to the largest and best organized farm groups like huge companies that produce commodities - corn and soybeans for example. About 90 million acres – half our farmland – goes to those types of (heavily subsidized) products.

[102] This analysis comes from Barth, Congress Finally Passed a New Farm Bill, January 7, 2019, Modern Farmer

Food producers, in turn, then use those products in processed foods. That helps explain why corn sugar (a.k.a High Fructose Corn Sugar, HFCS and corn syrup) is included in so many of our processed foods. Just check the ingredients of your favorite jars or cans of food. We'll discuss this more in the section on food tastes, below.

> Subsidized corn sugar helps control the cost of real sugar, thus expanding the market for sweeteners, about 15% of American's typical daily calories.

Meanwhile, only about 10 million acres, or 3% of our cropland, goes to fruits, nuts and vegetables, products not typically included in the farm subsidy programs. They're more expensive for 2 reasons:

- Consumers pay the full price for their production since production costs are not subsidized
- There is no excess supply since their acreage is constrained by market forces, not supplemented by subsidies. Tighter acreage means less supply. The standard economics of price being determined by supply and demand factors then takes over.

We subsidize the foods we're not supposed to eat much of, and fail to subsidize the foods we're supposed to eat in abundance.

But wait, there's more

Let's now discuss some additional, non-cost problems of switching from our typical to a Food Plate diet. The problems fit into 3 groups: hunger, taste, and convenience. How much of a financial incentive would be required to induce people to overcome these problems? That's over and above the $3320 per person food cost difference.

Hunger: as people eat fewer calories, they feel hungry. That's the prime behavioral reason so many diets fail: people want that satisfying full feeling.

> I sometimes hear people claim, 'I lost 25 pounds and never felt hungry.'
>
> I rarely see these dietary results replicated on a large group of people over a long time period, making me dubious. Indeed, studies suggest that the vast majority of dieters regain all their weight within 2 years. I suspect hunger or related food cravings is a primary culprit.
>
> But when people claim to have lost weight without feeling hungry, I often respond 'Why doesn't everyone do that?'. That generally ends the conversation.

I can identify only 2 large groups of people who successfully lose weight by dieting and keep it off for a long time period: actors and athletes. (Apologies if I unintentionally missed a group.) Actors and athletes often / always have body weight requirements included in their employment contracts. That's a tremendous economic incentive, far exceeding anything that employers, insurance companies or the medical establishment can provide to employees or patients.

A word about the long term issue facing of dietary incentives. Good food habits – eating certain foods, losing your taste for others, acclimating yourself to a certain 'appropriate' hunger – takes months if not years to develop. By appropriate' hunger, I mean accustoming yourself to feeling somewhat hungry much of the time and feeling only somewhat full immediately after meals. Most people, according to studies, need at least a few months to develop new food habits; other folks need much longer.[103] I needed a year when I lost 40 pounds in 2021 but that story comes later in this chapter.

How much of an economic incentive does Joe need to switch from his traditional 2650 calories per day to the Food Plate's 2237? Probably less than the $200,000 Matthew McConaughey earned for his 50 pound weight loss in Dallas Buyer's Club but I don't know how much less. Perhaps 3% of Joe's annual income? 5%? While I don't know the exact amount, I'm pretty sure that a calorie-restricted dietary program needs to address this issue.

Taste. Our Food Plate lacks many tastes common to the typical American diet – sugar, salt, salad dressings, mayonnaise, etc. People sometimes complain that healthy foods taste bland. They also sometimes describe food cravings, missing various tastes and sensations.

Food producers know this and have identified the 'bliss point', a combination of sweetness, saltiness and richness (generally some sort of fat) that people find satisfying. The right combination of these sends a jolt of endorphins to your brain causing a pleasure sensation and desire to do it again. That's why people like mayonnaise on sandwiches, salad dressing on their salads and cream and sugar in their coffee. It makes food more satisfying. How often have you heard 'I just couldn't drink black coffee'?

The combination of sweetness, saltiness and richness works better together than any one ingredient on its own. That's why a standard sized Hershey Bar contains 35 milligrams of sodium[104] and a Nestle Crunch Bar 66 milligrams[105] and why Jif peanut butter contains 2 grams of sugar per serving[106] and Barilla pasta 7 grams[107].

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[103] Grohol, Need to Form a New Habit? Give Yourself At Least 66 Days, PsychCentral, October 7, 2018 https://psychcentral.com/blog/need-to-form-a-new-habit-66-days ; UCL News August 9, 2009 Interview with Phillippa Lally https://www.ucl.ac.uk/news/2009/aug/how-long-does-it-take-form-habit

[104] https://www.hersheyland.com/products/hersheys-milk-chocolate-candy-bar-1-55-oz.html

[105] https://www.heb.com/product-detail/nestle-crunch-candy-bar/98268

[106] https://www.jif.com/peanut-butter/creamy/simply-jif

[107] https://www.heb.com/product-detail/barilla-traditional-sauce/1637428

Fruits and vegetables lack the bliss point. There's infinitesimal salt in an apple or yellow pepper, infinitesimal sugar in spinach or kale. And no fat.

The good news is that people can adjust their tastes to become satisfied with non-bliss point foods. The bad news is that it takes time to develop the habit, likely that same as to adjust to the new 'slightly hungry' or 'no longer totally full' eating feeling. Again, programs aiming to help people eat fewer-but-healthier calories need to maintain their incentives for this lengthy time period.

Convenience. Joe's typical meals included a store baked honey bran muffin as opposed to the Food Plate home cooked eggs and toast. His ham-and-cheese sandwich lunch with a bag of chips and Oreos was quicker to make than the Food Plate made-from-scratch spinach salad with chicken breast. Not only quicker to make, but also quicker and easier to eat.

And his industrially produced dinner Prego pasta sauce with canned peaches and ice cream for dessert was easier to prepare than the Food Plate home-made rice bowl.

Accessing these convenient foods is easy and relatively stress free – just open the can or package. Meanwhile, shopping for, cutting and preparing the less-convenient-but-healthier Food Plate meals is more difficult and time consuming, and therefore more stressful in our time compressed daily lives.

As one indication of convenience importance in our daily food decisions, consider the number of take-out food options now available. (I'm not sure if take-out counts as eating at home or out, but it doesn't much matter what we call it as long as people stay within their '10% of salary on food' parameter.) We had, for example, 71,856 pizza restaurants in 2012 but 78,092 in 2020.[108] That's almost a 9% increase in 8 years, not including other competitive take out options. All this suggests that increasing numbers of us order out to eat in, the definition of convenience.

How much should designers of wellness or diet programs incentivize people to eat more labor intensive / healthier foods as opposed to more convenient-but-less healthy? I don't know – sorry, not a program designer – but food convenience is one factor that such programs need to address. 'Address' here means 'provide economic incentives to do'.

Summary of the diet part of 'diet and exercise'

We have established so far that eating fewer-but-healthier calories costs more than eating more-but-unhealthier ones. The cost difference is about $9.12 per person per day or $3320 per year. Those are, of course, just estimates – take them with a grain of salt. (Bad pun.)

[108] Number of pizza restaurants in the US, Statistics https://www.statista.com/statistics/377597/number-of-pizza-restaurants-us/

We have also discussed

- how eating fewer calories makes people feel hungry
- how eating non-bliss point foods diminishes taste satisfaction, and
- how consuming less convenient foods is more difficult and time consuming.

Overcoming those behavioral obstacles requires additional financial incentives for the 6-to-8 months – or more – necessary for the new dietary habits to get formed.

Remember our discussion so far: we want to help people avoid prediabetes, metabolic syndrome and diabetes. We have explored the 'diet' part of that standard 'diet and exercise' recommendation. We learned that eating healthier foods is more expensive, less tasty, less convenient and less comfortable. The dietary goal is, therefore, difficult to achieve.

> Tons of real world evidence shows this, including increasing rates of obesity and diabetes in the past 20 years.

Let's switch focus and turn to the exercise side now, to see if that holds more promise for success.

Exercise

The April – May 2004 issue of Harvard Magazine summarized some then-current research at Harvard University and Medical School as follows (lightly edited for context):

> [Researchers are developing] a pill, a marvel of modern medicine that will regulate gene transcription throughout your body, helping prevent heart disease, stroke, diabetes, obesity, and 12 kinds of cancer—plus gallstones and diverticulitis.
>
> Expect the pill to improve your strength and balance as well as your blood lipid profile. Your bones will become stronger. You'll grow new capillaries in your heart, your skeletal muscles, and your brain, improving blood flow and the delivery of oxygen and nutrients.
>
> Your attention span will increase. If you have arthritis, your symptoms will improve.
>
> The pill will help you regulate your appetite, and you'll probably find you prefer healthier foods. You'll feel better, younger even, and you will test younger according to a variety of physiologic measures.
>
> Your blood volume will increase, and you'll burn fats better. Even your immune system will be stimulated.[109]

[109] The Deadliest Sin, Harvard Magazine, April – May 2004

There is just one catch. There's no such pill.

The prescription instead is exercise.

Everyone knows that exercise is good for you. The Harvard quote makes the point poignantly. But touting the overall benefits of exercise is not our aim here. Instead, our focus is diabetes prevention and, more specifically, the impact of exercise on people with prediabetes or metabolic syndrome. How does exercise impact these groups?

Several papers address this, mainly metabolic syndrome patients. I'll quote 3 below.

One study by the Norwegian University of Science and Technology Faculty of Medicine in 2008 found that 36% of patients with metabolic syndrome reversed the condition with 4 months of exercise.[110] "The study shows that shows that exercise in general, but especially interval training, is able to partially or completely reverse metabolic syndrome," according to lead author Arnt Erik Tjønna.

Second, a 2017 meta-review of 16 studies was, according to the authors, the "first to compare the effects of aerobic, and combined aerobic and resistance, exercise on clinical outcome measures in people with metabolic syndrome".[111]

The authors concluded that

- BMI was significantly reduced in exercise versus control groups.
- Fasting blood glucose was significantly reduced in exercise compared to control groups.
- Triglycerides were significantly improved, and LDL cholesterol was significantly improved in exercise versus control participants.
- HDL cholesterol was unchanged in exercise versus control participants.

Third, a 2019 metastudy, published in Nutrients suggested that "physical activity as a treatment for metabolic disease remains underutilized." [112] Among their findings

> In one component study "exercise training resulted in marked improvements in the metabolic profile of the participants, including triglycerides, HDL cholesterol, blood pressure, fasting plasma glucose, and waist circumference. Of the 105 participants with the metabolic syndrome at baseline, 30.5% (32 participants) were no longer classified as having the metabolic syndrome after training."
>
> A different component study found "strong support the use of aerobic exercise for patients with the metabolic syndrome who have not yet developed diabetes."

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[110] https://norwegianscitechnews.com/2016/08/exercise-to-combat-metabolic-syndrome/

[111] Ostman et al, The effect of exercise training on clinical outcomes in patients with the metabolic syndrome: a systematic review and meta-analysis, Cardiovascular Diabetology, 2017

[112] Myers et al, Physical Activity, Cardiorespiratory Fitness, and the Metabolic Syndrome, Nutrients, July 19, 2019

> A third component study totaling 77,000 patient hours of exercise for folks with metabolic syndrome found “In analyses comparing aerobic exercise training versus control groups, there were reductions in BMI, waist circumference, systolic blood pressure and diastolic blood pressure, fasting blood glucose, triglycerides and low-density lipoprotein.”

The authors concluded that “achieving the minimal physical activity guidelines (at least 150 minutes per week of moderate-intensity activity or 75 minutes per week of vigorous intensity activity) has been consistently demonstrated to have significant benefits on metabolic risk” and “Among subjects who meet the criteria for the metabolic syndrome, health outcomes are significantly improved by aerobic or resistance training, or their combination.”

Terrific benefits to people suffering from metabolic syndrome. Unfortunately, Americans don’t exercise much or enough.

The CDC recommends that adults get 2.5 to 5 hours of moderate cardio exercise per week and 30 minutes of muscle strengthening exercise. Only 23% of us meet these targets, skewed toward higher income folks.[113] Lower income folks, those most likely to find switching to the Food Plate diet more economically difficult, tend to exercise the least.

How much might it cost to incentivize people to exercise? An old economic rule-of-thumb suggests that people value their free time at 1/3 the amount they normally earn. Our hero Joe, earning the US male average of $1,144 / week, gets $28.60/hour and would therefore values his free time at $9.44/hour. He would, according to this economic theory, exercise in his free time if someone paid him $9.44 / hour or more.

Joe probably should exercise about 4 hours / week – that’s conservative, the mid-point of the CDC’s weekly recommendation. I exercised about 7 hours / week during my own weight loss period, mainly brisk walking, but again, that discussion comes later in this chapter. Joe’s 4 hours / week would cost $37.76, or $1964 in annual incentives. I don’t know who pays this – an employer, insurance company, hospital, TPA or other. At this point, I only want to suggest what the incentive would be. I focus here on why we fail to prevent diabetes and invite others to figure out the rest.

The Context of our Failure to Treat Metabolic Syndrome and Prevent Diabetes

Two socio-medical factors underly our failure to treat patients suffering from metabolic syndrome and to prevent diabetes. I’ll briefly address each in turn.

[113] Only 23% of adults meet guidelines, Time Magazine, Ducharme, June 28, 2018.

Television. Americans watch, on average, about 3 hours of TV each day.[114] The states in which people watched the most TV correlate closely with states having the highest percent of obese people – West Virginia, Alabama, Arkansas and Mississippi. Obesity often leads to diabetes. We begin to see the television link

"The best single behavioral predictor of obesity in children and adults is the amount of television viewing," according to Harvard School of Public Health's Professor Steven Gortmaker.[115] "The relationship is nearly as strong as what you see between smoking and lung cancer." Wow.

Unpack this:

> TV watching is non-weight bearing, non-aerobic, entirely sedentary activity that generates no metabolic system benefit or weight loss.
>
> TV watching exposes viewers to (generally less healthy) food products. That advertising leads to sales, otherwise companies wouldn't continue. Products advertised rarely include the fruits and vegetables that are supposed to account for half our food plate.
>
> > The average American child sees over 40,000 TV commercials per year according to estimates by the American Psychological Association.[116] That's a lot of low-quality food message reinforcement!
>
> TV watching, according to anecdotal evidence, is associated with munching less healthy foods. People report eating salty snacks, buttery popcorn, sugary baked goods and similar while watching TV; fewer (none?) report over-indulging in broccoli or kale.

The take-away about television watching: if you want to create an obese, diabetic population, get them to watch a lot of TV. Our bountiful viewing options including streaming services, seem ideally suited to this task.

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[114] Hubbard, Outside of Sleeping, Americans Spend Most of Their Time Watching TV, US News, July 22, 2021. Also Statistica, Average Daily Time Spent Watching TV, https://www.statista.com/statistics/186833/average-television-use-per-person-in-the-us-since-2002/#:~:text=Estimates%20suggest%20that%20in%202022,hours%20watching%20TV%20each%20day .

[115] The Way We Eat Now, Craig Lambert, Harvard Magazine, May-June 2004

[116] Protecting Children From Advertising, American Psychological Association, June 2004 https://www.apa.org/monitor/jun04/protecting#:~:text=The%20average%20child%20is%20exposed,a%20year%2C%20according%20to%20studies.

Cholesterol treatments. Our typical diet, referenced in the meal case study above, leads to high blood cholesterol, with statin prescriptions a primary treatment. About 1/3 of American adults currently take a statin.[117]

Statins, it turns out, may *increase* your risk of developing type 2 diabetes.

Statins prevent the buildup of fatty deposits in blood vessels and reduce the inflammation that occurs when arteries are blocked. This lessens your risk of having a heart attack, but it may also make cells more resistant to insulin, the hormone that helps regulate glucose levels in blood. The net effect according to various studies:[118]

- Statins increase your risk of developing diabetes by about 9% on average, but
- The higher the statin dose, the higher the diabetes risk, and
- The higher your blood sugar levels when you start taking the statin, the more likely you are to develop diabetes.

That means sicker people, taking higher statin doses, are more likely to develop diabetes, exactly the people most at risk.

One study found that, on average again, 1 in every 255 people who take a statin for 4 years will develop diabetes[119] but older patients especially those suffering from multiple health problems are at higher risk that younger, healthier people.[120]

Note the caveat here: though changes in blood sugar caused by statins are 'pretty modest' according to Dr. Jill Crandall, an endocrinologist at the Albert Einstein College of Medicine in New York, they may be enough to tip someone from prediabetes to full blown diabetes.[121]

Let's tie all this together:

- Diabetes and related medical costs account for up to 25% of all healthcare spending, with diabetes rates rising
- About 90% of diabetes is type 2, caused by lifestyle behavior
- The standard 'lose weight and exercise to avoid diabetes' prescription is both unaffordable and unpalatable to most of us; diets generally fail within 2 years
- The economic incentives required to keep people on their diet and exercise programs are unaffordable to employers, insurance carriers or similar

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[117] The 1/3 estimate is extrapolated from the trend. https://consumer.healthday.com/general-health-information-16/misc-drugs-news-218/number-of-americans-taking-statins-keeps-rising-cdc-694895.html or https://www.ahrq.gov/data/infographics/statin-use.html

[118] This analysis comes from Madhusoodanan, NY Times, October 25, 2022 Ask Well 'Do statins increase the risk of type 2 diabetes?'

[119] Sattar, Statins and risk of incident diabetes, https://www.ncbi.nlm.nih.gov/books/NBK78906/

[120] Madhursodanan, op cit

[121] Ibid.

- One common behavioral response to our high stress lifestyles – TV watching – may exacerbate the diabetes problem
- Medical treatments for other behaviorally related health problems, i.e. statins to lower cholesterol, may also exacerbate the diabetes problem.

Is there a medical solution?

Semaglutide

Semaglutide developed by Novo Nordisk, apparently treats obesity and diabetes quite well.

In one large random controlled study, for example, patients taking 2.4 milligrams of semaglutide lost an average of 6% of their body weight by week 12 and 12% of their body weight by week 28. That's impressive.

Other studies have suggested similar successes.[122]

In February 2022, the British National Institute for Clinical Excellence (NICE), the UK's medical rationing agency, approved Wegovy, Novo Nordisk's brand name for semaglutide to treat obesity. In the vernacular, NICE approval means the drug works; it has a higher approval bar than the US Food and Drug Administration.

> Eli Lilly has developed a competitor weight loss drug called tirzepatide, not yet approved as of time of writing. I assume other companies have already, or will, similarly design competition to semaglutide.

NICE's stringent use guidelines for semaglutide illustrate some underlying issues with the drug.[123]

- It is approved for people with at least 1 weight related medical issue and a BMI of 35 or more, or, only exceptionally, for people with a BMI between 30 – 34.9
- It can only be prescribed as part of a specialist weight management program including supervised weight loss coaching. This has implications for the US where only 1% of physicians are trained in obesity medicine.[124]
- Semaglutide can be prescribed for 2 years, maximum.

Novo Nordisk also sells semaglutide it for diabetes treatment under the brand named Ozempic.

But the pricing:

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[122] Weghuber et al, One-Weekly Semaglutide in Adolescents with Obesity, NEJM, Nov 2, 2022

[123] Much of this discussion comes from 'NICE approves Wegovy for obesity', European Pharmaceutical Review, February 10, 2022 https://www.europeanpharmaceuticalreview.com/news/168431/nice-approves-wegovy-semaglutide-for-obesity/

[124] Kolata, The Doctor Prescribed and Obesity Drug; the insurance company called it vanity, NY Times, May 31, 2022. Much of the following discussion comes from this source.

- Ozempic, semaglutide for diabetes, lists for $894 for 4 weeks in the US. Insurance companies normally cover it for diagnosed diabetics.
- Wegovy, semaglutide for weight loss, lists for about $1,350 per month. Insurance companies normally don't cover it, at least not without a fight.
- Saxenda, basically Wegovy lite also by Novo Nordisk, also lists for $1,350 per month. Ditto on the insurance coverage front.

This creates confusing incentives. In the US, having a high BMI does not necessarily quality a patient for Wegovy or Saxenda as in the UK. American doctors must wait until their patient becomes diabetic. Patients 'only' suffering from obesity and metabolic syndrome don't have access so must settle for less robust, older medications, often with unpleasant side effects. As the New York Times reported, one doctor 'finds herself rejoicing when patients have high blood sugar levels'[125], i.e., becomes diabetic and therefore eligible for treatment.

We don't yet know the long term effects of semiglutide because the it's too new:

- Does a patient who loses 12% of their body weight in 7 months then keep it off?
- What happens when, in the UK situation, semaglutide's prescription runs its full 2-year course: does the patient regain the weight or not?
- Is 2 years long enough for the patient to develop good eating habits?
- Can the patient afford to stay on the healthier diet?
- What is the medical cost difference between staying on Wegovy for life and returning to obesity and diabetes?

We also can't yet answer the most important economic question: how do semaglutide treatment costs compare with medical treatment costs over time? We can only, today, guess at the answer.

Semaglutide and, perhaps, Novo Nordisk's competitor's drugs, may be the light at the end of the obesity-to-metabolic syndrome-to-diabetes tunnel. Or they may be the proverbial headlight of an oncoming train. I certainly don't know which, but the future looks murky to me. At best.

Case study
My own experience with metabolic syndrome

My doctor diagnosed me with metabolic syndrome in August 2020 based on various numbers from my annual physical.

> A quick word on numbers and annual physicals. I consider these equivalent to a half-semester report card in high school, a rough indication of your academic health and direction. You might be a good student having a bad semester for some ephemeral reason. You might have a serious intellectual disease. Or you

[125] Ibid.

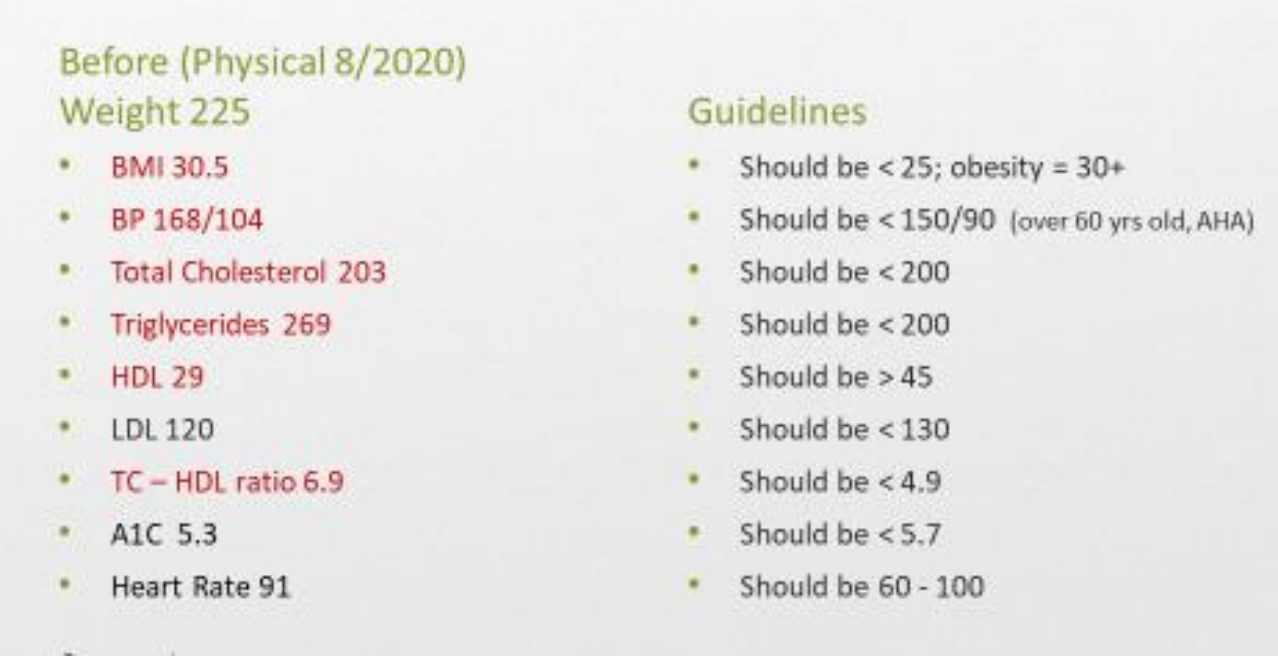
might be going in a bad academic direction, through lack of effort for example. Your half semester report card doesn't tell which.

A series of report cards over time might though. Consider a student with an A average in 8th grade, an A- average in 9th grade, a B average in 10th grade and a C- average on the first half semester report card in 11th grade. We see a trend. The report card suggests need for an intervention by the school, parents, community, or others to identify and address some issue or other.

Similarly, my 2020 annual physical numbers suggested an issue. What is was – lifestyle, individual biology or something else – remained to be determined.

Add to that my own idiosyncratic personality: I don't like to receive failing grades. I found myself annoyed more than concerned and determined to do something about it. I self diagnosed – always a bad idea – my problem as lifestyle and decided to lose weight, exercise more and see what happened.

My August 2020 numbers compared to the metabolic syndrome guidelines:

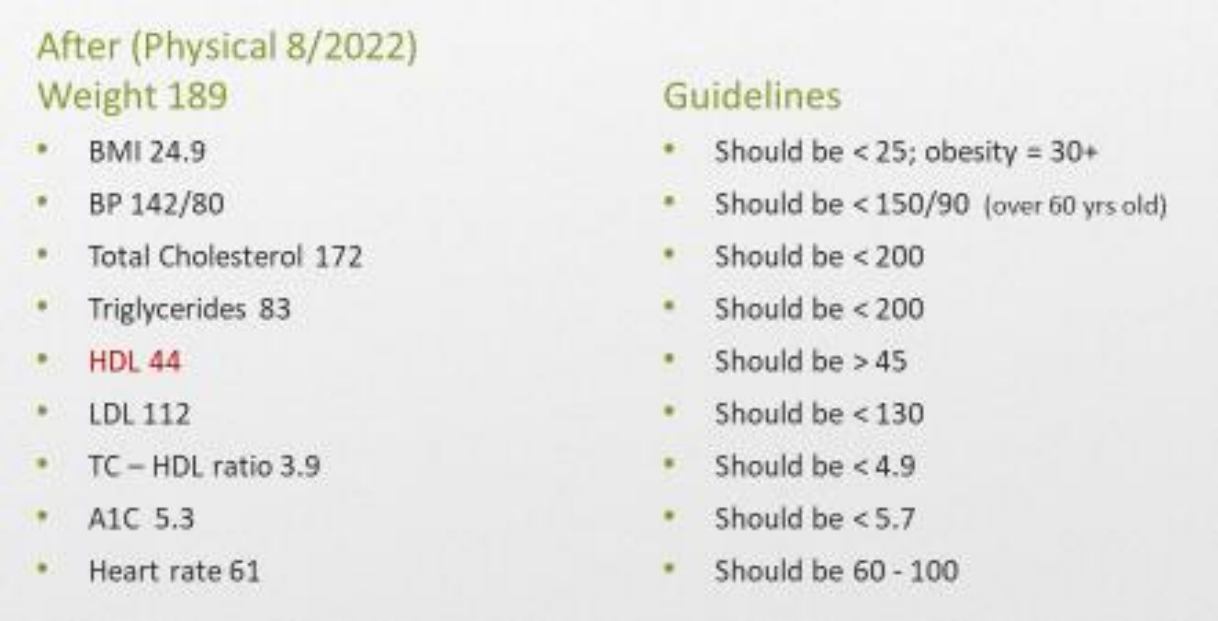


I put myself on diet-and-exercise program and lost about 40 pounds in a year. See the addendum to this chapter for details.

But the big question facing me: would the healthy habits, developed over a year, maintain themselves and keep me at a healthy weight at the 2 year anniversary? I know the 2 year failure rate of weight loss programs, well over 80% with some estimates as high as 97%.

Also, what would that metabolic profile look like 2 years later?

Here are the results from my August 2022 physical:



And here's the side-by-side comparison of all those numbers two years apart to show the remarkable impact of weight loss and exercise increase in one relatively easy-to-read chart.

Diet and exercise worked well to get me out of the metabolic syndrome.

It's a shame that cost, convenience, and other factors keep so many others from enjoying this success and the related good health / low healthcare costs.

Chapter summary

Diabetes accounts for up to 25% of all healthcare spending. Its incidence grows over time, along with the underlying causes: obesity, low quality caloric food consumption and insufficient exercise afflict many of us, perhaps a majority of Americans, perhaps a large majority.

Many afflicted folks progress through metabolic syndrome and / or prediabetes to full blown diabetes. Efforts to intervene behaviorally - typically referred to as lifestyle changes involving dietary improvements and exercise increases - generally fail, by some estimates up to 97% of the time.[126] They're

- Too expensive for average income Americans
- Too uncomfortable to maintain for years
- Too inconvenient
- Too dissonant with our normal lifestyles, TV watching for example.

New, promising medications are too expensive for widespread use, with 'widespread' meaning the 70 million currently obese Americans. Insurance companies balk at the cost.

I don't see a hopeful path forward. Instead, I see our diabetic population growing along with the associated healthcare costs.

A pessimistic end to a pessimistic chapter.

My calorie and cost spreadsheets

All data from Shaw's, Easton Massachusetts, October 2022. I made several trips to gather data.

In case you have trouble reading the spreadsheets below, the column headings are

- Item name
- Cost / package. The store publishes this.
- Servings / package. This is on the nutritional label of all packaged foods, or you can google it for fruits and vegetables.
- Calories / serving. Again, on the nutritional label. Google provides this information about other foods - calories / pound of apples for example, or calories in a medium apple.
- Cost / calorie. This is a simple division: cost / package divided by number of servings / package divided by number of calories / serving.
- # servings per meal. That's how much you put on your plate. You may choose 2 servings of spinach for example, or ½ serving of ice cream.
- Total calories = Again a simple calculation: the number of calories / serving times the number of servings on your plate.

[126] The Weight of the Evidence, Harriet Brown, Slate, March 24, 2015 https://slate.com/technology/2015/03/diets-do-not-work-the-thin-evidence-that-losing-weight-makes-you-healthier.html.

- Total cost = the cost / calorie for each food times the number of calories on your plate.

Item	Cost / package ($)	Servings / package	Calories / serving	Cost / calorie	# servings	Total # calories	Total cost ($)
Healthy breakfast							
2 jumbo eggs - range free	7.99	12	90	0.007398148	2	180	$ 1.33
2 pieces Arnold Multigrain toast	5.29	16	110	0.003005682	2	220	$ 0.66
Butter (Land o Lakes)	4.79	30	50	0.003193333	1	50	$ 0.16
1 banana	0.69	3	100	0.0023	1	100	$ 0.23
Black coffee	19.99	100	2	0.09995	1	2	$ 0.20
Total						552	$ 2.58
Healthy lunch							
Spinach salad	5.99	3.5	20	0.085571429	1	20	$ 1.71
Tomato	2.99	1	90	0.033222222	0.5	45	$ 1.50
Carrot	3.49	11	30	0.010575758	0.5	15	$ 0.16
Yellow Pepper	1.7	1	50	0.034	0.5	25	$ 0.85
Beets	3.99	2.5	50	0.03192	0.5	25	$ 0.80
Olive oil - Bertolli	7.49	33	120	0.001891414	0.67	80.4	$ 0.15
Balsamic vinegar - Filippo Berio	6.99	33	11	0.019256198	0.33	3.63	$ 0.07
.3 lb of chicken breast	3.99	1	748	0.005334225	0.3	224.4	$ 1.20
1 pita	2.99	8	90	0.004152778	1	90	$ 0.37
Apple	1.99	3	95	0.006982456	1	95	$ 0.66
Total						623.43	$ 7.47
Healthy dinner (Rice Bowl)							
2 cups brown rice	20.99	111	170	0.001112348	2	340	$ 0.38
Broccoli	1.99	1	154	0.012922078	0.33	50.82	$ 0.66
Summer squash	1.99	1	74	0.026891892	0.33	24.42	$ 0.66
Snap peas	2.99	3	35	0.02847619	1	35	$ 1.00
Green beans	3.29	4	25	0.0329	1	25	$ 0.82
Salmon	11.99	1	944	0.012701271	0.4	377.6	$ 4.80
Low salt soy sauce	3.29	20	20	0.008225	1	20	$ 0.16
Blueberries	2	1	229	0.008733624	0.5	114.5	$ 1.00
Strawberries	4.99	1	149	0.033489933	0.5	74.5	$ 2.50
Total						1061.84	$ 11.97
Total Daily Calories & Cost						**2237.27**	**$ 22.02**

Item	Cost / package ($)	Servings / package	Calories / serving	Cost / calorie	# servings	Total # calories	Total cost ($)
Typical breakfast							
Honey bran muffin (Shaw's)	$5.00	4	420	0.00297619	1	420	$ 1.25
Coffee	19.99	100	2	0.09995	1	2	$ 0.20
Cream (Coffeemate)	4.49	63	35	0.002036281	1	35	$ 0.07
Sugar (Domino's granular)	1.99	54	30	0.001228395	1	30	$ 0.04
Total						487	$ 1.56
Typical lunch							
Ham	7.99	1	885	0.009028249	0.25	221.25	$ 2.00
Cheese (20 slices / lb)	5.99	20	100	0.002995	1	100	$ 0.30
Sub roll	2.99	6	200	0.002491667	1	200	$ 0.50
Mustard (French's)	2.49	79	1	0.031518987	1	1	$ 0.03
Lettuce - ice berg	2.49	1	105	0.023714286	0.15	15.75	$ 0.37
Bag of chips	21.99	42	150	0.003490476	1	150	$ 0.52
3 Oreos	5.49	21	160	0.001633929	1	160	$ 0.26
Apple	1.99	3	95	0.006982456	1	95	$ 0.66
Coca cola	2.79	12	140	0.001660714	1	140	$ 0.23
Total						1083	$ 4.88
Typical dinner							
Regular pasta (Barilla)	2.99	8	200	0.00186875	1	200	$ 0.37
Pasta sauce (Prego traditional)	3.99	5	70	0.0114	1	70	$ 0.80
Ground beef - 80%	4.99	1	1152	0.004331597	0.25	288	$ 1.25
Grated cheese (Kraft parm)	5.99	45	20	0.006655556	1	20	$ 0.13
Green salad - Dole American	3	4	15	0.05	2	30	$ 1.50
Italian dressing (Ken's house)	3.99	16	120	0.002078125	1	120	$ 0.25
Canned peaches	3.49	7	100	0.004985714	1	100	$ 0.50
Ice cream (Friendly's)	4.99	9	210	0.002640212	0.5	105	$ 0.28
Beer (Bud) Walmart	8.27	6	145	0.009505747	1	145	$ 1.38
Total						1078	$ 6.46
Total Daily Calories & Cost						2648	$ 12.90

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Addendum: My battle with metabolic syndrome

A version of this is available from www.lulu.com as Gary's Guide to Weight Loss.

Foreword
Dr. David Mudd

Gary asked me to write a forward to his book while we were kayaking together. I told him I would be honored to do so.

I have worked for 30 years as a primary care physician in a mixed urban / suburban environment. Over these years obesity rates have skyrocketed. I have seen it in my own practice: young and old patients, blue and white collar, it doesn't matter. Far too many of my patients are heavier these days causing other health conditions to become more prevalent including diabetes, hypertension and heart disease.

I have had countless people come to me complaining of their inability to lose weight. The complaints are the same and the accounts of their food intake and exercise eerily similar. "I hardly eat anything" or "I eat the same amount I always have." Lacking hard data, I wonder about this.

When I ask about their activity level, they usually respond “I try to walk.”

They typically want to have their thyroid checked, assuming that there is a medical explanation for their weight gain and fatigue.

My message to them is always the same: “you need to cut back on your calories and become more active”. Unfortunately, we never have enough time together for me to understand their lifestyles, dietary norms and physical activity habits in enough detail. Invariably they return frustrated and unsuccessful.

Fewer than 1/10 patients actually make the changes necessary to lose weight and keep it off.

Patients such is Gary Fradin are few and far between but a joy to work with. Gary is the rare patient who understands nutrition and exercise and actively takes control of his own health. He formulated a plan to cut his calories and increase his activity level and enjoyed spectacular results, losing over 40 pounds and getting himself into good physical shape as well.

Gary summarized the process in this readable and informative book. His recommendations are science based, useful and appropriate. I heartily recommend it.

In fact, I plan to give this book to my own patients. Enjoy it and good luck!

Dr. David Mudd
Easton, Massachusetts
May, 2021

Preface

After Covid struck, after our lives turned upside down, after my business revenues fell by 50%, after all normal routines disappeared, my doctor told me I had metabolic syndrome and to lose weight.

I told him I was fit and healthy.

He repeated his order.

How to lose weight? Diet options ranged from A (Atkins) to Z (Zone). All claimed dramatic successes.

But all almost certainly fail over time. Research suggests that 97% of people regain their weight within about 3 years.[127] Here, for example, is Traci Mann from UCLA summarizing her group's study:

> "You can initially lose 5 to 10 percent of your weight on any number of diets, but then the weight comes back. We found that the majority of people regained all the weight, plus more."[128]

I didn't want to be one of the failures.

My doctor offered a nutritionist referral, which I postponed; I didn't like the odds, hate scheduling medical appointments and feared entering the modern diet culture even under the guise of organized medicine.

Instead, I decided to try on my own. I figured I could achieve at least the same dismal long- term weight loss result myself, and possibly do even better.

This chapter describes how.

The program isn't a unique, novel or brilliant but it's straightforward, practical and honest. You can easily adapt it to your own situation.

Just follow the steps, modify it to your own needs and give yourself time.

The Camera Adds 20 Pounds
Me, fit-and-healthy pre-weight loss

[127] The Weight of the Evidence, Harriet Brown, Slate, March 24, 2015 https://slate.com/technology/2015/03/diets-do-not-work-the-thin-evidence-that-losing-weight-makes-you-healthier.html.

[128] Dieting Does Not Work, Stuart Wolpert, UCLA Newsroom, April 3, 2007 https://newsroom.ucla.edu/releases/Dieting-Does-Not-Work-UCLA-Researchers-7832

Introduction

I’m not a doctor, nutritionist, dietician or exercise physiologist. I have no medical training.

Instead, I’m an economist. I measure things. Weight loss strikes me as a measurement problem:

- If you eat more calories than you burn, you gain weight.
- If you eat fewer calories than you burn, you lose weight.
- As you eat less, your metabolism slows so you need to exercise more.

Sustained, long term weight loss also incorporates a fourth, behavioral consideration:

- Do this all slowly enough to develop new habits. That increases your chance of long-term success.

This program incorporates all those issues.

As background, I’m a 68-year-old, 72-inch-tall man. I weighed 225 pounds in my doctor’s office on August 13, 2020.

I followed this program for 9 months and weighed 185 at my Sunday morning weigh-in April 4, 2021. I had lost 40 pounds over 36 weeks, about a pound per week on average.

It wasn't very difficult – more a task to accomplish than a mountain to climb - but I was hungry much of the time, especially at the beginning. That feeling dissipated as my new eating habits became ingrained and my body adjusted to its new setpoint. Dissipated but didn't disappear.

I'm optimistic about long-term success, optimistic that my habits have changed enough to maintain my new weight for years to come. Cautiously optimistic that is, not blindly. After all, 97% of people who lose weight ultimately put that weight back on.

We'll see. The future is a long time.

Step 1: Calculate your daily calorie needs.

There's a weight loss mantra 'eat 500 calories less each day and lose a pound a week'.

Maybe true – I don't know - but I needed a starting point. 500 calories less ***than what***? No idea. I hadn't tracked my previous consumption.

I initially tried cutting cream from my morning coffee and dessert from lunch and dinner. But I didn't use the same amount of cream every day. Nor did I eat dessert every day but when I did, the type and size varied. Did that cut 500 calories? No idea.

I tried eating smaller portions. Small enough? Too small? Again, no idea. I only knew that I felt hungry. I worried that if I felt hungry without seeing results, I'd get frustrated and stop.

I needed a plan.

So instead of eating 500 calories *less* than some unknown number, I decided to calculate how many calories I *should* eat each day to lose a pound a week, an absolute number.

I googled 'calories per day to lose weight' and found lots of websites that base their estimates on age, height, weight, gender and daily activity level. Most suggested roughly the same amount – 2300 calories per day to lose a pound a week from that 225 pound starting point. (Your own amount will vary.)

The agreement among websites gave me a reasonable degree of confidence.

I aimed for 2200 calories per day, slightly below the 2300 estimate to allow for measurement errors.

Interestingly, 2200 calories per day isn't a starvation diet. Far from it. In fact, the US Department of Agriculture estimates that the average American consumed 2234

calories per day in 1970.[129] My 2200 calorie target simply mimicked America's pre-obesity food consumption level.

Three thoughts on eating according to your daily calorie estimates and watching the impact on your weight:

1. Remember to recalculate as you lose weight. Your calorie needs drop.
2. Set reasonable weight loss goals – neither too fast nor too much – to avoid frustration.
3. Weigh yourself on the same scale, at the same time, every week. This generates the most consistent data, necessary to keep you on track. I choose Sunday mornings, first thing. Those are the weights I show in the **Results and Lessons** chapter.

I started thinking 'if I can get down to 215, I'll be successful'. Then, upon reaching 215, I wondered about losing another 5 pounds. Then I aimed for 200, a nice round number. Then 195, a 30-pound loss and enough to write a book. Maybe others could benefit from this program?

But losing 40 pounds sounded better than 30, so I aimed for 185 and made it. Low enough! My doc said to stop here.

Remember that my initial goal wasn't 185. It was 215. Try to define success for yourself as a goal you can reasonably reach in a relatively short period, something that will make you feel proud. Then let the future take care of itself as you gain confidence through success.

Step 2: Divide your daily calorie target into 3 meals and a snack.

I used this rule-of-thumb for my initial 2200 calorie per day program.

Breakfast - 400 calories (18% of total daily calories)

Lunch - 600 calories (27%)

Dinner - 800 calories (36%)

Snacks or dessert - 400 calories. You can add these to your breakfast, lunch or dinner.

Your own calorie target and meal amounts may differ.

[129] Wells and Buzby, US Food Consumption Up 16% Since 1970, Economic Research Service US Department of Agriculture, November 1, 2005 https://www.ers.usda.gov/amber-waves/2005/november/us-food-consumption-up-16-percent-since-1970/

You'll find calorie estimates for specific foods on packages or online. Simply google 'calories in a medium potato' or 'calories in a cup of blueberries' or whatever. It's easy and close enough for our purposes.

Meal timing: I ate according to the clock throughout this program and expect to in the future:

- Breakfast at 9:00
- Lunch at 1:30
- Dinner at 6:30. Regular as clockwork.

Try not to eat whenever you feel hungry because those feelings come and go. Stick to the clock. It's honest, reliable and will keep you on track.

See the discussion of hunger below, for more on this.

Food choices: I learned several things through trial and error about my own reaction to food groups. You probably will too, though perhaps different lessons.

First, I feel fuller, longer eating vegetables probably because of their high fiber and water contents. I eat lots of vegetables these days.

Second, I prefer healthy food tastes. I look forward today to my English muffin, peanut butter and banana breakfast as enthusiastically as I had previously anticipated pancakes with syrup or eggs with bacon, sausage and toast.

In fact, I no longer want those overly-sweet, overly-salty, overly-filling, low-fiber meals, not because they're so high in in calories but because they make me feel lousy afterward. They sit like a rock in my stomach and leave me stuffed and thirsty, then surprisingly hungry relatively quickly.

Third, I don't miss those previously routine, calorie-rich tastes, things like cream in my morning coffee, cheese and crackers between meals or rich desserts after dinner. I now prefer blueberries, raspberries or strawberries for dessert, sometimes with a drop of honey on top. Berries are sweet and delicious, and I feel good after eating them.

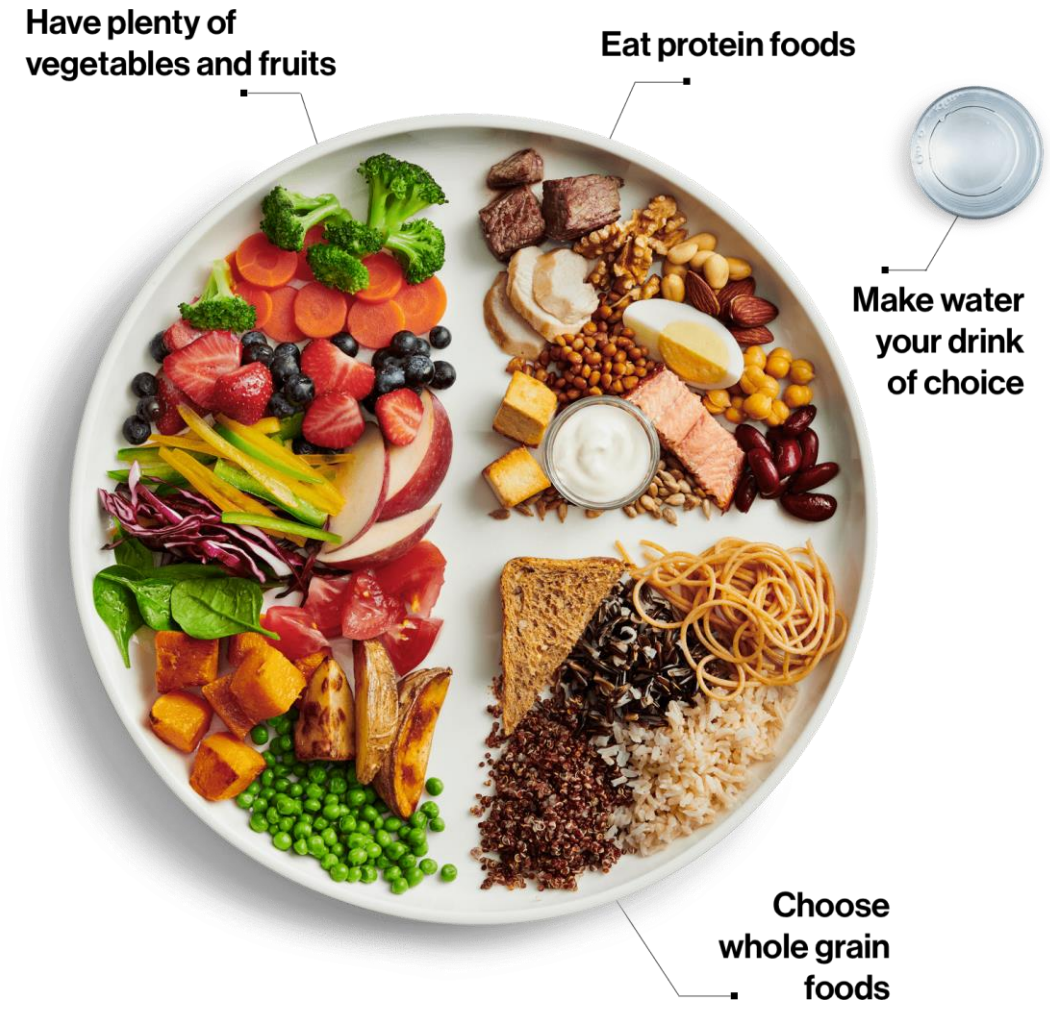
Plus I don't have that sugary thirst like I used to after eating cookies or cake.

My experiences mirror recommendations from 2 thoughtful sources. Michael Pollan, New York Times contributor, best-selling author, and Berkeley professor famously advises people to "Eat food. Not too much. Mostly plants." Consider each phrase.

- **"Eat food"** means eat real, identifiable farm products like fruits, vegetables, whole grains, meat and fish. Avoid ingredients you can't pronounce and foods your grandmother wouldn't recognize.
- **"Not too much"** means stick to your daily calorie limit.
- **"Mostly plants"** means lots of fruit and vegetables.

The Canadian Food Plate, photo below, suggests the proportion of each food group – plants, grains and proteins – to eat daily. Remember that nuts, beans and legumes count as proteins.

About half your plate should be fruits and veggies – aim for lots of different colors - a quarter protein and another quarter whole grains.



Eat food. Not too much. Mostly plants.

Tastes and habits: When people say, ‘I can’t drink coffee without sugar’ or ‘I can’t eat an egg without salt’, I wonder if they remember what got them into their overweight situation in the first place.

Changing eating habits is a process, both challenging and rewarding. The good news is that you really can change.

The bad news is that it takes time. Most people require at least 2 months for a new taste preference to become fully automatic though some people take up to 8 months

according to research.[130] Understand and accept this. Give yourself time to change your habits.

This habit development process may suggest why our modern diet industry so often fails people. It operates within two mutually exclusive constraints.

- First, it has to deliver weight loss results quickly enough that people don't drop out and post negative reviews online.
- But second, long term sustained weight loss and new habit creation takes a long time.

You can't generate fast results slowly! That's why I didn't want to get involved with it. I wanted a program without commercial or time pressure.

Hunger. Eating fewer calories per day makes you hungry. That's simply reality. I learned to differentiate three types of hunger.

*** Hunger as not feeling completely full.** I had previously enjoyed eating until I was 'pleasantly satisfied'. I don't get that feeling anymore.

Instead, I feel 'full enough' these days, not exactly hungry but not completely full either. I could happily eat an additional muffin at breakfast, a bigger sandwich at lunch, an extra helping at dinner or a second bowl of fruit in the evening. But I don't.

I've learned to embrace feeling 'full enough' when I reach my calorie limit per meal. It's my new normal, my new habit. Today it feels right.

You can adapt to this new feeling too. Just give yourself time. And remember your goal.

*** Hunger as deprivation**, actual physical need. This is sometimes called 'belly hunger' as opposed to 'head hunger', below.

I wasn't worried about physical deprivation as long as I ate every 4 – 5 hours. I knew that my 2200 calorie per day program was sufficient for good health; the 1970 era US food experience proved that. Two hundred million Americans ate that way every day. End of story.

Some people, of course, might have special nutrition or health issues. I can't speak to those. Still not a doctor.

***** Head hunger differs from **belly hunger**. Head hunger goes away when you think about something else. Belly hunger does not.

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[130] Grohol, Need to Form a New Habit? Give Yourself At Least 66 Days, PsychCentral, October 7, 2018 https://psychcentral.com/blog/need-to-form-a-new-habit-66-days ; UCL News August 9, 2009 Interview with Phillippa Lally https://www.ucl.ac.uk/news/2009/aug/how-long-does-it-take-form-habit

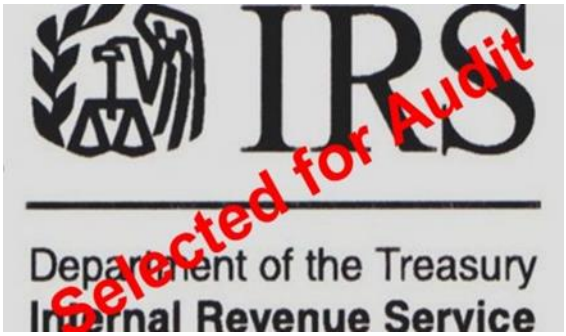
Try this thought experiment to understand the difference: visualize a delicious burger or juicy steak or moist chocolate cake or juicy mango. Imagine the taste. Picture it. Anticipate the sensation as you bite in.

Hold that thought.

Feel hungry? It's head hunger.

Now think of an IRS audit or root canal surgery. Visualize it. Hold onto it. Lose the hungry feeling?

Causes head hunger



Removes head hunger

Head hunger is a mental state. You can feel it equally few hours after either a big or small meal. When you feel it, think about something else. Easier said than done of course.

Food costs. Vegetables, per calorie, cost more than most other food groups due to various food subsidy and tax programs. Understand this and be prepared for a food budget increase.

Restaurants pose a problem for calorie restricted diets. Here are four suggestions that might help:

- Split a main course with someone and complement each portion with a side salad.
- Ask the restaurant to bring a doggie-bag containing half of your meal ***when they serve it***. I find this works better than attempting to estimate and eat half first, then asking for a doggie bag later.
- Stick with salads and protein toppings. Careful with the dressing. This option might make the restaurant experience less special, but it will make your calorie intake more predictable.
- Pay attention to drinks, both alcoholic and non. Wine has about 120 calories per glass, beer 150, gin and tonic 170, Long Island iced tea 280 and Margaritas up to

450.[131] Coca-Cola classic has 140 calories per 12 ounces, orange juice about 110 per cup and chocolate milk about 200. Those all count toward your daily total.

Cheating: Try not to. You'll only sabotage your progress and depress yourself at your next weekly weigh in. Be honest with your measurements and anticipate that you'll be on this program for several months at least, maybe for life (maintenance period).

Summary: Eat according to the clock and follow your grandmother's advice: eat the foods she would approve, don't eat foods she wouldn't recognize and control your portions.

Allow yourself time to develop new habits.

****

I invented some recipes, unexpected food combinations that satisfied me. Several became my new habits. If you like any, use them. Feel free to invent your own!

Breakfasts

Toasted English muffin with peanut butter plus a banana with almond butter. I eat this most frequently, perhaps 5 times per week. Cut a whole wheat English muffin (100 calories) in half and toast both halves. Then spread one tablespoon of salt-free peanut butter – about 100 calories – onto the 2 halves, about half a tablespoon per half. I don't add jam because I don't like very sweet tastes for breakfast, but that's just me.

Then cut a ripe banana, about 100 calories, in half and spread one tablespoon of almond butter – about 100 calories - onto it, again half a tablespoon per half. I prefer almond butter to peanut butter with bananas but again, my own preference.

Poached eggs on oatmeal. Instead of 2 scrambled eggs and 2 pieces of toast for breakfast, I substituted 2 poached eggs over oatmeal with a splash of ketchup, again my own taste preference. Oatmeal instead of wheat, one grain for another. Make it thick. One-third cup of steel cut oats is 170 calories, two jumbo eggs total 180.

Sometimes I add tomato slices or steamed broccoli. Tasty. Other times I melt Swiss cheese into the oatmeal, then put one egg on top. Delicious!

Plenty of other breakfast options exist within that original 400 calorie constraint. You're only limited by your imagination.

[131] Best and Worst Booze While Dieting, Carolyn Williams on cookinglight.com https://www.cookinglight.com/healthy-living/weight-loss/best-alcohol-drink-on-diet

Lunch

I often eat leftovers for lunch, generally vegetables with some protein and fruit for dessert. Sometimes I add peanuts, cashews or butter beans - I really like butter beans - depending on our refrigerator's contents. Remember to estimate your calories honestly when you do this.

Here are some creative combinations that I enjoyed.

Tuna fish sandwich with pickles and a chocolate banana smoothie. I use chunk light tuna, only 90 calories per can, oilier than solid white so requiring less mayonnaise; add about ½ tablespoon, 50 calories. Then 2 slices of bread @ 100 calories each, a tomato slice and lettuce with a side of pickles for a 360 calorie, filling sandwich. Maybe add a splash of mustard (!) for flavor.

Then, assuming your taste buds require (mine generally do), make a frozen banana smoothie. One cup of skim milk (100 calories), a banana (another 100) and 2 tablespoons of Ovaltine (40 calories). I prefer Ovaltine to other chocolate syrups, but again, that's just me. Total about 240 calories, making your tuna sandwich plus smoothie a tasty 600 calorie lunch.

Beans or mussels in tomato sauce over steamed vegetables. One 8-ounce packet of frozen mussels (I use PanaPesca) contains 175 calories; 3 cups of broad beans about 150 calories. One cup of tomato or marinara sauce has about 120 calories depending on the brand. Put this modified bolognaise sauce over steamed zucchini, broccoli or cauliflower and sprinkle with parmesan cheese for a delicious and filling 300 calorie lunch. Enjoy a couple pieces of fruit for dessert.

I sometimes substitute chicken, garbanzo beans or left-over steak.

And I sometimes, though rarely, put this over a cup of pasta, about 200 calories.

Plenty of options to try.

A word about vegetables and salad. Per volume, vegetables contain fewer calories than most other foods. It's hard to overeat spinach or broccoli!

Try mixing three cups of raw spinach (25 calories) with a cup of raw beets (45 calories), a large tomato (25 calories), left over veggies from your refrigerator and any other vegetables you have on-hand. Then top with your favorite cheese, nuts or protein.

Careful with the dressing though. I limit myself to 1 tablespoon, generally of Italian or Greek dressing, 50 - 75 calories depending on the brand. Sometimes I make my own, mixing olive oil, vinegar and mustard or horseradish.

A word about fruit. I normally eat at least 3 pieces of fruit every day in addition to my frequent morning banana. I'm partial to apples, oranges, clementines, strawberries,

raspberries and blueberries. We're not, in my family, big melon, pineapple or mango people but if we were, I'd include those too. It's a matter of taste again.

Dinner

We enjoy broiled vegetables at almost every dinner during the winter and grilled veg in the summer, generally broccoli, cauliflower, green beans, Brussels sprouts or eggplant. I char them slightly and sometimes sprinkle lightly with salad dressing. ('Lightly' means about a tablespoon per pound of veg.)

We typically eat this as a side dish with grilled meat, chicken or fish, most often fish. Sometimes my wife and I split a sweet potato too, about 80 calories per half. That adds natural sweetness to the meal.

Remember to control your portions! Steak has more calories per pound than chicken; salmon more than white fish.

We also try more creative dinners too.

Tomato sauce with turkey or beans and vegetables. This becomes a stand-alone stew; no pasta required. We use low fat ground turkey, a low calorie / low salt pasta sauce (read the labels) and add broccoli, cauliflower, peas, onions, mushrooms, peppers or fresh tomatoes. Then flavor with red wine.

We sometimes substitute butter beans for the turkey.

One issue with this meal: estimating calories accurately, especially leftovers. I generally add up all the calories in the entire batch, then estimate portion size – a quarter, a third, etc. Close enough for our purposes. Overestimating your portion today leads to underestimating it tomorrow or vice versa.

I then label the leftover calories in the fridge because I forget otherwise.

Baked feta and vegetables. Cut a block of feta cheese into 300 calorie chunks then bake or broil with red onions and cherry tomatoes. Sprinkle lightly with Greek salad dressing. Add a glass of chilled white wine, about 100 calories.

We sometimes add or substitute tofu for feta. Same idea but a different flavor.

Homemade oatmeal muesli, a sweet, Swiss-themed change from veggies and protein. Mix together 1/2 cup of steel cut oatmeal (255 calories), ½ cup of unsalted cashews or peanuts (320 cal.) or almonds (414 cal), a cup of blueberries (85 cal.), a cup of strawberries (50 cal.) and a banana (100 cal.). Total about 800 calories depending on your specific ingredients. Top with yogurt or honey, another 70 calories or sprinkled coconut. Eat hot or cold.

Snacks and Deserts

Some of my favorite quick-and-easy snacks include:

- Baked apples with cinnamon
- Blueberries or raspberries. 85 cal. per cup each + 1 tablespoon honey, 70 cal. equals 155 calories total
- Yogurt with Ovaltine. ½ cup fat free, sugar free yogurt, 60 cal. + 2 tablespoons of Ovaltine, 40 cal. = 100 calorie version of chocolate mousse. OK, not *exactly* mousse but it's pretty good. I sometimes double this if I'm ahead on my daily calories. (Haven't tripled it yet.)

You'll invent your own recipes. Write everything down so you remember which worked best for you.

Step 3: Go for a daily brisk walk.
or get some other form of daily exercise

Our metabolisms slow down as we eat fewer calories. To counter this, exercise every day. I normally enjoy a brisk daily walk, equal emphasis on **brisk** and **daily**. 'Brisk' means you can *just barely* keep a conversation going. Walk with a friend to find your own speed using this metric. (Check with your doctor to make sure you're healthy enough first.)

Our frighteningly unfashionable hero in his winter walking outfit, 2021

I average about 420 minutes – 7 hours – of brisk walking per week. I measure minutes of exercise per day instead of steps or total walking distance to allow for variety - swimming, bike riding, exercise classes, weight-lifting, cross country skiing or similar activities.

Interestingly, both the CDC and British National Health Service recommend *at least* 150 minutes per week of brisk exercise for everyone. More is better. That weekly 420 minutes of brisk walking helped keep my metabolism from slowing down as I ate fewer calories. The simple form at the end of this book helped me stay on track. Try it yourself.

Daily exercise – walking in my case - like everything else in this book, becomes a habit. You miss it on days you don't go. Allow yourself time for this habit to develop.

I like to measure both my daily exercise time and walking distance. The goal is to maintain at least, and hopefully increase, both. Various smart phone apps can help.

One day, early in this program, I walked 4 miles in 70 minutes, about 17.5 minutes per mile, finishing tired and certain I couldn't go farther or faster. Six months later, on a mid-February walk, I averaged 15:30 per mile for 5 miles, equally certain that I couldn't go faster … but pretty sure, this time, that I could go farther. (I actually went 7 miles a week later though at a slower 16:30 pace.)

Some people prefer to track total daily mileage or total daily steps. These are different ways to measure the same thing. I prefer exercise minutes since I can plan and control these, but again, just my preference. As long as you walk briskly during your exercise minutes, any measure can work.

One trick that keeps me motivated, even enthusiastic about walking every day: I listen to novels, generally long ones that keep me engaged. I prefer historical fiction and mysteries but again, personal preference.

I've walked with Winston Churchill during the Blitz of London, young Nigerian intellectuals as they navigate life, Sherlock Holmes, seafaring merchants, unscrupulous criminals, clever detectives and many others. I look forward each day to reconnecting with my audio friends and often – oddly – feel sad when each book ends. Listening while walking has become another habit, one that I increasingly enjoy.

Confessionary addendum: I know that I should add strength training to my exercise regime. I keep meaning to start but, truth be told, I never enjoyed lifting weights or doing sit-ups. Maybe I'll start tomorrow.

Probably not.

Step 4: Write *everything* down.

Write down your food consumption after every meal and snack, and your exercise time (or whichever exercise metric you choose) every day. That keeps you on track to achieve your goals.

The forms below can help. Completing them becomes another habit. It takes a minute or so. I expect to continue this for years since I plan to stay in the 185 pound weight range for a long time.

Writing down your food consumption each meal also makes you think twice about what you eat. It acts as a speed bump, forcing you to ask ‘Do I really want to use this many calories on this food?’ I found it a useful exercise.

Weight I weigh myself first thing every Sunday morning, always on the same scale. That’s my ‘official’ weight though I confess to checking more frequently. I worry, slightly, that daily weigh-ins will drive me crazy, or, more likely, my wife. I’m already obsessive enough!

Beware of salt and water retention at your weigh-ins. Eating a salty evening meal – feta cheese or pasta sauce for example – can increase my weight by 2 to 3 pounds the next morning. Factor this into your calculations and, perhaps more importantly, watch your daily salt consumption. Harder to do than say unfortunately.

Meals You can use the attached simple form to track your daily calories. You’ll see patterns emerge pretty quickly. Plus this will keep you from overeating in response to head-hunger. I’ve inserted a week of meals simply as an example. You can set up these forms very easily in Excel and design your own meals.

Date	Breakfast	Lunch	Dinner	Snack(s)	Total
Sun	Eng Muffin (100) Pnut butter (100) Banana (100) Almond butter (100) Total 400	Salad bag (50) Tomato (30) Chicken left overs (300) Italian dressing (75) Apple (100) Total 555	Turkey stew (ground turkey, pasta sauce and veg) (750) Salad and dressing (100) Pineapple (120) Total 970	3 Clementine (105) Yogurt & Ovaltine (100) Blueberry + honey (150) Total 355	2280
Mon	Oatmeal (170) 2 jumbo eggs (180) Ketchup (20) Total 370	Cauliflower left overs (75) Butter beans (150) Dressing (75) Chicken (150) Apple & cashew butr (190) Total 640	Salmon (300) Broccoli (100) Salad (50) & Dressing (75) Wine (100) 3 clementines (105) Total 730	Bana & Alm butr (100) Blueber & honey (150) Yogurt & ovaltine (200)	2190

Tues	Eng Muffin (100) Pnut butter (100) Banana (100) Almond butter (100) Total 400	Broad beans (200) Steamed veg (150) Dressing (75) 2 sm oranges (180) Total 605	Cod & panko (450) Salad & beans (200) Dressing (75) 1 slice bread (100) Total 825	Blueberries & Activia (220) Orange (100) Apple (100) Total 420	2250
Wed	Eng Muffin (100) Pnut butter (100) Banana (100) Almond butter (100) Total 400	Impossible burger (270) 2 x Bread (200) L & T, mustard, pickle (30) Apple (100) Total 600	Oatmeal (170) Cashews (320) 2 cups frozen fruit (140) Honey (70) Total 700	Baked apple & cinn (200) Yogurt & Ovaltine (200) Total 400	2100
Thurs	Eng Muffin (100) Pnut butter (100) Banana (100) Almond butter (100) Total 400	Tuna (90), mayo (50) 2 x Bread (200) Pickles, L & T (40) Skim milk & banana (200) Ovaltine (40) Total 640	Swordfish (400) Broccoli (200) Green beans (100) Dressing (75) Blueberries (85) Total 860	Apple (100) Orange (100) 2 x Clem (70) Total 270	2170
Fri	Oatmeal (170) 2 jumbo eggs (180) Ketchup (20) Tomato (30) Total 400	Broccoli (100) Green means (50) Swordfish (200) Dressing (50) Pear & orange (200) Total 600	Baked feta (300) Tomatoes, onions (50) Broccoli (100) Potato (200) Wine (100) Total 750	Blueberries & honey (180) Yogurt & Oval (200) Clem (100) Total 480	2230
Sat	Oatmeal (170) Swiss cheese (100) 1 egg (90) Ketchup (20) Total 380	Tuna (90), mayo (50) Eng muffin (100) Pickles, L & T (40) Skim milk & banana (200) Ovaltine (40), Apple (100)	Beans (200) Rice (200) 1/3 cup cashews (250) Salad and dressing (150) Blueberries (100)	Baked apple & cinn (200) Yogurt & Oval (100) Orange (100) Total 400	2260

		Total 580	Total 900		

Exercise Use this form to track your daily exercise, total mileage or steps. If you track exercise minutes, focus on brisk walking minutes, the time your heart beats more quickly than normal so you can just barely keep a conversation going.

Exercise minutes per day, mileage or steps

	Sun	Mon	Tues	Wed	Thurs	Fri	Sat	Total
date								
date								
date								

Results and Lessons

This program worked for me. It may also work for you. No promises but I hope so.

If you decide to try, give it an honest effort. Stick with it for at least 6 months, long enough to develop new food habits.

You'll likely be pleased with the results.

Below, a sample of my own experience over 3 months, enough to make the point.

Weekly Food Consumption, Exercise and Weight Change
4th quarter, 2020

Week Ending Date	Average Calories Consumed per Day	Total Minutes Walked per Week	Sunday Morning Weight	Weight change, pounds, rounded
Oct 4	2120	465	207	
Oct 11	2020	535	206	-1
Oct 18	2230	465	204	-2
Oct 25	2110	550	203	-1
Nov 1	2300	360	202	-1
Nov 8	2019	475	201	-1

Nov 15	2087	455	200	-1
Nov 22	2657 (Thanksgiving)	580	198	-2
Nov 29	2069	540	199	+1
Dec 6	2157	320	196	-3
Dec 13	2452	485	195	-1
Dec 20	1999	340	197	+2
Dec 27	2400	410	196	-1
Jan 3, 2021	2332	600	195	-1
Averages over 14 weeks	2210	470		-.9 **lb. per week**

Plan Design Overview and Issues

Let's start with an analogy.

Clayton Christensen, a professor at Harvard Business School best known for studying business innovation - and particularly disruptive innovation - wrote an insightful article about the US educational system in the May 11, 2014 Boston Globe.[132] As you read some highlights from that article, consider the analogy to our healthcare system.

- *Tuition costs have been ballooning faster than general inflation…and what do we get in return?*
- *Nearly half of all bachelor's degree holders do not find employment or are underemployed upon graduation. At the same time, employers have not been satisfied with degree candidates.*
- *Two recent Gallup polls showed that although 96% of chief academic officers believe they're doing a good job of preparing students for employment, only 11 percent of business leaders agree that graduates have the requisite skills for success in the workforce.*
- *And this is all occurring while higher education leaders were convinced that they were innovating all along.*

Now let's substitute 'healthcare' for 'education' and rewrite:

- *Premiums have been ballooning faster than general inflation…and what do we get in return?*
- *Lower life expectancies, higher infant mortality and poorer access than other countries.*
- *At the same time, employers have not been satisfied with broker services.*
- *A recent poll showed that although most brokers believe they're doing a good job of developing benefit strategies and communications, only about half of business leaders agree that brokers do a good job implementing and executing desired programs.*
- *And this is all occurring while brokers are convinced that they were innovating all along.*

[132] Clayton Christensen et al, Thank You MOOCS, Boston Glove, May 11, 2014

The poll in question was Zywave's 2013 study of customer satisfaction with broker services that received 5500 responses. Some highlights: [133]

- Creates strategic plan that aligns with company goals: **43% unsatisfied**
- Offers employee benefits and consumerism communication / education: **41% unsatisfied**
- Assists with creating or maintaining a workplace wellness program: **66% unsatisfied**

Part of the problem comes from our employer based health insurance distribution system. We are the only major advanced, industrialized country that uses employer based health insurance as the primary mechanism of financing healthcare. Other countries use employer based coverage – if they allow it at all – to supplement the national health insurance system.

We, in the US, use public programs like Medicaid and Medicare to supplement employer based coverage, exactly the reverse of everyone else. If you can get health coverage through your employer, you (generally) cannot get public coverage. How does employer based primacy impact our overall healthcare system?

Princeton economic professor Uwe Reinhardt answered that question in his New York Times piece 'The Culprit Behind High US Health Costs' in 2013. [134] Here are some direct quotes:

- *Most health-policy analysts I know regret that employers appointed themselves their employees' agents in the markets for health insurance and health care*
- [Employers are] *the sloppiest purchasers of health care anywhere in the world. For more than half a century, employers have passively paid just about every health care bill that has been put before them, with few questions asked.*
- *One reason for the employers' passivity in paying health care bills may be that they know, or should know, that the fringe benefits they purchase for their employees ultimately come out of the employees' total pay package.*
- *In a sense, employers behave like pickpockets who take from their employees' wallets and with the money lifted purchase goodies for their employees*
- *[Carriers] are merely the conduits for the employers' wishes.*

[133] This study was summarized at the Massachusetts Association of Health Underwriters annual 'Benefest' in a presentation by Sarah Lucas of Marshberry entitled 'Trends and Best Practices in Employee Benefits Agencies'.

[134] Uwe Reinhardt, The Culprit Behind High US Health Costs, NY Times, June 7, 2013

- *When agents perform poorly, one should look first for the root cause at the principals' instructions.*
- *a decade of health care cost growth under employment-based health insurance has wiped out the real income gains for an average family with employment-based health insurance.*

Reinhardt then provided his data. In 2013, for an average family of 4, employer based health insurance cost $22,000, up $10,000 since 2003, compared to median family income of $55,000. He then suggests

- *One must wonder how any employer as agent for employees can take pride in that outcome*

I would extend that query to brokers, echoing the Christensen and Zywave points above.

Over time we developed more and more 'fill in' programs to cover people excluded from the employer based system – old people, unemployed people, veterans, children and others. Combining and coordinating these various programs leads to confusion, inefficiencies and costs.

One confusing consequence of employer based primacy and myriad fill in / supplementary programs, for example, is that our system treats people differently based on non-health factors, like who they are or where they work. Unlike other advanced countries, we have different systems and rules for

- Full time employed people
- Part time or low income people
- Very poor people, provided they are also either **i** children, **ii** blind or disabled, **iii** elderly, **iv** mentally ill, **v** pregnant women or **vi** mothers (if they don't fit into one of these six categories, they are treated like 'part time or low income people'. Understand?)
- People over 65 years old
- Young people who don't otherwise qualify for health insurance
- Military veterans provided their medical problems are 'combat related' and
- People with kidney disease, among others.

As you move from group to group – in other words, as your economic conditions change (generally) - you face different medical access rules, different financing rules and tons of paperwork. This does nothing to improve health and adds no efficiencies to our system.

We, in other words, base our healthcare financing and access systems on non-health related categories of people. Since the groupings are arbitrary, much more a function of interest group lobbying than healthcare distribution efficiency, compliance becomes extraordinarily difficult: compliance experts can't apply logic or reason to regulations. Instead, they must memorize or continuously consult the regs. This makes absolutely no medical or economic sense except, perhaps, to the favored business interest groups.

It only adds overhead, inefficiencies and costs to the system.

Complexity and confusion add costs more in the US than in other countries

Consider the relative inflation rates in the US and some other advanced countries. Inflation, of course, is driven by many factors, only one of which is systemic complexity. But it's difficult to design rational, cost-cutting, efficiency-promoting reform on top of an inefficient, irrational structure.

I use 2003 as my comparison basis because that was the year we introduced tax advantaged deductibles, designed to reduce unnecessary utilization and costs. Policy makers in the W. Bush administration figured that if patients pay with their own money they'll be more frugal and less wasteful. That was a big change from the traditional first-dollar-coverage in managed care that many saw as promoting unnecessary care.

	2003 healthcare spending	
US	$3788 per capita	
Canada	$2054 per capita	US spends 1.84x as much
United Kingdom	$1344 per capita	US spends 2.82x as much
France	$2093 per capita	US spends 1.81x as much
Germany	$2943 per capita	US spends 1.29x as much

	2011 healthcare spending	
US	$8508 per capita	
Canada	$4522 per capita	US spends 1.88x as much
United Kingdom	$3405 per capita	US spends 2.50x as much
France	$4118 per capita	US spends 2.07x as much
Germany	$4495 per capita	US spends 1.89x as much

From passage of the Medicare Modernization Act in 2003 at least under passage of the Affordable Care Act in 2010, our relative healthcare spending position has worsened vis-à-vis other countries. We not only spend *more* than these countries but, on average over time, we spend *more* more.

An underlying problem, at least from the broker or 'benefits advisor' perspective is that the enormous complexity of our healthcare system leads brokers to become expert at compliance, not at healthcare or healthcare systemic efficiency. In fact, 'health' insurance brokers today need understand nothing about 'health', only about compliance, to have successful, financially lucrative careers.

But compliance, as I suggested above in the discussion of Christensen and Reinhardt, does nothing to control costs or improve systemic value. Benefits advisors who *only* advise about compliance provide far less value to their clients than they could.

This was made poignantly clear to me one day in a lecture. I asked an experienced broker why she attended, as her agency normally didn't contract with me. Her response:

> *I sell CDH plans, understand HSAs, HRAs, deductibles, FSAs, networks and all the rest.*
>
> *But I recently switched employer, and I now have a high deductible plan…*
>
> *And **I** don't know how to use it!*

Consumer engagement to the rescue … or not

My somewhat depressing response to her comment: if the pros don't know how to navigate our healthcare system for themselves – don't know which services to use, which are wasteful and harmful – how much can they help their clients? Too often, their compliance advice only helps their clients access unnecessary, inappropriate or wasteful services, with up to some 40 or 50% of all healthcare spending going to services that do nothing to promote health.[135] The compliance focus only promotes easier access to care, much of which is unnecessary.

Brokers, and far too often also their clients, lack the tools to differentiate necessary from unnecessary interventions. That's the real impact of the broker comments quoted above.

Indeed, today's 'consumer engagement' emphasis falls into the same quagmire as the rest of our system. 'Consumer engagement' to health insurance brokers means knowing deductibles, plan design details, tax implications and the like. Knowing these things does not decrease costs, waste, unnecessary care or improve patient outcomes.

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[135] Several scholars at Dartmouth Medical School, notably Elliott Fisher and John Wennberg, have written extensively about this. Shannon Brownlee's excellent Overtreated provides plenty of detail. I'll belabor this point myself later in this book. The 'up to 50%' estimate is mine, not theirs.

But better outcomes are (almost) always cheaper than poorer outcomes!

Healthier people cost our healthcare system less, and the more efficiently our system turns people from *un*healthy to healthy, the less we spend on them. Poorer outcomes – infections, returns to operating tables, ineffective medications, high false positive test rates etc – always cost more. (Yes, I know that MRI costs vary significantly. But no one wants the cheapest unnecessary MRI.)

That's why the medical community, as opposed to the brokerage community, defines consumer engagement as knowing ***how well*** medical care works, not how to access it financially or where to get the cheapest. The well informed consumer, to the medical community, knows about the 'health' part of health insurance.

Note the discrepancy between the insurance and medical definitions. The insurance definition does nothing to improve outcomes or reduce waste and thus can't have much cost control impact.

But the medical definition directly attacks waste and improves outcomes so ***can*** significantly reduce costs. In fact scholars like Dr. Michael Barry of the Informed Medical Decisions Foundation and Dr. Albert Mulley of Dartmouth Medical School, suggest that well informed (medical definition) patients cost roughly 20% less than poorly informed patients. Much more on this coming up.

Unfortunately, our medical consumer engagement process falls trap to yet *another* definitional problem. Here's Dr. Suzanne Koven, summarizing it in the Boston Globe: [136]

- I appreciate patients informing and advocating for themselves
- I don't appreciate patients arguing with me about anatomy and physiology

In the 10 or so minutes patients typically spend with doctors, they can either question their doctor's competence ('arguing about anatomy and physiology') or discuss treatment options. They probably don't have time to do both.

And they'll probably lose the anatomy and physiology argument. Doctors know much more about medical care and technology than the typical patient ever will. Four years of medical school really do provide a solid technical foundation. Your doctor can out-fact you many times over. (Yes, your doctor may have misdiagnosed your problem. But that's best remedied by a second opinion, not an argument about physiology.)

You, however, know much more about your own treatment preferences than your doctor does. That's the real goal of consumer engagement: aligning treatment processes with patient preferences. That process – having doctors and patients explore treatment

[136] Suzanne Koven MD, Is physician burnout really a problem? Boston Globe, May 26, 2014

options to choose the best for each patient – can have a huge impact on utilization and costs. [137]

We have not, in this country, developed a standard definition of 'consumer engagement' or 'well informed patient' because, I suggest, of the 'mess' [138] that our system has become, largely due to the irrational employer based financing model upon which it rests. Compliance issues have become so overwhelming that brokers, and often their clients, simply don't have the time or energy to discuss more impactful issues.

As brokers struggle with compliance and plan designs, physicians with appropriate consumer information and advocacy, and the internet explodes with medical factoids and information, consumers get overwhelmed. Who gives them direction for their own research? What do they need to know? Which information is correct? Which is valid and appropriate?

Six faulty assumptions

Too often patients make assumptions and medical decisions that are, simply, wrong. I'll give some examples. How many of these resonate with you?

Faulty assumption #1: Good medical care leads to good health

Many people believe that good medical care leads to good health. As one thoughtful and articulate broker once said to me over an informal lunch, describing his young family, 'I have great healthcare for my kids. They're doing really well.'

Nonsense, I responded. 'Your kids are doing well because they're intellectually and emotionally within the normal range, have a mother and father who love them, live in a safe neighborhood, get plenty of good food and fresh air, have friends, and are warm in the winter and cool in the summer. The quality of their physicians and hospitals has virtually nothing to do with their health.'

Indeed, overwhelming evidence shows that good health comes from, in no particular order, good nutrition, exercise, emotional security, environment, public safety, socio-economic status *and* medical care, but that medical care is a relatively small component of good health.

How small a component? About 10%, according to the Massachusetts Health Policy Commission's 2013 cost trends report. Here are direct quotes from page 22:

[137] We'll discuss preference sensitive decision making in detail later in this book

[138] "Mess' comes from the title of Dr. Julius Richmond and Rashi Fein's 2005 book 'The Healthcare Mess'. Both authors were professors at Harvard Medical School.

- Massachusetts residents have better overall health than the United States average, with an additional 1.6 years of life expectancy and 0.9 fewer physically or mentally unhealthy days per month.

but

- Research shows that such outcomes are driven largely by social and behavioral factors, along with public health policies, while health care services delivered account for only 10 percent of general variation in health status.

Richmond and Fein, the two highly respected Harvard Medical School professors, echoed this in their 2005 book The Healthcare Mess: [139]

> Health gains since World War II were largely the consequence of progress in applying our knowledge of health promotion and disease prevention rather than improved clinical care.

Dr. William Frist, cardiologist and former US Senate Majority Leader, estimates medical care's impact slightly higher than the Massachusetts Health Policy folks, at 15 – 20%, saying

> Health is not health services. Health is behavior, it's genetics, it's socio-economic status, it's disparity, it's environment. Health services has about a 15 – 20% impact. [140]

We all know this but we forget it when we, ourselves, get sick or frightened. One reason, I submit, is that we have not been taught how best to use our medical care system. (Now *that's* an interesting value added role for brokers. Don't worry – I'll go into it in detail later.)

Here are some numbers to bolster my argument that 'more medical care isn't better for you'. Compare average medical spending per capita in various states with average longevity in those states. The assumption, of course: if more medical spending had a big impact, people who live in high spending states would live longer than people in low spending. That is not nearly the case.[141]

State	**$/capita 2009**	**Longevity at birth** 2013
Massachusetts	$9,278	80.5
Minnesota	$7,409	80.9

[139] Richmond and Fein, The Health Care Mess, pages 92 and 94

[140] CNBC Meeting of the Minds: The Future of Healthcare, broadcast in July 2009.

[141] Spending data from Kaiser Family Foundation. Longevity data from Measure of Americans. I used longevity data 4 years in the future to account for any potential health benefits of high 2009 spending.

Washington state	$6,782	79.9
Utah	$5,031	80.2
Mississippi	$6,571	75.0
Oklahoma	$6,532	75.9
West Virginia	$7,667	75.4

Good medical care doesn't necessarily lead to good health. Lots of other things are far more important.

By the way, based on the state data presented above, should a broker provide the same benefits advice in Minnesota and West Virginia? Or Massachusetts and Utah?

Faulty assumption #2: Lower deductibles and wider networks = better health insurance

Brokers and consumers too often equate better health insurance policies with lower deductibles and wider provider networks. Poorer policies have the opposite.

Unfortunately, there's no evidence - none that I've seen, at least, and I've looked - that lower deductibles or wider networks lead to better patient outcomes.

One reason for the faulty equation of wider networks with better policies: we have very poor outcome data by provider in this country. Lacking such data, consumers apparently prefer easier access to lots of (potentially mediocre) physicians and hospitals, figuring that one of them should be good in a crisis I guess.

Though we lack evidence that lower deductibles and wider networks lead to better patient outcomes, we have some evidence that lower deductibles and generous benefits can lead to patient harm. Here's Bernard Rosof, Chairman of Huntington Hospital in New York:

> Often people with generous insurance plans can run up large bills and face life threatening complications from unnecessary care. [142]

We also have extensive evidence that *better decision making* leads to better outcomes.

Faulty assumption #3: Newer technologies and medications are better

This is almost a mantra in this country: newer technologies / newer meds / robotic surgeons etc are better, so, when in doubt, get the newest.

This overlooks the fact that 'newer' is a very poor proxy for 'better'. Extensive evidence shows that *outcome based decision making*, not the newest shinny object, leads to better outcomes.

[142] More care is not necessarily better care, Connolly, Washington Post, 9/29/09

Consider Pradaxa, a newer blood thinner than warfarin, heavily advertised on TV and designed to overcome warfarin patient's need for excessive testing. Pradaxa's annual sales hover around $800 million. Its TV ads claim

> *In a clinical trial, Pradaxa was proven superior to warfarin at reducing the risk of stroke in patients with Afib not caused by a heart valve problem*

suggesting to the poorly informed, who don't know the right questions to ask or how to make outcome based decisions, that the newer drug was better. However…

In their legal settlement announced in May of 2014, Pradaxa paid **$650 million** to settle **4,000 claims** that company didn't adequately warn of risks including severe or fatal bleeding. (If death is a side effect, what's the main effect?) Unlike warfarin, there is no known reversal agent or antidote for Pradaxa.

Or consider robotic surgeries for hysterectomy patients. The da Vinci robot, approved by the FDA in 2005, is designed to generate better results and an easier recovery that traditional laparoscopic surgery, meaning less pain and fewer complications [143] all of which sounds great to the uninformed.

But a massive study of 264,000 women who had either laparoscopic or robotically assisted hysterectomies at 441 hospitals between 2007 and 2010 showed no benefits from robotic surgery when benefits are measured as complication rates or blood transfusion rates. The robotic procedures, however, cost about $2000 more. That's roughly 1/3 more.

Again an interest group, the robot manufacturers, benefited by making more money, while patients did not, at least in terms of enjoying better outcomes. Just higher costs.

The morale of these stories, and there are many more: *newer* isn't necessarily better in medicine. *More heavily advertised* isn't necessarily better. Instead *better* is better, based on outcomes from comparative studies. Well informed patients learn the right questions to ask and types of information to consider when evaluating their treatment options.

Faulty assumption #4: Publishing price lists will save money

Today, almost as an article of faith, brokers, carriers and healthcare consumers claim that knowing prices will save money. This is commonly called 'transparency' and the theory runs rampant among health insurance thinkers.

While I agree that a wise consumer should compare prices of similar quality products, then choose the least expensive to get the best value, I *don't agree* that simply publishing price lists will lead to any benefit, either systemic or individual. Remember:

[143] Rabin, Questions about Robotic Hysterectomy, New York Times, Feb 25, 2013

- You don't want the cheapest *unnecessary* care
- You also don't want the cheapest *poor quality* care
- You don't want cheap *inappropriate* care when slightly more expensive care might be preferable.

Let's consider tonsillectomies in northern New England. Here are tonsillectomy rates per 1000 children in various pediatric service areas during the period 2007 – 2010.[144]

Middlebury, Vt	5.6	Burlington, Vt	2.9
Berlin, NH	10.4	Lewiston, Maine	5.2
York, Maine	7.3	Portland, Maine	4.0
Presque Isle, Maine	5.8	Bangor, Maine	2.7
Dover, NH	8.1	Waterville, Maine	3.6
Manchester, NH	8.1	Ellsworth, Maine	3.8
Exeter, NH	8.4		

We know from these data that having about 3 tonsillectomies per 1000 children is appropriate, since there are no reports of kids in Burlington Vermont, Bangor Maine, Waterville Maine or Ellsworth Maine suffering poor health due to an insufficient number of tonsillectomies.

We also know that about 2/3 of tonsillectomies in Berlin New Hampshire, and half the tonsillectomies in York Maine are unnecessary since their tonsillectomy rates are so high.

Shopping for the least expensive tonsillectomy in Berlin or York leads to a bad medical care decision over half the time: people doing that get the cheapest unnecessary care. Imagine that your child has a bad reaction or needs a surgical re-do from an unnecessary tonsillectomy!

A far better approach is to learn the service quality and necessity first, and then, for two equally necessary services of similar quality, choose the least expensive. Don't put the cart before the proverbial horse.

Perhaps a better way to understand transparency is to consider the many types necessary to enhance good medical decisions. A wise patient would want access to transparency data addressing:

[144] These data come from the Dartmouth Atlas of Healthcare, Tonsillectomies per 1000 Children by Pediatric Surgery Area, 2007 – 2010. 'Pediatric service areas' are the geographical regions served by a specific pediatrician office. Kids in Burlington Vermont, for example, typically use Burlington pediatricians, not Berlin New Hampshire docs.

- Prices
- Treatment intensity as, for example, our tonsillectomy example above, or C-section rates by hospital, mastectomy rates by region or similar
- Clinical quality/ infection rates by provider and by treatment
- Treatment benefits
- Provider conflicts of interest

Providing only 1 may distort the message and lead patients away from making wise decisions rather than toward systemic efficiencies.

Another way to express this: homeowners who hire the cheapest plumber, framer, roofer, electrician and painter end up with the most expensive house that leaks. We tend to forget this when we consider healthcare prices.

Faulty assumption #5: Getting the least expensive care saves money

This variation on 'publishing price lists will save money' ignores a key factor in physician compensation: that doctors want to maintain their incomes and that time is their main inventory. When they receive less money per patient, they respond by seeing more patients.

This has negative, foreseeable but generally unforeseen consequences.

Dr. Sandeep Jauhar MD, PhD, and director of the heart failure program at Long Island Jewish Hospital, claims that 'there is no more wasteful entity in medicine than a rushed doctor'. [145] Because we're so rushed, he says, 'we order tests, prescribe drugs, hospitalize patients and — one of the costliest decisions a doctor can make today — call specialists for help' rather than explain to patients why some tests are unnecessary and specialist referrals inappropriate. 'Specialists in turn,' he says, 'order more tests, scans and the like.'

Cutting payments to physicians becomes a self defeating strategy.

Faulty assumption #6: Raising deductibles saves money

Deductibles, generally running about $1000 per year, are designed to act as a speed bump when patients consider medical care. Patients will spend their own money more wisely and frugally than they would spend the insurance carrier's money, according to the theory, thus avoiding unnecessary care and saving money.

Deductibles, unfortunately, act as a blunt instrument, perhaps doing more harm than good by failing to differentiate necessary from unnecessary medical care. Reducing

[145] Sandeep Jauhar, Busy Doctors, Wasteful Spending, New York Times, July 20, 2014

unnecessary care can, indeed, save money. But reducing *necessary* care can lead to poorer outcomes and higher costs.

Consider, by contrast, the French approach to deductibles. The French modify or exempt from cost sharing by **person** (disabled, elderly or sick), **treatment** (expensive, effective or necessary) and **medical condition**. The deductible is waived for people suffering from one of 30 'long and costly diseases' like cancer, severe chronic disease or long term psychiatric illness *for medical care is related to that condition*. But these people are still responsible for unrelated medical deductibles, say a broken leg or sprained ankle.

Our 'one size fits all' deductibles, by not differentiating among people, treatments or medical conditions sometimes actually add to costs rather than reducing them. One Medicare study showed that adding a modest copayment reduced the number of outpatient visits by about 20% per year.

But that came at the cost of 2 additional hospitalizations per 100 patients per year. The study conclusion, published in the New England Journal of Medicine:

> uniform increases in cost sharing for prescription drugs can have deleterious effects on health [146]

without reducing costs at all.

These faulty assumptions – and the system developed from them – lead to these types of conclusions by eminent scholars:

- American health outcomes among insured populations lag substantially behind those of other countries.[147]
- Americans at top income levels live longer than people at bottom income levels, *but less long than people at top income levels of other countries* [148] and
- Even the people most likely to be healthy, like college-educated Americans and those with high incomes, fare worse on many health indicators …[149]

Despite us paying more for medical care than any other country in the world!

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[146] Trivedi 'Increased Ambulatory Care Copayments and Hospitalizations Among the Elderly, NEJM Jan 28, 2010

[147] Bradley and Taylor, The American Healthcare Paradox, page 9

[148] Gudrais 'Unequal America' Harvard Magazine July 2008 referring to research by Harvard Prof Majid Ezzati

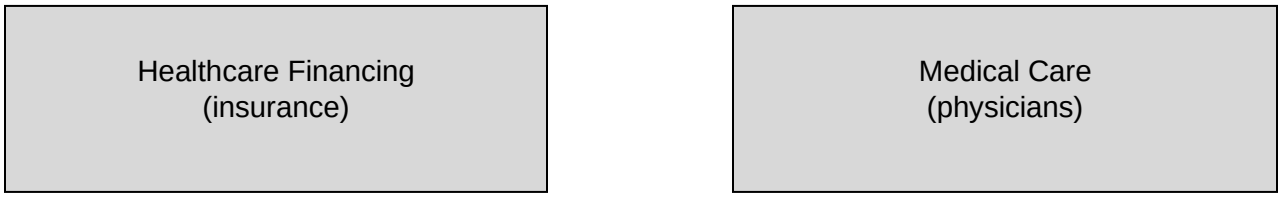
[149] For Americans Under 50, Stark Findings on Health, Tavernise, NY Times, Jan 9, 2013

The Fundamental Problem: Old School Thinking

Our systemic confusion and complexity has led to remarkable levels of specialization, not only in medical care but even in the brokerage community. Some brokers focus on Medicare, others on large group benefits, others on small group, some operate only in 1 state, others in many. Some agencies have wellness specialists, tax specialists and CDH specialists, others contract these functions out.

But few advise their clients about medical care issues, leaving that arena to physicians, often harried, often leading time compressed lives.

Our healthcare distribution system looks like is:



Two equally important but completely unrelated boxes. In the Old School, brokers provide financing programs while physicians provide medical care, but never the twain shall meet.

Brokers typically explain that they can't give medical advice because they're not trained or licensed to do this, which is, of course, true. **But I think they've conceptualized the problem incorrectly, relying more on superficial thinking than serious analysis.** Read on…

In the Old School 'nonintegrated' model, we expect physicians to address the following issues during an average 15 minute meeting with each patient:

- Patient's personal health status
- Disease diagnosis
- Treatment recommendations and alternatives
- Lifestyle issues and impacts on health
- Medication options, benefits and risks of each
- Individual risk factors and likelihood of future medical events
- Specific tests including benefits and risks of each
- Trends in medical care and new information since the patient's last visit
- Risks of having / not having specific tests or treatments
- Referral options *and more*

It's obviously very difficult to address all these issues satisfactorily in 2 hours, let along 15 minutes.

Five concerns about leaving all medical education to doctors

First, doctors respond to uninformed patient demand.

Studies show that about 1/3 of physicians would order a clinically unwarranted MRI if the patient demanded it, which raises patient risks without benefits since the MRIs in question are 'clinically unwarranted'. [150]

Many patients assume, as discussed above, that more medical care is better medical care, so a physician who doesn't prescribe a medication, test or treatment is a poorer physician.

Increasingly, physicians are compensated based on patient satisfaction survey results. Patients who believe 'more care is better care' penalize doctors who withhold painkillers, fail to prescribe a requested drug or test or skimp on referrals. This decreases the physicians' ability to counter the 'more is better' argument, even if they want to.

Studies show that, perhaps as a result of these factors, when faced with a potential screening test option, 95% of physicians recommended the screening test to their patients, and when faced with the option to prescribe medications, over 90% of physicians prescribed. [151]

Second, doctors respond to our legal / tort system, in which fear of malpractice lawsuits leads to excessive testing, Rx prescribing, excessive diagnoses and treatments. In one Gallup survey, physicians attributed 34 percent of overall healthcare costs to defensive medicine and 21 percent of their practice to be defensive in nature. Specifically, they estimated that 35 percent of diagnostic tests, 29 percent of lab tests, 19 percent of hospitalizations, 14 percent of prescriptions, and 8 percent of surgeries were performed to avoid lawsuits. [152]

Third, doctors get burned out so sometimes order tests, medications or treatments because it's easier than not ordering. One doctor described his interaction with a patient this way:

> *I could tell she wasn't happy. I decided that discussing the evidence would have been futile and I was too tired anyway*

Fourth, doctors pathologize or medicalize normal human behavior. Consider the patient who tells his doc 'I sometimes forget people's names in social settings.' Early stage dementia? (There's a drug for that). Social anxiety (There's a drug for that too.)

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[150] O'Reilly, Patient satisfaction: when a doctor's judgment risks a poor rating, AMED News, November 26, 2012

[151] Data from presentation by Benjamin Moulton at Dartmouth's 2014 Summer Institute for Informed Patient Choice

[152] Hettrich, The Costs of Defensive Medicine, AAOS Now, December, 2010. AAOS Now is the Journal of the American Association of Orthopedic Surgeons

Or a normal human reaction to noise and social stimulation? (There may even be a drug for that but it's probably not necessary.)

Or the patient who went to the beach last weekend and tells his doc 'I love watching the women parade around in their bikinis.' Diagnosis: hyper-sexual disorder.

But the next patient, who went to the same beach, reports that 'I completely ignored all the women parading around in their bikinis.' (Low-T and, of course, there's a pill for that)

Pathologizing, of course, ties closely to malpractice issues described above as well as the problem of uninformed demand.

Fifth, physicians favor interventions. This is sometimes called 'supply sensitive care' which simply means that if medical technologies or interventions are available, physicians will use them.

This is also sometimes called Roemer's Law after Professor Milton Roemer who first discovered the relationship between medical supply and utilization in the 1950s. Roemer found that as more hospital beds are built in a community, more hospital beds are used. His law: a hospital room built is a hospital room occupied because physicians, whether consciously or not, tend to use all the medical resources at hand.

Let's apply Roemer's Law to radiologic scanners. Consider the growth of scans since the mid 1990s as more and more machines became available.

Scans per 1000 people/year [153]

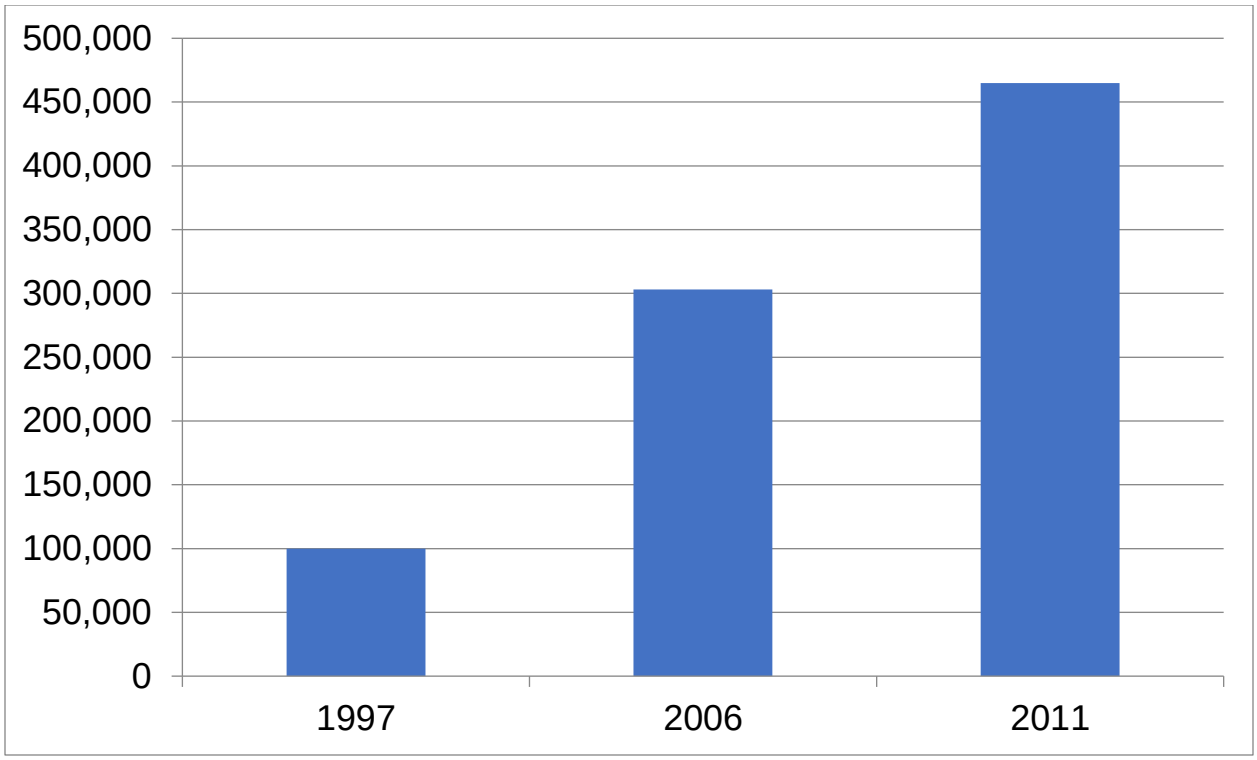
	MRI	CT
1996	52	17
2010	149	65

Note in passing the (non) impact of the internet on reducing medical care intensity. Google doesn't have much impact on reducing excessive or unnecessary care, despite most patients today claiming that they're 'well informed' since they do online research before engaging in medical care. Sorry, I don't buy it.

Now look at the impact of graduating more orthopedic specialists from medical schools:

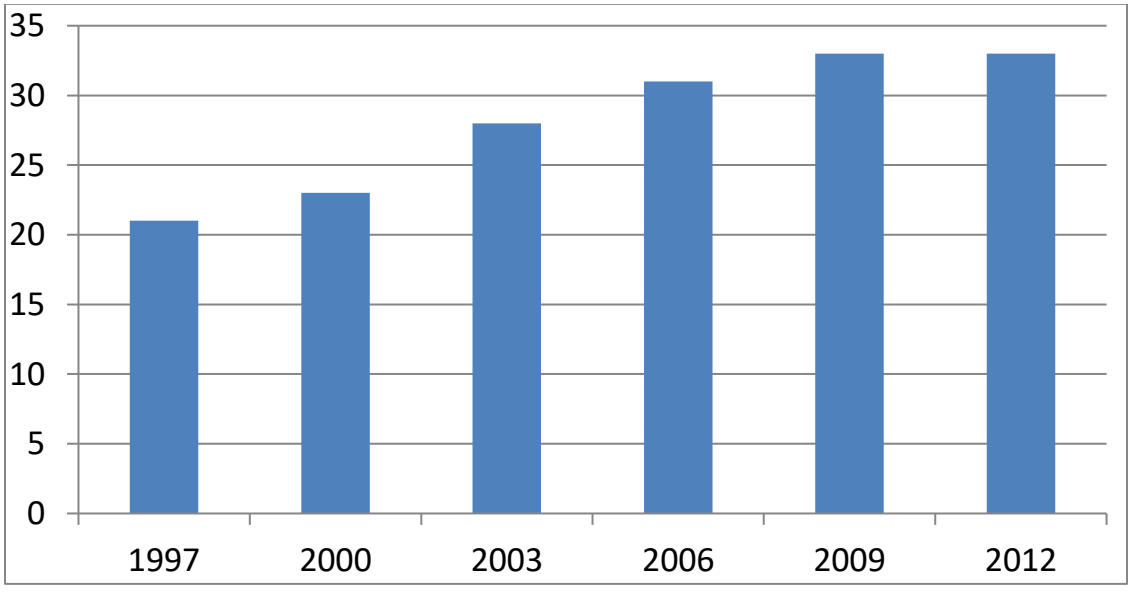
Number of Spinal Fusion Surgeries
performed annually in the US

[153] These data presented by Dr. Steven Woloshin at Dartmouth's Summer Institute for Informed Patient Choice, 2014



Since the mid-late 1990s, fetal oxygen sensors have become almost universally adopted in delivery rooms, despite the US Preventive Services Task Force not endorsing this technology in birthing. Fetal oxygen sensors identify stress on the fetus' heart and can lead to emergency C-sections. That's one of potentially many reasons for our increased rate of C-section deliveries since the mid-1990s.

Rate of C-sections
as percentage of all US births



Many more examples exist. But to summarize: Doctors face different financial, corporate and emotional pressures and incentives from the patients they advise. Here are some of those differences:

Physician Issues and Concerns	Patient Issues and Concerns
Success	Success
Fear of lawsuit	Pain
Fear of feeling guilty	Recovery process
Local / regional / hospital norms	Infection / readmission risk
Income and time constraints	Impact on family
Personal preferences (religion, experience, etc)	Personal preferences (religion, personal image, etc)

Asking ‘Doc, what would you do if you were me?’ tends to get answers from the Physician List, while patients worry about issues on the Patient List.

Doctors may also have different goals and risk tolerances from patients. Research suggests, for example, that 72% of oncologists advising early stage breast cancer patients rate ‘keeping your breast‘ a top goal while only 7% of patients do.

Meanwhile, 0% of oncologists rate ‘avoid using prostheses’ highly while 33% of patients do. [154]

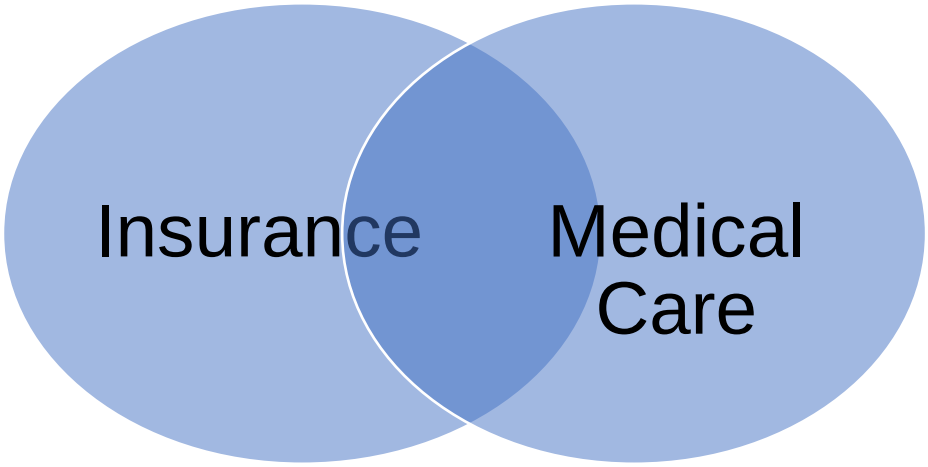
We have learned, over the past few decades, that leaving medical education entirely to physicians - even with a bit of online research - has led to healthcare inflation at approximately gdp + 3 to 5% with, unfortunately, poorer national statistics than other countries that spend less on medical care.

Splitting healthcare financing from healthcare delivery has been proven inefficient. It’s time to reconsider the Old School model.

New School: Integrating Finance and Care Delivery

Rather than continue with the ineffective Old School model, let’s introduce a New School approach.

[154] Data from presentation by Benjamin Moulton at Dartmouth’s 2014 Summer Institute for Informed Patient Choice



In the New School, financing and medical care overlap.

- Doctors understand networks, deductibles, plan designs and prices and *include them in treatment prescriptions.*
- Brokers understand medical terms, preference-sensitive decision making, outcome metrics, treatment intensity issues and *include them in plan designs*.

To do this, brokers need to understand and communicate 3 fundamental concepts to their subscribers:

- **Outcomes**, meaning how well does a medical intervention work. Brokers who help their clients focus on medical outcomes will help them avoid unnecessary medical care and choose higher quality care over lower.

  The best way to determine outcomes is from studies comparing patients who had a specific medical intervention with patients who did not. Other attempts to quantify outcomes are less robust, provide less good information and can lead to suboptimal medical decisions.

  We too often in this country, use proxies for outcomes. Proxies include ‘famous hospital’, ‘well known surgeon’, ‘well advertised medication’, or ‘game changing therapy’. Proxies may or may not correlate closely to actual patient outcomes.

  The important point for brokers to communicate to their clients: shop for medical care based on outcomes. They’ll enjoy better outcomes that way.

- **Process**, meaning *how* providers implement a particular treatment.

  Extensive evidence shows that some hospitals favor C-sections in situations that other hospitals do not, and that doctors in some regions routinely treat early stage breast cancer with mastectomies while doctors in others routinely prescribe other treatments. The Dartmouth Atlas of Healthcare has tracked these differences at hospital, regional and state levels for years.

One simple tool for brokers here: advise patients to ask their physician 'am I in a high or low intensity region / hospital for this procedure?' They can use that information when they obtain a second opinion.

- **Preference-sensitive**, meaning that two patients with similar diagnoses and prognoses may choose different treatments *and both be right*.

  This is, perhaps, the single most important issue in American medicine. Scholars ranging from Harvard Business School's Regina Herzlinger to Dartmouth's John Wennberg suggest that patients enjoy the best outcomes, often at the lowest costs, when they make well informed decisions. 'Well informed' means knowing the likely treatment outcomes (both benefits and risks), their process options (mastectomy or lumpectomy for example) and the prices.

  Laura Landro, writing in the Wall Street Journal, summarized the impact: [155]

  Studies show that when patients understand their choices and share in the decision making process with their doctors, they tend to choose less-invasive and less expensive treatments than they would otherwise have received.

The broker's educational role in this New School paradigm is to inform patients that they have choices and help them access key information to make wise choices; it is **not** to give specific medical advice.

My Proposed Decision Making Tree
that integrates clinical and insurance information

Brokers and benefits advisors can teach people to use this Decision Tree. It can organize your thinking and ensure that you address the key issues in making your medical decisions.

First identify the most likely benefits and risks of a particular medical intervention and the chance of each. Ask 'do the likely benefits of this medical intervention outweigh both the treatment risks and doing nothing?'

I you answer 'no, the likely benefits do not exceed the risks and are not better than doing nothing' then stop.

But if you decide that the likely benefits exceed the risks, continue.

Second identify your intervention options. You almost always have them. You can have surgery or physical therapy for example, take a brand name medication or generic, have an injection or take a medication, change your diet or take a pill.

[155] Laura Landro, Weighty Choices in Patient's Hands, Wall Street Journal, August 4, 2009

Decide which process you prefer. Research shows that different processes often generate similar outcomes. There's often no objectively right or wrong process decision. Rather these are personal choices or preference-sensitive decisions.

Third decide which provider generates the best outcomes using the treatment process you prefer. Some orthopedic surgeons may generate better spinal fusion surgical outcomes than others; some physical therapists better knee pain reductions.

Provider outcomes often – though not always – correlate with experience. The more shoulder surgeries a surgeon performs, the better his/her shoulder surgery patients tend to do.

If you can't determine actual outcomes by physician, use volume or experience with patients like you as a responsible proxy. Though not perfect, it can lead you in a positive direction.

Fourth, if two providers generate the same outcomes using the process you prefer, consider price.

Be sure to consider price 4th, only after you've determined that an intervention is likely beneficial, that you're getting the process you prefer and that you've chosen the best provider available.

Follow this 4-step process and you'll likely end up with better outcomes, be more satisfied with your care and perhaps even save some money along the way.

America's research community is developing tools to help patients with these tasks.

The Affordable Care Act on Decision Aids and Shared Decision Making

Section 3506 of the Affordable Care Act or Obamacare addresses Decision Aids and the Shared Decision Making process. The goal is to engage patients in *informed* decision making with healthcare providers.

Decision Aids are **tools** that present clinical evidence of risks and benefits of treatment options; they focus on likely outcomes. Decision Aids are not simply articles describing how a medical treatment works but without quantifying likely benefits and harms; that's an encyclopedia, not an Aid.

Shared Decision Making, on the other hand, is a **process** in which patients and their physicians decide together how to proceed. Unlike the old school paternalist model in which physicians *tell* patients which treatment to have, in the Shared Decision Making model physicians *help patients decide* which treatment option best suits their goals.

Shared Decision Making acknowledges that about 85% of medical decisions are 'preference sensitive', meaning the patient has more than 1 reasonable option and that two different patients suffering from the same medical condition can make different treatment decisions but both be right.

This may seem intuitively obvious to many. Unfortunately, research shows that physicians only discuss alternatives with patients about 14% of the time, and only about 9% of physicians inform patients that they have choices. [156] As a result, the impetus to inform patients that options exist most of the time may fall on the insurance community.

Decision Aids and Shared Decision Making also implicitly acknowledge a new vision of the physician's role. The ideal modern physician, suggests Dr. Atul Gawande of Harvard Medical School insightfully

> should be neither paternalistic nor informative but rather interpretive, helping patients determine their priorities and achieve them. [157]

This means patients need to learn basic outcome and intensity information outside the doctor-patient framework and opens a new, and potentially role redefining opportunity for brokers and carriers.

A Decision Aid Example

Decision Aids, currently under development at several medical schools and institutions, provide outcome data quantifying risks and benefits of medical interventions.

Consider the Number Needed to Treat. This tells how many people need to take a medication, have a test or have a treatment for 1 person to benefit from it.

The NNT acknowledges that medicine doesn't work perfectly, equally well on all people, all the time. But various interventions work - to paraphrase Abraham Lincoln - on some of the people, some of the time. The NNT tells how often, so how likely you are to benefit from a particular intervention.

The most comprehensive source of NNT information is a website entitled, not surprisingly, TheNNT.com.

Here's an example: 18 adults suffering from acute sinusitis need to take a course of antibiotics for 1 to benefit by having a faster resolution of symptoms. [158] The Number Needed to Treat for adults with sinusitis to benefit from antibiotics is 18.

Another example: 5 kids suffering from the croup need to take steroids for 1 to enjoy respiratory improvement. The NNT here is 5.

Some more NNT examples [159]

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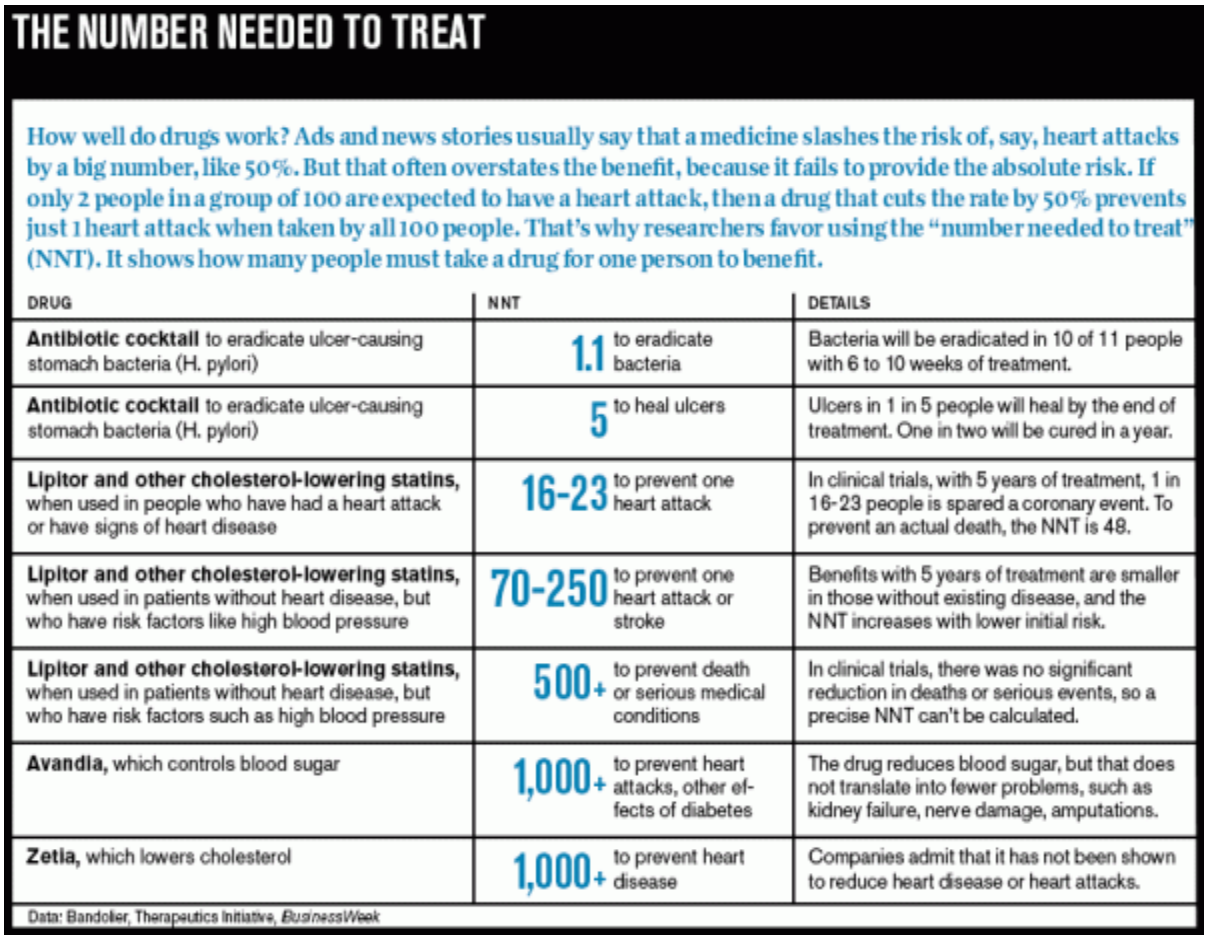
[156] Benjamin Moulton, op. cit.

[157] Sheri Fink's review of Atul Gawande's Being Mortal, New York Times Book Review, November 6, 2014

[158] http://www.thennt.com/nnt/antibiotics-for-clinically-diagnosed-acute-sinusitis/

[159] This chart appeared in BusinessWeek, January 2008.



THE NUMBER NEEDED TO TREAT

How well do drugs work? Ads and news stories usually say that a medicine slashes the risk of, say, heart attacks by a big number, like 50%. But that often overstates the benefit, because it fails to provide the absolute risk. If only 2 people in a group of 100 are expected to have a heart attack, then a drug that cuts the rate by 50% prevents just 1 heart attack when taken by all 100 people. That's why researchers favor using the "number needed to treat" (NNT). It shows how many people must take a drug for one person to benefit.

DRUG	NNT	DETAILS
Antibiotic cocktail to eradicate ulcer-causing stomach bacteria (H. pylori)	1.1 to eradicate bacteria	Bacteria will be eradicated in 10 of 11 people with 6 to 10 weeks of treatment.
Antibiotic cocktail to eradicate ulcer-causing stomach bacteria (H. pylori)	5 to heal ulcers	Ulcers in 1 in 5 people will heal by the end of treatment. One in two will be cured in a year.
Lipitor and other cholesterol-lowering statins, when used in people who have had a heart attack or have signs of heart disease	16-23 to prevent one heart attack	In clinical trials, with 5 years of treatment, 1 in 16-23 people is spared a coronary event. To prevent an actual death, the NNT is 48.
Lipitor and other cholesterol-lowering statins, when used in patients without heart disease, but who have risk factors like high blood pressure	70-250 to prevent one heart attack or stroke	Benefits with 5 years of treatment are smaller in those without existing disease, and the NNT increases with lower initial risk.
Lipitor and other cholesterol-lowering statins, when used in patients without heart disease, but who have risk factors such as high blood pressure	500+ to prevent death or serious medical conditions	In clinical trials, there was no significant reduction in deaths or serious events, so a precise NNT can't be calculated.
Avandia, which controls blood sugar	1,000+ to prevent heart attacks, other effects of diabetes	The drug reduces blood sugar, but that does not translate into fewer problems, such as kidney failure, nerve damage, amputations.
Zetia, which lowers cholesterol	1,000+ to prevent heart disease	Companies admit that it has not been shown to reduce heart disease or heart attacks.

Data: Bandolier, Therapeutics Initiative, *BusinessWeek*

Knowing the NNT can help patients in two different ways:

- First, patients can decide if a medical intervention works well enough to have. An NNT of 300, for example, make work so poorly – in your opinion – that it's not worth having.

  But an NNT of 2 works so well that you may decide to have this treatment.

- Second, the NNT helps patients decide which intervention works better. The lower the Number Needed to Treat, the better the medication intervention works.

How to determine the Number Needed to Treat

Researchers compare two similar groups of people, as alike as possible, except that one group gets the medication while the other does not. This comparison study identifies the medication as the independent variable. Researchers then note the outcomes from both groups and quantify the medication's impact.

That helps explain why the NNT numbers above seem so high: most adults recover from sinusitis and most kids recover from croup even without medication.

TheNNT.com lists dozens of medical interventions.

A second type of Decision Aid

ChoosingWisely, an initiative of the American Board of Internal Medicine Foundation, invited dozens of specialty medical associations to list *5 Things Patients and Doctors Should Question*. The ABIM Foundation then posted these lists on a website called ChoosingWisely.

Here are 3 examples from the hundreds listed:

- *Don't do imaging for low back pain within the first six weeks, unless red flags are present*, a recommendation of the American Academy of Family Physicians.

  The Family Physician Academy's justification: Imaging of the lower spine before six weeks does not improve outcomes

- *Don't indiscriminately prescribe antibiotics for uncomplicated rhinosinusitis*, a recommendation of the American Academy of Allergy, Asthma & Immunology.

  The Allergy, Asthma & Immunology Academy's justification: Viral infections cause the majority of acute rhinosinusitis and only 0.5 percent to 2 percent progress to bacterial infections.

  Most acute rhinosinusitis resolves without treatment in two weeks.

- *Don't perform annual stress cardiac imaging as part of routine follow-up in asymptomatic patients*, a recommendation of the American College of Cardiology.

  The College's justification: Performing stress cardiac imaging or advanced non-invasive imaging in patients without symptoms on a serial or scheduled pattern (e.g., every one to two years or at a heart procedure anniversary) rarely results in any meaningful change in patient management. This practice may, in fact, lead to unnecessary invasive procedures.

As of January, 2015, some 63 medical associations participated in the ChoosingWisely campaign, posting more than 300 treatment recommendations.

Other Decision Aids exist and are being developed all the time.

Decision Aids help focus doctor-patient discussions. No longer need patients argue about anatomy and physiology. Instead, doctors and patients can interpret Decision Aids together and discuss treatment outcomes and processes – far more fruitful discussions.

Decision Aids: necessary for Shared Decision Making

The Decision Aids listed above – and others - are a necessary step toward true patient involvement in medical decisions. 'Involvement' is sometimes called 'Shared Decision Making' in which patients and doctors together decide how to proceed.

Decision Aids are tools; Shared Decision Making is a process. Both work together.

How impactful are Decision Aids and Shared Decision Making?

Research presented at the Dartmouth Summer Institute for Informed Patient Choice, Hanover New Hampshire, June 2014 shows the following:

- Patients with stable coronary angina who used Decision Aids and engaged in Shared Decision Making with their physicians, were 20% less likely to choose stent insertion than patient who did not so engage
    - Absent Decision Aids, 88% of patients thought stents would help them
- Patients suffering from hip or knee arthritis were 25% less likely to choose hip or knee replacement after viewing Decision Aids
- Back pain patients with herniated disks opted for spinal fusion surgery30% less frequently
- Men diagnosed with early stage prostate cancer were 50% more likely to choose 'watchful waiting' than more invasive treatments.

Using Deductibles and HRAs with Decision Aids

The broker can now evolve from CHD version 1, deductibles with some tax benefits, to CDH version 2, deductibles that can incorporate consumer education into a true employee engagement / benefits program.

To move successfully from CDH 1 to CDH 2, brokers need to incorporate three components into their programs:

- Content
- An employee communication program, and
- Plan design incentives

Let's brainstorm, first with a radiology education program:

Consumer Engagement Example: Radiology

Incentive: $25 per employee to complete the following educational module. Then, $50 toward the out-of-pocket costs if an employee decides to have a back MRI.

Module content: Low back pain is the fifth most common reason for physician visits. This brief tutorial can help you *benefit* from your physician visit and *avoid unnecessary costs and medical harms.*

Medical research shows that getting an X-ray, CT scan or MRI shortly after the pain begins rarely helps since most people feel better in a month or so with or without the scans.

But imaging raises costs and risks of unnecessary care:

- Lower back MRIs cost about $1000
- CT scans about $1200
- X Rays about $250

One study found that back-pain sufferers who had an MRI in the first month were *eight times more likely* to have surgery, and had a *five-fold* increase in medical expenses—but didn't recover faster.

The excess imaging problem is that people both with and without back pain can show similar imaging results, meaning an identified abnormality in the test may not be the cause of your pain.

Once identified however, abnormalities need further evaluation. This can subject patients to costs and treatments which are often unnecessary since they don't speed recovery.

Review Questions:

1. How common are visits to the doctor due to back pain?
    - Uncommon
    - Very common. Back pain is the 5th most common reason for physician visits
2. If you have back pain, should you automatically, immediately get an imaging exam, like an MRI, CT scan or X-ray?
    - Yes, as soon as you feel any kind of back pain
    - Maybe not, since people who have imaging tests don't seem to get better medical results than people who wait before having the test
3. About how much does a lower back MRI cost?
    - About $20, my radiology co-payment,
    - About $1000 on average

Content continues: Some medical organizations recommend *against* imaging tests for back pain within the first month.

The American Academy of Family Physicians, representing 105,000 primary care physicians advises:

- Don't do imaging for low back pain within the first six weeks, unless red flags are present.

- Imaging of the lower spine before six weeks does not improve outcomes, but does increase costs.

The North American Spine Society, representing 7500 doctors, advises:

- Don't have advanced imaging (e.g., MRI) of the spine within the first six weeks for non-specific acute low back pain in the absence of red flags.
- In the absence of red flags, advanced imaging within the first six weeks has not been found to improve outcomes, but does increase costs.

The American College of Physicians, representing 126,000 physicians, advises:

- Don't obtain imaging studies in patients with non-specific low back pain.
- In patients with back pain that cannot be attributed to a specific disease or spinal abnormality, imaging with X-ray, CT scan or MRI does not improve patient outcomes.

The American Society of Anesthesiologists – Pain Medicine, representing 50,000 members who advocate for patients in pain, advises:

- Imaging for low back pain in the first six weeks after pain begins should be avoided in the absence of specific clinical indications
- Most low back pain does not need imaging and *doing so may reveal incidental findings that divert attention and increase the risk of having unhelpful surgery*.

Review Questions:

1. Do many medical professional organizations recommend that you wait 4 – 6 weeks before having a back imaging test, or have the test immediately upon feeling pain?
    - Wait 4 – 6 weeks unless specific red flags are present
    - Have the test immediately
2. Why do several medical professional organizations recommend waiting 4 – 6 weeks before having an imaging test?
    - To reduce patient costs and risks
    - To harm patients

Here are some Red Flags:

- a history of cancer or unexplained weight loss,
- fever or recent infection ,
- loss of bowel or bladder control,

- abnormal reflexes or loss of muscle power or feeling in the legs.

And here are some Key Questions to ask your doctor:

- Do you agree with the recommendations from the American Academy of Family Physicians and others that I wait 6 weeks before having a scan for my back pain?
  - If not, why not?
  - Do you think those recommendations apply to me?
- Do you worry that back imaging tests may incorrectly identify the cause of my back pain?
- Do I have the red flags listed above?
- And What other therapies do you recommend?

Many more Decision Aids and Educational Modules exist

Research organizations are continuously developing Decision Aids about the major healthcare cost drivers. A short research project will identify some of these for you. That's the easy part.

The hard part is integrating the clinical information with insurance plan designs. Though difficult, it's necessary if brokers want to change the Zywave reported client satisfaction numbers:

- Creates strategic plan that aligns with company goals: **43% unsatisfied**
- Offers employee benefits and consumerism communication / education: **41% unsatisfied**
- Assists with creating or maintaining a workplace wellness program: **66% unsatisfied**

Brokers face a dilemma: whether to remain in their comfort zone which we call CDH version 1, providing spreadsheets, products and compliance services or move to CDH version 2 that integrates financial and clinical considerations into plan designs.

I encourage anyone who has read this chapter to consider: If you were a client, would you prefer a broker who engaged in traditional insurance brokerage or who integrated clinical education into plan designs?

I'd also encourage people to consider their own history: Are you satisfied with health insurance trend and utilization rates?

I suggest that if you consider these two questions, your path forward becomes clear.

Robert Frost articulated the options poetically:

Two roads diverged in a wood and I –

I took the one less traveled by,

And that made all the difference

Review Questions

Answers on next page

1. One consequence of having employer based health insurance as the central mechanism of financing medical care in this country is the development of various 'fill in' programs for non-employed people. Examples include Medicare for elderly people and the Veteran's Healthcare Administration for military veterans, each with its own eligibility requirements, access criteria and payment programs. About how many such major programs exist in the US?

a. 1
b. About 6
c. About 295
d. About 13,500

2. We have two different definitions of 'well informed consumer'. The health insurance industry defines a well informed consumer as one understanding deductibles, network restrictions, referral requirements and similar. How does the medical industry define well informed consumer?

a. The same way, someone who understands deductibles, network restrictions and referral requirements
b. As someone who understands how well medical care works
c. As someone who has read lots of books about medical care
d. As someone who uses google to research their treatments

3. Can we usefully separate healthcare *financing* from healthcare *service* provision?

a. Yes. A professional broker, for example, only need describe the insurance policy to provide a complete service to his/her customers
b. No. We cannot usefully separate healthcare financing from service delivery. Every attempt to do that has resulted in higher costs and poorer outcomes
c. Sometimes. We can usefully separate financing from service deliveries for orthopedic conditions but not for cardiovascular
d. Sometimes. We can usefully separate financing from service deliveries for acute conditions but not for chronic

4. What is the best way to determine a medical care outcome?

a. From a comparative test, one that compares a group of people who had a specific medical intervention with a similar group that did not
b. By reviewing the relevant biological information
c. By reviewing the relevant anatomical information
d. By reviewing the relevant genetic information

5. What does 'preference sensitive' mean in medical care?

a. That one patient may prefer one treatment process while another, similar patient may prefer something different and that both patients can make the right decisions
b. That some people prefer one physician while others prefer someone else
c. That some physicians prefer one type of patient while other physicians prefer a different type
d. That some patients may prefer one hospital while others prefer a different hospital

6. What is the Number Needed to Treat?

a. The number of patients who need to have a treatment for one to benefit
b. The number of doctors who need to perform a surgery for 1 to get it right
c. The number of patients a doctor needs to treat in order to have one patient benefit from his/her care
d. The number of surgeries a hospital needs to host to get optimal outcomes

7. What are Decision Aids?

a. Decision Aids are tools that present clinical evidence of risks and benefits of treatment options; they focus on likely outcomes.
b. Techniques that can aid a physician who needs to make an important decision
c. Surgical tools to help hospital residents make better use of their time
d. Computer programs that determine the optimal treatment protocol for a specific patient

8. Which, below, is NOT a credible decision aid?

a. TheNNT
b. ChoosingWisely
c. The US Preventive Services Task Force
d. Brochures developed by Pfizer, the manufacturer of Lipitor, that explain the benefits of taking statins

Review Questions

Correct answers in bold

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c. About 295
d. About 13,500

2. We have two different definitions of 'well informed consumer'. The health insurance industry defines a well informed consumer as one understanding deductibles, network restrictions, referral requirements and similar. How does the medical industry define well informed consumer?

a. The same way, someone who understands deductibles, network restrictions and referral requirements
b. As someone who understands how well medical care works
c. As someone who has read lots of books about medical care
d. As someone who uses google to research their treatments

3. Can we usefully separate healthcare *financing* from healthcare *service* provision?

a. Yes. A professional broker, for example, only need describe the insurance policy to provide a complete service to his/her customers
b. No. We cannot usefully separate healthcare financing from service delivery. Every attempt to do that has resulted in higher costs and poorer outcomes
c. Sometimes. We can usefully separate financing from service deliveries for orthopedic conditions but not for cardiovascular
d. Sometimes. We can usefully separate financing from service deliveries for acute conditions but not for chronic

4. What is the best way to determine a medical care outcome?

a. From a comparative test, one that compares a group of people who had a specific medical intervention with a similar group that did not
b. By reviewing the relevant biological information
c. By reviewing the relevant anatomical information
d. By reviewing the relevant genetic information

5. What does 'preference sensitive' mean in medical care?

a. That one patient may prefer one treatment process while another, similar patient may prefer something different and that both patients can make the right decisions
b. That some people prefer one physician while others prefer someone else
c. That some physicians prefer one type of patient while other physicians prefer a different type
d. That some patients may prefer one hospital while others prefer a different hospital

6. What is the Number Needed to Treat?

a. The number of patients who need to have a treatment for one to benefit
b. The number of doctors who need to perform a surgery for 1 to get it right
c. The number of patients a doctor needs to treat in order to have one patient benefit from his/her care
d. The number of surgeries a hospital needs to host to get optimal outcomes

7. What are Decision Aids?

a. Decision Aids are tools that present clinical evidence of risks and benefits of treatment options; they focus on likely outcomes.
b. Techniques that can aid a physician who needs to make an important decision
c. Surgical tools to help hospital residents make better use of their time
d. Computer programs that determine the optimal treatment protocol for a specific patient

8. Which, below, is NOT a credible decision aid?

a. TheNNT
b. ChoosingWisely
c. The US Preventive Services Task Force
d. Brochures developed by Pfizer, the manufacturer of Lipitor, that explain the benefits of taking statins

Risk Management Overview

This chapter was originally written as the introduction to a book on the history of medical education by Andy Lazris, a primary care physician in Maryland. My thanks to Dr. Lazris for allowing me to include it here.

It was a chilly fall day in Baltimore, 1911, and Abraham Flexner was preparing for his meeting with William Welch. He meticulously parted his thinning, dark hair that sat on a long and stern face, barely cracking a smile. He slipped into his dark suit and wide tie, and then trod over to the kitchen for a cup of black coffee. He stood tall at just over six feet. He Semitic features were somewhat obscured by a bushy mustache that was curled at its edges. He wore small wire spectacles over his beady black eyes. He was neither engaging nor distant; he seemed to exist is a space all his own, and, as his friends and enemies often said, he lived within his own perception of reality. In a mere year, this former minor educator vaulted himself to fame and prominence, taking the entire medical world by storm. He understood the significance of his accomplishments and his new-found worth, and today he hoped to transform that into something that would forever alter American health care.

His hotel sat just outside the Johns Hopkins medical campus, in a well-manicured area of East Baltimore well beyond the stench of its more industrial harbor. Here there was a mix of poverty and wealth, and the Johns Hopkins Hospital, an innovative leader in medical education, had catered to both, transforming itself into the beacon of American medical excellence. Flexner himself had graduated from Hopkins many years ago with a degree in education. He obtained his diploma in just two years before moving to Indiana to establish a school. His brother, Simon, was a prominent doctor on staff, a man who had gained fame in discovering a bacterial infection that still bears his name. Now Abraham even eclipsed Simon in fame; William Welch, Johns Hopkins Hospital's president and a pathologist on staff, sought to meet with him to discuss perhaps the most significant change that the medical school, and all of American health care, would ever incur.

To Abraham Flexner, who believed in process and order, it was going to be just another day. One year earlier he had penned a comprehensive report sponsored by the Carnegie Foundation that scrutinized all of the nation's medical schools and picked winners and losers from among them. For Flexner and his allies, the report that would ultimately bear his name was the first requisite step in professionalizing and standardizing not only medical education, but the entire field of American health care. This was the culmination of work from the American Medical Association (AMA), an organization that had been fighting for half a century to gain control over the training and practice of doctors. Now with Flexner's report, the AMA, whose prior work had spurred Flexner's findings, put itself in a position to be the final arbiter regarding what a school must prove to be worthy of graduating "credentialed" physicians. Many schools did not make the cut and quickly died a natural death. Many doctors—women, blacks,

alternative practitioners, those without certified education—lost their ability to practice medicine. In an instant, because of Flexner, the entire medical landscape changed.

Flexner believed that it was about time that American health care followed the European example and adapted a rigorous scientific approach to education. And it was at Hopkins he hoped to drive in the first stake of a grand new program of reform. As he finished his single slice of toast and coffee, Abraham Flexner prepared to meet with Welch, an ally of his, and the most powerful man at Hopkins since Sir William Osler retired. Doctors Welch and Osler had personal enmity for each other and proclaimed very different visions about what health care, and specifically Johns Hopkins' mission, should encompass. One of American's premier medical institutions, Johns Hopkins stood at the forefront of the medical world, but both Welch and Flexner knew that it could be even better. With Osler gone, and with both Flexner's report and the promise of large amounts of corporate money in his back pocket, Dr. Welch now could do as he had always hoped. He would conspire today with Abraham Flexner to transform Johns Hopkins from a clinical institution that taught students how to care for patients to the nation's most prominent research facility, replacing clinical staff with full time scientists, and instituting a rigid curriculum for students that emphasized a pursuit of pure science, a curriculum (based on Flexner's recommendations) ultimately that every credentialed school would be compelled to follow, and one that largely has remained intact even today.

To exorcize the ghost of William Osler from Hopkins, Welch needed money and a template, and on this day in Baltimore, Abraham Flexner was prepared to offer him both. Now working for the Rockefeller Foundation, Flexner promised Welch with enough money to hire full-time research faculty, increase lab facilities, and institute a rigorous 4-year scientific curriculum. With Osler gone, William Welch could have his way.

Osler had established a program of clinical instruction, in which community physicians like him and his colleagues trained Hopkins students. As Osler said, "Medicine is learned by the bedside and not in the classroom. Let not your conceptions of disease come from words heard in the lecture room or read from the book. See, and then reason and compare and control. But see first." Osler not only reformed Hopkins and transformed it into a premier medical institution through his novel bedside patient-centric approach to teaching, but he did it with part-time instructors who were actual doctors and made their living by seeing patients. While he valued research and teaching, he believed that both were subservient to an education obtained in the real world by working with real patients. "He who studies medicine without books sails an uncharted sea," he said. "But he who studies medicine without patients does not go to sea at all." Osler never did any research on his own; he published books and gave lectures around the world about how to take care of patients, and how to raise a new class of physicians who would be expert in patient care. Hopkins was his grand laboratory for change.

William Welch despised Osler and sought to move Hopkins away from the community and into the lab. As a pathologist and a disciple of the scientifically-oriented German school of thought, he believed that clinical teachers were no more than greedy hacks who would sully students and prevent them from achieving medical greatness. Osler held sway at Hopkins, at least while he remained. But once he retired, his hand-picked clinical colleagues lacked the influence to maintain Osler's vision. Welch slowly drove them out, one by one, replacing them with scientists. When Flexner approached him with money and new method of education—one that Welch himself help to formulate through his position at the helm of the AMA—Welch now had the power and authority to entirely expunge Osler's stamp from Hopkins. He hired full-time faculty and fired all the clinical staff, including many of Osler's friends. Students now received their education in the class, in labs, and on the wards, not with patients in the community. They were taught by doctors who did not practice medicine but who merely read and researched it. All of this happened rapidly once Welch and Flexner shook their hands and made a deal on that chilly fall day in 1911. Hopkins was entirely transformed, and a new epoch of medical education began.

But 3500 miles west in London, Sir William Osler was fuming mad. A man known for his biting wit, his sardonic insults, and his medical genius, Osler had laid the path of modern medicine in America through his teaching and writings. Now, with Flexner's report taking root at Hopkins and elsewhere, all that he held dear was being threatened by the very man now glibly eating a piece of toast in Osler's city of Baltimore, a man who knew nothing about patients or medical care, a man prepared to exterminate all that Osler had accomplished for his profession by allying with no other than Osler's nemesis, William Welch. So, Osler wasted no time; he found his allies and used his influence to save the very field and institution to which he had devoted his life.

The struggle between Osler and Flexner set medical education and the entire health care industry on a trajectory that continues to this day. Not much has changed since the battle ended. One of the men continues to be quoted and well known, although his ideas have evaporated from our medical horizon. That is William Osler, whose books and innovations are thought to have initiated the birth of modern medicine, but whose soul was permanently shattered by the battle that commenced. The other was Abraham Flexner, a man known to very few, neither a physician nor a person with any knowledge about health care, but one whose report on medical education stamped a template upon medical care in America that we use even today. Its message is the very antithesis of what William Osler had so passionately advocated, and the changes it sparked transformed health care from a field devoted to the patient, as Osler so desperately endorsed, to one devoted to science alone and to the corporate foundations that funded scientific pursuits. And when we look at the proliferation of low value medical care today, at the trillion dollars of health care money that is squandered every year on medical interventions that help no one, at the generic medical school curriculum that emphasizes rote memorization and irrelevant sciences instead of critical thinking and patient-centered care, we owe all of that to Flexner. Osler's vision was just the

opposite of what we have today. And upon Osler's ashes, the medical system took a jagged turn and went far off course.

Medical care in America sat on a precarious spire through the latter part of the nineteenth century. Most medical schools were diploma mills with few standards, and those who could pay were able to obtain a degree. Hundreds of such schools were scattered across the country, producing far too many doctors as was necessary. (B12) Educated people typically eschewed the medical field; a survey in 1851 showed that from top colleges 26% of students became clergymen and lawyers, and only 8% became doctors. The salaries were low and the competition for patients fierce, a situation that remained in tact at least until 1900. (G82-4) The result were poorly trained doctors who held no mastery of their skills. A popular book in the 1880's, *The Physician Himself*, by DW Catheell, encouraged doctors to be more concerned with showing an image of competence rather than actually being competent. According to Paul Starr, "Cathell's guide reflects the exceptional insecurity of the 19th center doctors, their complete dependence on their clients, and their vulnerability to competition from laymen as well as colleagues." (g86-8)

In many ways to counter the beleaguered state of health care, a group of physicians in 1846 started a small organization called the American Medical Association (AMA). Meeting in New York, these doctors orchestrated a national organization whose goals were to raise and standardized medical degrees with the aim of improving the caliber of practice, decreasing the physician pool, and increasing doctor salaries. Throughout the century, the AMA met only once a year and remained small, exerting most of its influence on state medical societies. By accommodating with other forms of medical practitioners, especially homeopaths and eclectics, and by becoming a confederation of local medical societies instead of a top-down voice of change, the AMA gained members and influence. It also consolidated medical licensing state by state, (G90-112) setting standards by which physicians would be required to practice. This went a long way toward creating a set of licensed doctors would could now distinguish themselves from the mass of untrained practitioners dotting American's medical landscape.

The AMA's rise was not beneficial for all physicians, nor necessarily for patients. African-American doctors, unwelcome in many local medical societies, became marginalized, unable to obtain credentials. Similarly, women and doctors who practiced non-orthodox medical care, such as chiropractors, were excluded from those able to be credentialed. At this juncture, the AMA never elucidated a vision of health care that encompassed science and patient-centered care as the core of a viable medical system; its concrete objectives were much more nuanced and vague. It essentially was more a trade association that imposed laws and restrictions that were favorable to its members. Only in 1900 did it begin to see the advantage of "touting itself as a promotor of scientific education" to advance its agenda. (H2-3) In fact, even as late as 1906, the AMA promoted a pharmaceutical policy that on the surface sought to remove

sham drugs from the market, but in reality promoted a regulatory system to “withhold information from consumers and re-channel drug purchasing through physicians.” (G129-32) The ultimate intent of the AMA was not necessarily to improve the drug market, but to make sure that doctors have control over it, so as to increase the power of physicians in health care delivery.

But one ingredient was essential for the AMA and its licensed physician members to improve their status: better control of medical education. And that is the crux of the Flexner – Osler conflict. As long as medical schools remained unregulated, as long as they could proliferate without any rules or standardization, as long as diploma mills and substandard schools could produce large numbers of poor physicians, then American doctors could not achieve the status, money, and exclusiveness that the AMA sought. And as long as the AMA did not directly control the apparatus of medical education, then the less its influence would be over the health care delivery system. The AMA sought to cultivate a landscape with fewer schools training fewer doctors that were directly controlled by the AMA’s regulatory system. To that end, in 1904 the AMA established a council of medical education, formulating minimal standards that should be implemented in all medical schools. In 1906 it inspected all 160 medical schools and made judgments about which ones (82 in all) met minimal standards. But it kept its findings secret, fearful that any judgment it imposed on medical schools would be viewed as being self-serving, (G11-18) which of course it was.

To appear more objective, the AMA commissioned the Carnegie Foundation essentially to repeat its survey of medical schools and render an opinion about which schools met standards, so as to get “independent and presumably disinterested support for its efforts.” (B73) By 1908, when the AMA sanctioned this second survey, medical education had already been improving on its own, primarily due to state regulations and also the high cost of providing of running a school. The 450 schools training doctors in the late 1800’s had already been whittled down to 150. Many schools were already undergoing reforms to improve themselves. Many other schools remained marginal; they did not have any lab equipment or hospital affiliations, some even had sparse curricula and were situated in one room homes. 60% of schools did not have requirements for admission, only an eighth of the schools required two years of colleges, and many remained for-profit institutions. (B70-1) The Carnegie Foundation, led by Henry Pritchett, had similar concerns about medical education as the AMA, so their collaboration made sense. (B 73)

Many in the Carnegie Foundation touted the German model of medical education as a good template upon which any recommendations should be made. German schools utilized a hard science curriculum; students were well versed in chemistry, physics, biology, and math, and this provided the crux of their education. Labs and classroom work constituted requisite ingredients of education; clinical experience was far less important. The goal was to develop a very rigid science-based curriculum that would be the same in every American medical school without variation, emphasizing lab science,

qualifiable data, and a view of disease as a scientific entity that was not patient-specific. (I598) To orchestrate and implement the survey, Pritchett chose Abraham Flexner, an unknown former educator, a man with no medical training or background, but someone who adhered to the German model. Flexner also had a famous physician brother at Johns Hopkins, and the Carnegie Foundation had very close ties to that school and its president, William Welch. Welch, a pathologist, had transferred Hopkins into a living example of the model medical school that Carnegie and the AMA espoused.

But why Flexner? Why not a medical doctor or someone privier to the controversies in medical education? Or even someone who had set foot in a medical school? According to one source, Pritchett's hiring of Flexner was "one of the strangest appointments in education history." But Pritchett was counting on the AMA to lead the actual effort, with Flexner being more of a figurehead who followed the AMA roadmap. (B68) But Flexner was not a type of man who liked to be directed. As someone who had lived in Germany, who graduated from Hopkins, and who had experience in education, he had very established ideas about what he hoped to achieve with his survey. He made very profound decisions about many schools by only spending a few hours studying them. After consulting with doctors from Hopkins and others in the AMA, his report would do more than just set standards for medical schools; it would profoundly alter the very foundation of American medical education and practice, a legacy we will live with today, over 100 years later.

Who was Abraham Flexner? Born in Louisville, Kentucky in 1866 he was a son of Jewish German immigrants. He received a Bachelor of Arts at Johns Hopkins after only two years. He moved back to Kentucky where he founded an experimental school based on the German model, a school that ultimately failed. He met his wife, Annie Crawford, a former student in his school, and she ultimately became a successful Broadway playwright, bringing the couple to New York. Buoyed by her income, he then studied psychology both at Harvard and at the University of Berlin, never receiving a degree. While in Germany he was influenced by Fredrich Paulsen, a leader of the German school system, who believed that American education was not sufficiently serious and fact driven. Like German physician Fredrich von Mullen, from whom Flexner also learned, Paulsen advocated a stringent gymnasium system of learning whereby teachers taught students through a very formulaic and scientific fact-based curriculum. (B59, 91) After returning to New York, Flexner landed a job with the Carnegie Foundation through his brother Simon, a medical researcher at Hopkins and a good friend of Henry Pritchett's. (A63, B63)

The President of Johns Hopkins medical school, William Welch, a pathologist who also adhered to the German school of education, happened to be the president of the AMA at this time. Welch and Simon Flexner were good friends, and Welch was also connected to the Carnegie Foundation and supported its proposed survey of medical schools. Welch had co-authored the AMA's report on medical education in 1907 with Simon Flexner, a report many people think that Abraham Flexner's report is based.

Welch believed in a rationalistic and scientific view of medical education: if students can master science, they can figure out a patient's diagnosis and treatment without necessarily seeing or speaking with the patient. They just need data. Welch felt that medicine was a branch of pathophysiology, the science of studying the human body's operating system. He also insisted that all doctors, and all teachers, needed to be proficient in lab science rather than clinical skills; the vector of treatment for Welch ran from the lab to the bedside. In other words, doctors need only understand science and engage in research, and they will then be able to diagnose and treat diseases. (I599) As a corollary, Welch was adamant that all medical educators should be full time lab faculty; the clinical faculty (those who actually practiced medicine) were too busy and not sufficiently qualified to teach, he said. (K1860)

Abraham Flexner attacked tasks with purpose and an unbending agenda. Although often funny, and a person who enjoyed teasing colleagues, he also could be brutal and one-sided. He was known to be verbally abusive, scornful of compromise, self-centered, and only receptive to ideas and suggestions that mirrored his pre-conceived notions. (B2,3). Said one source, "Flexner did not tempter his language to please readers—a quality that was to become typical of Flexner's style. He was as tenacious as a bulldog in holding to his positions." (D64-5). And what were his positions regarding the report he was charged to write? Clearly, Flexner derived many of opinions from the people at Hopkins and the AMA with whom he conversed, people like Welch and his own brother, who believed that research and science must be the bedrocks of all medical schools, that faculty must be research based and full time, that schools needed to have a uniform science-based curricula, and that AMA would henceforth regulate medical schools and its graduates to ensure compliance with very strict, unwavering regulations. In other words, his report would match his own personality, and reflect the German-focused vision of William Welch and the program he had constructed at Johns Hopkins. In fact, Hopkins became Flexner's model school.

Flexner felt that two-thirds of the schools were hopeless and should not be allowed to survive, and that most of the others needed significant reform. All but two African-American schools were told to shut down, and the remaining two were expected to train black "practitioners" whose main job was to care for the black community and assure that they don't spread disease to whites. Said Flexner, "The practice of the Negro doctor will be limited to his own race, which in its turn will be cared for better by good Negro physicians than by poor white ones. But the physical well-being of the Negro is not only of moment to the Negro himself. Ten million of them live in close contact with sixty million whites. Not only does the Negro himself suffer from hookworm and tuberculosis; he communicates them to his white neighbors…. The Negro must be educated not only for his sake, but for ours. He is, as far as the human eye can see, a permanent factor in the nation" (Flexner report) Similarly, all schools that trained women, and all that trained alternative doctors, were eradicated by Flexner's report. Those schools deemed salvageable all were primarily white institutions with close ties to the AMA. If they complied with the report's recommendations regarding curricular,

structural, and faculty reform, then they would be accredited by the AMA's Association of American Medical Colleges, be eligible for philanthropic funding from groups like Carnegie and Rockefeller to help defray full-time faculty and structural cost, and look to Hopkins as a model of how to succeed. (H2)

The report was front page news across the country. The New York Times headline stated that most medical schools were "Factories for the making of Ignorant Doctors," lauding the Carnegie Foundation for uncovering the basest features of medical education and practice in the United States. (B69) No organization or newspaper said much about Flexner or his motivations, linked the report to Hopkins or the AMA, or questioned the report's conclusions. The report, it was believed, represented a milestone in American medical care, a turning point whereby the health care delivery system in this country would be purged of its most corrupt and loathsome elements. The response was fairly uniform adulation.

The focus of the report, and the model of what a reconstructed American health care system would look like, could be found at Johns Hopkins. Medical schools now looked to Baltimore for guidance, to William Welch, and to the German model. All doctors henceforth trained and credentialed in America would be scientifically oriented and experts in research. They would be taught by full time researchers, not clinicians who saw patients. And they would follow a science-based pre-medical and medical curriculum uniform in structure. But in reality, a purely scientific bent to medical education did not reflect the reality of Johns Hopkins. Hopkins was much bigger and broader than how Flexner portrayed it, mostly because of the tremendous presence of William Osler, the most respected and well-known doctor in America, who now was knighted and retired in England. His legacy was the blood and soul of Hopkins Medical School.

"It is much more important to know what sort of a patient has a disease than what sort of disease a patient has," said William Osler as he and his contingent of practicing physicians taught the medical students of Johns Hopkins through the late 1800's. "Listen to your patient, he is telling you the diagnosis." To Osler and the clinicians of Hopkins, the vector of education ran from the patient to the lab; students learned from seeing and working with patients, not from research or lectures, and then brought that information back to the scientific theater. Teachers needed to be practicing physicians, and students needed to learn at the bedside. Osler believed in the very opposite ideals of his nemesis William Welch and of the German school. And until his retirement, Osler's word was law at Hopkins.

William Osler was born in Ontario, Canada in 1849. After graduating from medical school in Canada, and working at McGill, he was recruited in 1889 the be the lead physician at the new Johns Hopkins Hospital in Baltimore, and in 1893 he helped create and lead the new Johns Hopkins Medical School. He essentially created the school from scratch, designing a curriculum based on his primary dictate: that students learn

only through immersion in direct patient care. To that end he eschewed a focus on science and the lab, and he hired as instructors practicing physicians in Baltimore. From the day they entered the school, students interacted with patients, an act that became their only forum of learning in the third and fourth year. To further their clinical proficiency, Osler invented the residence, whereby after graduating from medical school, new doctors would essentially take apprenticeships for several years before going off to practice on their own.

While men like William Welch did expose students to lectures and lab work, this was not the focus of Hopkins. Said Osler, "I cannot imagine anything more subversive to the highest ideal of clinical school than to hand over young men who are to be our best practitioners to a group of teachers who are ex officio out of touch with the conditions under which these young men will live…" To Osler, researchers and scientists should not teach medical students; this, after all, was the very lifeblood of Hopkins' Zeitgeist. (C387-9) The thrust of Osler's educational focus was to emphasize problem-solving and critical thinking skills, and the evaluation of medical information through directive observation of and interaction with real people, whose problems not only were medical but were socio-economic and cultural as well. He specifically rejected the "inculcation of facts through rote memorization" and the assumption that one could apply scientific dogma to patients without knowing the patient first. (F6-8)

When Osler left Hopkins in 1905 he was not only the primary driver of Hopkins' medical educational philosophy that vaulted the new school to the very pinnacle of American medical institutions, but he was also a national celebrity, having authored the widely read *The Principles and Practice of Medicine* and given lectures all over the country. He retired to England and left the cherished institution he created to his many clinical colleagues and friends.

But to William Welch and the scientists at Hopkins, a different type of school was needed to push Hopkins into the new age of medical education, one based on science, one in which full-time researchers and scientists taught students, and one in which practicing physicians (who men like Welch felt were greedy and contemptuous for earning money by seeing patients) were absent from the faculty. Welch was a powerful man, he was President of the AMA, he helped to write the first national review of medical schools, he had connections at the Carnegie Foundation. And he helped Flexner turn Hopkins away from a clinical institution to one that was inexorably married to hard science, research, and an inflexible curriculum based on the German school of thought.

By painting Hopkins as his model school, Flexner was in fact looking at a Hopkins that existed not in the realm of reality, not in the blueprint of its founder and primary architect, but rather through the stilted lens of non-clinical researchers like Welch, who sought to increase their power and influence now that Osler had slipped away. That Hopkins was the type of school that Flexner revered is a great absurdity; in many ways

it was the very anthesis of the rigid science-based bastion of learning that Flexner sought to promote in his report. But by painting the school using brushes and canvas supplied by Welch, Flexner in essence altered the very heart of Hopkins by making it comply with what he believed it already was.

From his perch in England, Osler did not stay subdued for long. Known for his fiery personality and pointed wit, he immediately conferred with his clinically-minded friends still at Hopkins, many of whom were being threatened by Welch with dismissal and demotion. Osler rejected Flexner's conclusions, believing that researchers should be in research institutions and not medical schools because they were poor teachers and they lacked the ability to enable students to learn how to practice medicine and interact with patients. (I600) He read the report "as a brutal and ignorant attack on his staff, his principles, and his sense of professionalism." Osler did not understand how faculty could be composed of anyone other than physicians actively practicing the art of medicine. "We chance the sacrifice of something that is really vital, the existence of a great clinical school organically united with the profession and the public," he said. He believed that the report will "likely spell ruin to the type of school I have always said should be and which we have tried to make it…," a place of refuge for the poor, a place where the best that is known is taught to the best students, where "men are encouraged to base their art upon the science of medicine…." Stating that Flexner had a "very feeble grasp of the clinical situation at Johns Hopkins Hospital" and that the institution was "more brilliant from the clinical side than the laboratory side," he felt that the report would diminish the educational experience of its students drastically. "The danger would be of the evolution throughout the country of a set of clinical prigs, the boundary of whose horizon would be the laboratory, and whose only human interest was research, forgetful of the wider claims of a clinical professor as a trainer of the young…." (C385-88)

Osler and others fought back as best they could. He wrote to Welch and to his clinical colleagues, asking them to repudiate the report, and not move Hopkins and the entire medical educational establishment in a direction he knew to be deleterious to the field. At Harvard, Francis Peabody, another clinician who was trying to inculcate medical education with real-life experiences, similarly assailed the Flexner report. Peabody who famously stated that "The secret of the care of the patient is in caring for the patient," (F20) felt that Flexner's approach "weakened the soul of the clinic." He, like Osler, sought a less rigid and lab-based means of teaching students how to practice medical science that focused on actual patient care rather than theoretical scientific theories that may not apply to the individual patient for whom they were caring. (B15) They both believed that Flexner's report "fossilized medical education into following a standardized format" that moved so far away from patients as to be useless in training competent physicians. (H3). Said one author: "Osler and Peabody recognized the danger of reducing the patient to simply a pathophysiology characterized by laboratory tests" while fearing that such a parochial focus blinds doctors from "the broader contextual issues that so often play a crucial function in disease." (I600-1)

But there were larger forces afloat than merely a few men who fought over medicine's direction. Despite the experience, status, and wisdom of men like Osler and Peabody, their words evaporated in the report's wave of acclamation. In fact, although Flexner's report did reflect what he and others believed to be the most logical path upon which the American medical system needed to tread, replacing corruption and incompetence with the scientific rigor of the German school of thought, the report was also a tool used by others to achieve a very specific agenda. Not only did the AMA gain power and notoriety by now grabbing the reigns of American medical education and licensing, but other corporate philanthropic groups like the Carnegie Foundation, who sponsored Flexner's study, and the Rockefeller Foundation, where Flexner worked for much of his subsequent life, had carefully crafted the report to create an American medial system that met their needs and expectations.

For the next 15years of his life, Flexner worked in the Rockefeller Foundation general education board, dictating which schools would receive foundation money and which would not. During that time, he approved the donation of half a billion dollars to schools that met all the rigid criteria of his report and in the process "profoundly altered the medical education landscape;" the schools that did not follow Flexner's script received no money and could not afford to stay afloat, (B1) failing too to be granted requisite accreditation by the AMA. As one author states, "Money was power, and contributors to medical education knew that." (F12)

What was the agenda of groups like the Rockefeller foundation, and why did they buy into Flexner's model? Essentially, their hope was to create great bastions of medical research, whereby American medical institutions could engage in scientific study that matched that of Europe and created breakthroughs that would advance the medical industry and, undoubtedly, generate financial gain for the foundations and their parent corporations. These foundations had very specific agendas for the many schools they sponsored, and their donations were tied to the realization of those agendas, which typically required moving the schools from a clinical direction to one that was purely scientific and lab-based. (F12) Schools had to eliminate clinical faculty, hire full-time science based faculty, emphasize basic science research in their teaching, and adhere to the very rigid science-based curriculum that Flexner laid out in his report. This instigated bitter struggles between old line clinical teachers like Osler who used to have clout, and the newer research scientists who were now taking over. Full time faculty could only exist if the schools were subsidized, and these large foundations were happy to pay the schools so long as the schools adhered to their rules. (B21-3)

As the tide of funding and accreditation became clear in the years after Flexner, most schools accommodated to the new reality. As clinical professors disappeared from these schools, full-time researchers took their place. The foundation leaders—who were in fact agents of the large corporations who funneled money to them—then dictated to these schools the forms of research they desired. Hence began a cycle in American medicine in which clinical skills fell prey to basic science, and in which

corporate entities dictated the direction of medical education and medical practice. "Whether their motives were shrewd business instincts or noblesse oblique, the influence of these industrialists and financers was profound, some would say pernicious." (B19) Within years, the clinical institution that Osler always envisioned, ones in which patients and clinicians taught students, and in which students would leave the school with both a scientific and humanistic knowledge of disease and treatment, completely vanished from the medical landscape. Osler's name remained well-known and respected, but Flexner's ideas won the day. All this occurred because the corporate boards gained enough power to impact the direction American medicine would flow. "Though the board represented itself as a purely neutral force responding to the dictates of science and the wishes of the medical schools, its staff actively sought to impose a model of medical education more closely wedded to research than to medical practice. These policies determined not so much which institutions would survive as which would dominate, how they would be run, and what ideals would prevail." (B121)

On that chilly day in 1911, when a well groomed and stern-faced Abraham Flexner walked through Baltimore to meet with William Welch, he planned to describe to Welch a plan that both men had already conspired to create. Flexner had been working with Frederick Gates of the Rockefeller Trust, who wanted to provide Hopkins with a $1 million grant if the school transformed to the model school described by Flexner's findings. Essentially, Hopkins would be the nation's premier research institute, with salaried researchers paid in part by the grant spearheading all teaching responsibilities, with all students following a rigid curriculum focused on science (A74), and with strict guidelines for admission and graduation. The clinical realm championed by Osler and his colleagues would be relegated to a footnote. Clinicians "have long ceased to be scientifically significant…. Whether the extremely prosperous physician or surgeon should have a place in such an institute as the Johns Hopkins Hospital seems to me most doubtful," said Flexner to Gates. (C-381)

In the realm of large foundations like Rockefeller and Carnegie, medical schools served as the best repositories of research and the production of scientists, upon which these companies were focused. Often, they sought to promote research pertinent to their own corporate interests. In fact, under Flexner's new guidelines requiring full-time faculty and ample research facilities, schools needed foundation money if they were to survive. As a result, within a decade all medical schools became dominated by researchers and not clinical physicians and teachers. "Many have argued that this was a mistake. They would have preferred to see only a few schools like Johns Hopkins training scientists and specialists, while the rest, with more modest programs, turned out general practitioners to take care of the everyday ills that make up the greater part of medical work. But this was not the course that American medical education followed…." (G123)

Despite emphatic and frequent protests from Osler in England, the world that he created at Hopkins and beyond quickly dissolved. His colleagues were fired and replaced by a

purely research-based staff. No longer did clinicians teach students, and no longer did students learn from their patients, as Osler so vehemently insisted. Welch readily accepted the million dollar grant from Rockefeller, and spearheaded a dramatic transformation in medical education and practice that relied on Flexner's template, the AMA's leadership, and Corporate dollars. Flexner went on to spend most of his career working for the Rockefeller Foundation.

The other winner in the battle for medicine's soul was the AMA, which stood as the only organization capable of assuring that Flexner's vision was properly implemented and executed. After Flexner, "the AMA would largely control medical school accreditation which would become bureaucratized and sclerotic. It also became the officially recognized entity authorized to speak on behalf of all physicians." (H3) Because doctors had to be licensed, and because licensing was controlled by the AMA, and because only AMA sponsored medical schools could graduate certified physicians, the AMA in fact controlled the global American medical system, and in many ways it was beholden to corporate foundations that help fund them and the schools. Flexner himself believed that medical education and practice would change and grow as times changed. "The flexibility and freedom to change—indeed the mandate to do so—was part of the system's mission from the very beginning. Contrary to popular myth, the system was always intended to evolve." (F25). Unfortunately, groups like Rockefeller and the AMA were not interested these changes.

Today, medical schools, and the entire health care network in this country, reflect the legacy of Flexner. As one author stated, "The practice of medicine was seen as a rigorist science with clear answers to defined questions, the foibles of patients being the province not of the laboratory-trained physicians but of clergymen and social workers." (K1860-1) The medical system would now focus on "disease organically defined, not on the system of health care or on society's health more generally." Patient-centered care, prevention, and the nuances of disease all were extirpated from training as a very parochial view of science as fact reduced medical education to a technical pursuit. (F25). Using a narrow set of courses in chemistry, physics, and biology to determine which students best qualified to be physicians, and then teaching students the science of the human health through a set curriculum that today is nearly identical to the one recommended by Flexner, medical schools have moved far away from the vision of Osler. Humanistic qualities, critical thinking, and a patient-focused approach to care have lost all significance both in the selection of students and in their training. "Isn't it astonishing that the medical school curriculum structure has remained unchanged for more than 100 years? And if we omit the 'dynamic sociological encounter between patient and physician' [as Osler advocated], is it any wonder a health care crisis would emerge?" (H3)

The legacy of Flexner's report and the rise of the AMA has left many scars with which we are living today. On the positive side for physicians, many charlatan practices have disappeared, and physician competency and income increased considerably. In 1900

the average doctor earned $750-$1500. By 1928 they were already earning on average $6354, with salary escalating continually due to a deliberately low physician supply and strong advocacy by the AMA. (G142)

But the physician class changed dramatically. Now only one, scientifically-based model of medical care predominated; the field became quite homogeneous and dependent on a scripted formula of practice to achieve success. The increased cost of medical education, required to help defray costs for full-time faculty and research facilities, eliminated all but the wealthy from the ranks of medical students. And Flexner's report and its ramifications triggered deliberate policies of discrimination against women, African-Americans, and Jews. (G124) Only two African-American medical schools remained, and the black doctor only survived through the efforts of the newly created National Medical Association (NMA) which sponsored a parallel black medical system given the pervasive bigotry sewed into the AMA and the American medical system it helped to create.

The other casualty of Flexner was the slaying of Osler. Today many people know Osler, or at least have heard the name. Virtually no one has heard of Flexner, the Rockefeller and Carnegie Foundation, or men like William Welch. Yet Flexner's report and its subsequent embrace by the AMA, charitable foundations, and established medical schools like Hopkins have secured Osler's irrelevance to the practice of medicine and the training of physicians. Researchers and specialists have trumped clinical generalists, the very physicians Osler's bold reforms were promoting as the cure to health care's ills at the turn of the century. After Flexner, researchers were "regarded as of greater intellectual worth than clinical practitioners which, not lending itself to grants, publications, or academic glory, was deemed a lesser calling." Even when schools trained non-research physicians, the emphasis on clinical education revolved around specialization and a scientific view of disease. (K1861) According to historian Howard Berliner, Flexner's "language leaves little doubt that he held the mass produced 'family doctor' in low esteem and he considered the new standard among physicians to be the highly scientific and sophisticated clinicians molded in the Hopkins environment of its equivalent." (B15)

In 1984 an AAMC report recommended changes in medical education that would move clinical medicine beyond the narrow confines of Flexner's report, changes they predicted would take root within just a few years. These were to:

- Develop analytic skills and instill patient-centric values into the curriculum.
- Encourage a broad liberal arts pre-med education
- Emphasize critical thinking over memorization
- Ensure that clinical clerkships encourage respect and concern for patient values
- Reward doctors who are educators. (I598)

Needless to say, none of those reforms transpired. Pre-meds are required to focus on science, and the Medical College Admission Test (MCAT) requires memorization and regurgitation of a large quantity of purely scientific data. Even through medical school, memorization, not critical thinking, is the skill that is necessary for testing success. Virtually no generalists teach students, and students are exposed almost entirely to specialized highly-scientific medical practices and ideas. Most significantly, patient-centered care as advocated by Osler has become a token gesture rather than the crux of all medical education.

We are indeed in a health care crisis. In our country we spend a trillion dollars of health care dollars for interventions that have been shown to be ineffective or even dangerous. Almost 50% of all we do as doctors is considered low value. Despite all we spend on health care, we rank among the worst in outcomes among all industrial countries. We are a nation of specialists, of high-tech medical practice, and of excessive drug use. Virtually all research is financed and controlled by industry and is conducted within medical schools whose research faculty are dependent on industry to survive and thrive, thus leading to conclusions that are sullied by self-interest. Patients feel frustrated, and their needs often fall prey to generic protocols and an emphasis on rigid scientific dogma. Students continue to be trained as scientists and not as physicians. Said one historian, “The Flexner Report… has taught us the danger of establishing a confining (and ultimately damaging) standard” in medical education and practice. (I601)

Can our health care delivery system ever change? To do so, we first must understand why it has moved so far off the rails of common sense and medical sanity. Today, over 100 years after Flexner, we should ask why we have not changed yet. Are there too many people and organizations benefitting from the current system? Do medical thought leaders believe that Flexner’s formula is still the best one for our health care delivery system? Or is it perhaps inertia and a lack of understanding of what needs to be fixed? In the end, we should peak back to a time before Flexner and grasp what William Osler had already gifted to the medical world. When read today, Osler’s words and ideas make sense. Certainly, if we are ever to transcend the health care mess in which we are embroiled, me must understand and embrace Osler and finally acknowledge the flaw of Flexner’s errant course.

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Review Questions

Answers on next page

1. Which statement below best summarizes the European or Flexner approach to medicine?

a. Medicine is entirely scientific. As long as doctors gather enough data on the patient and are well enough trained, they will make the correct diagnosis and prescribe the correct treatment
b. Medicine is entirely an art. Tests and data are irrelevant since each patient is unique
c. Medicine is a combination of science and art. Doctors need to combine patient hard data from tests with wisdom and experience
d. Medicine is a religion. As long as patients believe strongly enough, they will recover from their medical ailments

2. Who said “It is much more important to know what sort of a patient has a disease than what sort of disease a patient has…Listen to your patient, he is telling you the diagnosis.”?

a. William Osler
b. Abraham Flexner
c. Alfred E. Neuman
d. Albert Einstein

3. Which type of physician would you prefer to diagnose and treat you: one trained in the Flexner style or one trained in the Osler style?

a. Flexner
b. Osler

4. How can a patient determine which type of physician – a Flexner or an Osler follower – treats them?

a. By interviewing the physician before receiving care. Note that this requires that the patient be well informed (medical definition) about care and treatments
b. There is no good mechanism available today to help patients make that choice
c. By staying ‘in-network’ based on your health insurance plan
d. By getting all your medical care overseas

Review Questions

Correct answers in bold

1. Which statement below best summarizes the European or Flexner approach to medicine?

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2. Who said “It is much more important to know what sort of a patient has a disease than what sort of disease a patient has…Listen to your patient, he is telling you the diagnosis.”?

a. **William Osler**
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3. Which type of physician would you prefer to diagnose and treat you: one trained in the Flexner style or one trained in the Osler style?

a. Flexner
b. Osler
c. **The correct answer is up to each individual patient**

4. How can a patient determine which type of physician – a Flexner or an Osler follower – treats them?

a**. By interviewing the physician before receiving care. Note that this requires that the patient be well informed (medical definition) about care and treatments**
b. There is no good mechanism available (either a or b can be correct)
c. By staying ‘in-network’ based on your health insurance plan
d. By getting all your medical care overseas

Some Risk Management Problems in today's health insurance environment

As Andy Lazris so eloquently discussed in the previous chapter, Abraham Flexner believed in science and facts. He idealized the then-cutting-edge German approach to medical education that focused on 3 laboratory based disciplines - physiology, pathology and bacteriology – at the expense of the humanities and experience. Science gives answers, 'facts', and the medical student's role to Flexnerians, is to collect them.[160]

The more facts the student accumulates, the better the student.

The better the student, the better the doctor.

The ideal physician accumulates as many scientific facts about medicine in general, and then the patient in particular, as possible in order to make the best diagnosis and treatment recommendation. Facts drive the process.

It's not even necessary to see the actual patient in Flexner's world. To quote Andy's comments on the German approach:

> if students can master science, they can figure out a patient's diagnosis and treatment without necessarily seeing or speaking with the patient. They just need data.

Or, stated differently, Flexnerians believe that the human body is a mechanical object to be understood and fixed when it malfunctions, a huge wall of knobs and dials that doctors optimize with medications, therapies and surgeries. Treating a patient essentially becomes the same as baking a cake or building a car. Cake too sweet? Dial down on the sugar. Cholesterol too high? Dial up on the statins. Knee pain? Arthroscopic debridement.

An extension of the Flexnerian mechanical world view is that there's always some way that medicine can improve the patient's condition, leading to the proposition that more medical care is better than less. Why settle for a *pretty* healthy patient when we can create, through science, a *very* healthy one?

This scientific-mechanical approach to medicine minimizes the problem of complexity, sidesteps the problem of overreach and ignores the issue of patient preference. Each independently poses a significant objection to this mechanical view of medicine. Altogether, they pose a mortal one. We'll explore below.

The Problem of Complexity

[160] *Flexner's exact quote was 'The student is to collect and evaluate facts.' Abraham Flexner (1910). "Medical Education in the United States and Canada: A Report to the Carnegie Foundation for the Advancement of Teaching"*

The human body, as any practitioner or recipient of medical care knows, is north of unbelievably complex. Each medical intervention creates primary effects, side effects and rebound effects which may serve to mitigate the intended impacts. Statins, for example, have a primary effect of preventing heart attacks, which they do, on average according to Pfizer's estimates of patients without known heart disease but with risk factors, about 1% of the time. [161]

But statins cause diabetes about half as often. [162] Diabetes, in turn, can cause heart attacks. So the statin rebound effect ultimately negates some of the primary impact.

Michael Porter and Elizabeth Teisberg, in their massive Redefining Health Care treatise, summarized the medicine complexity problem. 'There are too simply too many dimensions of process to track and too much heterogeneity among patients,' they write.[163] Clinicians may tend to focus not on the most important medical variables but on those most easy to identify, quantify and affect.

Often these become 'guidelines', 'checklists' or 'established protocols.'

We humans, it appears, like guidelines and protocols. It's one of our foibles. Checklists help us reduce the number of potentially important variables to a manageable handful, help us target our investigations and streamline the medical diagnostic and treatment process. Guidelines help us avoid starting every patient analysis from the underlying biological and physiological principles, then reasoning toward a specific diagnosis and treatment. Protocols tell us which interventions commonly succeed with a particular type of patient.

Those efficiency gains are the good bits.

The bad bit comes from a second human foible: intellectual and bureaucratic inertia. Once we accept a standard approach, we tend to ignore contrary evidence, put blinders on in other words. Some research suggests that this is the reason it takes up to 10 years for a new medical process to become widely accepted even if it's clearly scientifically based and clearly better than the old process, or even longer for an outdated one to disappear. [164]

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[161] See the Lipitor ad, Dec 4, 2007 Wall Street Journal. The small print, bottom left of that ad states 'in a large clinical study, 3% of patients taking a sugar pill or placebo had a heart attack compared to 2% of patients taking Lipitor.' This study was of patients without known heart disease. The number differ for patients with heart disease.

[162] See Statin Drugs Given for 5 Years for Heart Disease Prevention (Without Known Heart Disease), 2017 version by John Abramson on TheNNT.com.

[163] Porter and Teisberg, Redefining Health Care, page 87

[164] See Vinary Prasad, Ending Medical Reversal and Richard Pearl, Mistreated for more on these estimates.

In Flexner's model, physicians would, theoretically, constantly review and revisit guidelines and protocols to ensure their accuracy in the face of new research and information. But that's simply not what happens in real life. Our foibles – fatigue, complacency, greed, intellectual laziness perhaps - don't permit it.

As Atul Gawande summarized in his 2015 Overkill New Yorker article:

> We can recommend care of little or no value because it enhances our incomes, because it's our habit, or because we genuinely but incorrectly believe in it.

Flexner apparently thought well trained physicians wouldn't take this approach; Gawande, the product of our Flexner based medical education system, admitted to it.

How often does this actually happen? Vinay Prasad answered that in a brilliant analysis of medical reversal. [165]

Prasad and his team reviewed every article in the New England Journal of Medicine between 2001 and 2010 and pulled out those that tested an established medical practice, one commonly used on patients like intensively lowering blood sugar in Type 2 diabetics to reduce cardiovascular events … interventions, in other words, that were scientifically fact based and that the medical community embraced.

363 studies qualified.

Prasad then asked 'Of those 363 studies, how many *affirmed* the practice?' i.e. found that it benefited patients.

38% affirmed the practice, 40% negated the practice, (found it ineffective or harmful) and 22% were ambiguous.

The Prasad team's research shows that if you base your medical decisions on biology, physiology, anatomy and logic – *exactly as Flexner prescribed* – you are wrong about as often as you are right.

That strikes me as a pretty dismal report card on the Flexner / Germanic approach to medical education.

Porter and Teisberg attack Flexner's medicine-as-mechanics approach from a second point of view also. Mediocrity, errors and the important human / personal interaction factor in doctor-patient relationships go unaddressed. Even if two physicians have managed to master Flexner's scientific facts equally well, one may be a better medical practitioner. Fact based knowledge and process compliance don't always lead to similar outcomes.

Consider cystic fibrosis treatment and outcomes. [166]

All CF patients receive care from one of 117 ultraspecialized centers that follow the same extremely detailed treatment guidelines. CF specialists attend the same

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[165] Prasad, A Decade of Reversal, Mayo Clinic Proceedings, August 2013

[166] This discussion comes from Atul Gawande's article The Bell Curve in his book Better, 2007.

conferences, shared the same knowledge base, focus on the same variables and facts, and treat patients the same way. But they generate different patient outcomes.

The two primary CF outcome metrics are lung function and longevity. The Flexner / German expectation would be that all centers would generate approximately similar outcomes on these two measures, within a fairly narrow margin. After all, they all use the same science and facts in their diagnostic and treatment protocols and treat similar patients.

But research shows that the 117 cystic fibrosis facilities generate quite discrepant outcomes. The average clinic, according to a 1997 study, generated patient life expectancies of just over 30 years. But the best managed 46.

Ditto for lung capacity.

That's only part of the issue. Perhaps the more astonishing thing is that one CF center routinely outperformed the others. It was at Fairview-University Children's Hospital in Minneapolis. (This is based on an early 2000's study, is likely out of date and I don't give cystic fibrosis treatment advice.) Patients at Fairview apparently routinely had lung capacities equal to the average non-CF population, higher than at most CF clinics.

How could a facility far outperform the average, and how could the same one outperform the average year after year? The answer appears to be some amorphous combination of physician-patient connections, a corporate culture that wouldn't accept sub-par outcomes and the personality of the director.

Flexner's mechanical model doesn't describe or account for these results.

But William Osler's does. 'The good physician', he claims, 'treats the disease. The great physician treats the patient who has the disease.' Medical excellence is only partially grounded in science and facts – those are necessary but not sufficient conditions. Excellence also requires empathy, interpersonal connections, clinician perceptiveness and a human connection that somehow, almost indescribably, adds therapeutic value. That's the art of medical care, present to Osler but missing from Flexner.

The difference between good and great to Flexner is some measure of scientific understanding and fact accumulation. The difference between good and great to Osler appears in other arenas like human connections, the non-scientific ones that medical education too often leaves out.

But we've so far only discussed the 'complication' critique of Flexner's approach. Let's now turn to the treatment overreach objection.

Low Quality and Unnecessary Care

The US medical care system, and perhaps others with which I'm unfamiliar, offers an astonishing amount of poor quality care. I'll define poor quality in a couple of ways:

- Unnecessary care or waste: Care that generates no patient benefit according to comparative studies. In other words, outcomes from the control and treatment groups are the same or practically so.
- Low quality care: Care that generates some benefit to a clearly specified group of patients according to studies but that is offered to a wider group so likely generates no benefit to the wider population.

Consider statins to prevent heart attacks as a simple example.

TheNNT.com estimates the Number Needed to Treat (NNT) is 39 for people with known heart disease, meaning that for every 39 people with known heart disease who take statins for 5 years, 1 will avoid a heart attack.

The Flexnerian, caring physician might look at a patient *without* heart disease though and say 'This patient shares certain important biochemical and physiological factors with the studied group. I think patients without heart disease will also benefit though probably not quite as much' and prescribe statins to the wider group, expecting somewhat similar results.

But that's not the case, at least not by an order of magnitude. TheNNT.com estimates that only 1 in 217 patients without known heart disease will benefit by avoiding a heart attack over 5 years. [167]

Are 1 in 39 and 1 in 217 similar care quality? I think not. There seems to me at least, a qualitative difference here. I'll postulate as a thought experiment that if 1 in 39 is 'good quality care', then 1 in 217 is 'low quality care'.

And if 1 in 39 is 'low quality care', then 1 in 217 is 'unnecessary care or waste'. (Yes there's some benefit but differentiating value from waste at these levels strikes me like splitting hairs with an axe.)

And we haven't even considered the treatment risks.

Where would a caring physician, draw the line between high and low quality care, or between low quality and unnecessary? I certainly don't know.

And neither, I'll postulate, does a Flexnerian, fact based scientist.

Extending this argument – that care generating reasonable quality care to a narrowly defined group might generate low quality care to a larger group – uncovers tremendous waste throughout our medical system.

[167] http://www.thennt.com/nnt/statins-persons-low-risk-cardiovascular-disease/

David Cordani, Cigna's CEO estimates somewhat conservatively, that 'slippage' or care that should benefit patients but doesn't, accounts for at least 25% of all US healthcare spending but probably much more. [168]

Aetna, another huge national health insurer, says less conservatively on its website that

> Wasteful spending likely accounts for between one-third and one-half of all US healthcare spending. [169]

And the Dartmouth Atlas, generally considered the bible of healthcare utilization analytics, uses a widely quoted estimate of 'up to about 1/3' of all US healthcare spending but added 'we view this as an underestimate given the potential savings even in low cost regions'.[170]

I think they're right, especially about the 'underestimate' bit.

This shouldn't happen according to Flexner's German school view. Physicians should accumulate all the facts and develop the right interventions. That's what science is all about – being right.

They shouldn't miss 30 – 50% of the time!

Let's put some meat on this low quality and unnecessary care bone by reviewing a 2018 Washington State study.[171] The Washington Health Alliance analyzed utilization and billing data from 2.4 million commercially insured patients and found that 45% of services delivered were wasteful. 45%!

Why does our system engage is so much low quality care? I think our human foibles are largely to blame. These fall into 3 general categories:

- Physician role definition, basically 'this treatment *might* benefit my patient and I don't want to withhold any potential benefit'. We might call this the medical plausibility foible – 'it might happen';
- Tort issues, basically 'I might get sued it I don't do it'; and
- The Upton Sinclair insight that 'it's difficult to get a man to believe something when his salary depends on him not believing it.' That's why surgeons tend to recommend surgery, therapists therapy and urologists interpret PSA study results differently from the US Preventive Services Task Force.

None of these foibles fit Flexner's world view. They're not science and fact based.

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[168] Cordani's Keynote Address at the 2015 Yale Healthcare Conference

[169] http://www.aetna.com/health-reform-connection/aetnas-vision/facts-about-costs.html

[170] http://www.dartmouthatlas.org/keyissues/issue.aspx?con=1338

[171] First, Do No Harm: Calculating Health Care Waste in Washington State, February 2018, www.wacommunitycheckup.org

But they're all human characteristics and all impact the actual practice of medicine.

And they all, in various ways, touch on the third major flaw in Flexner's approach, the problem of patient preferences.

Preference sensitive decisions

Unnecessary care to one person might be reasonable care to another just like in our statin example above. John Wennberg, founder of the Dartmouth Institute calls this a 'preference sensitive' decision, meaning that one patient might opt for the statins while another declines and **both may be right**. This is a tacit admission that there are rarely clear cut medical decisions.

Wennberg calls these relatively few obvious medical decisions 'effective care' defined as services that, on the basis of reasonably sound medical evidence, are known to work better than any alternative. [172] This group of treatments accounts, based on his research, for only about 15% of all medical care.

It's the category in which Flexner's analysis applies and probably flourishes. Examples include childhood immunizations, lifesaving drugs for patients with heart attacks, and regular blood tests and eye exams for diabetics.

A far larger category is 'preference sensitive' care meaning care for which there is more than one option and in which different people can make different decisions and all be correct. Preference sensitive care requires judgment to evaluate the risk-benefit tradeoffs. Wennberg estimates it's at least 25% of medical care. [173]

We've already discussed preventive services – statins as primary prevention. Now consider treatment for torn or injured rotator cuffs. A surgeon will likely recommend surgery after examining the patient and identifying a rotator cuff tear. But a physical therapist, reviewing the same data on the same patient, might well suggest PT.

That rotator cuff situation arose for a student of mine. He recounted that he first saw an orthopedic surgeon who took an MRI, identified the cuff tear, showed him the picture and recommended surgery. 'I would have agreed to surgery' he went on to say, 'prior to hearing your discussions about preference sensitive decision making.' (See – there actually is some value to continuing education classes!)

'But I asked the surgeon if all physicians would agree with that analysis and recommendation.' (In other words, was this an effective care situation in Wennberg's terms?) The surgeon 'answered with a snort that some clinicians might suggest physical

[172] Wennberg, Tracking Medicine, pages 8 – 10, then Parts II and III

[173] Wennberg's definitions of 'preference sensitive' and 'supply sensitive' care overlap. According to some interpretations, 'preference sensitive' may describe 85% of medical care. The exact definition and amount doesn't matter for this analysis; it's a lot no matter how we define the terms.

therapy but that would be a waste of time and that I'd be back in his office shortly thereafter.' (In other words, this was a preference sensitive decision.)

My former student decided to try PT and reported when next I saw him that his shoulder was pain free and that he had regained 99%+ range of motion – it might have been 100% but he wanted to be conservative - in the same time as surgical recovery but without the costs and risks of surgery. 'Thanks' he smiled as he relayed the story.

Was the surgeon wrong? Probably not. Surgery probably would have worked.

Was the patient right to ask about therapy? Clearly. Not only did it solve his problem but he preferred it. His choice defined the best medical treatment.

None of this makes sense in Flexner's the-human-body-is-a-big-mechanical-device world view. There's an answer in the Flexnerian world and the doctor's job is to find it.

But in the real world, doctors have foibles. They don't always diagnose and prescribe correctly because the human body is so complex. They frequently overreach because of their desire to help, combined with their economic incentives. And often misunderstand their patients' preferences.

Together these three problems doom Flexner and his Germanic approach.

Atul Gawande summarized the modern physician's role more appropriately by acknowledging that emotion complements science and that each patient has individual hopes, aspirations, fears and conditions:

> The ideal modern doctor should be neither paternalistic nor informative but rather interpretive, helping patients determine their priorities and achieve them.[174]

That approach, far more than Flexner's, warms my heart as a patient.

[174] Sheri Fink, Atul Gawande's Being Mortal, NY Times Book Review, Nov 6, 2014

Review Questions

Answers on next page

1. What is medical reversal?

    a. Stop providing medical care when studies show that it doesn't benefit patients
    b. Save a dying patient. In other words, reverse the biological process
    c. Have a different specialist undo the treatment you previously received
    d. Have a doctor change his/her mind as in 'I thought that Treatment A would help you but I was wrong, so now we'll try Treatment B.'

2. What is one definition of low quality care?

    a. Care that generates some benefit to a clearly specified group of patients according to studies but that is offered to a wider group so likely generates little to no benefit to the wider population.
    b. Cheaper care when more expensive care is available
    c. Care based on virtually any non-state of the art equipment
    d. Low technology care when higher technology care is available

3. What is the NNT or Number Needed to Treat?

    a. The number of patients who need to receive a treatment or test in order for 1 patient to benefit
    b. The number of physicians who need to treat a patient for the patient to benefit
    c. The number of times a physicians must perform a test or treatment in order to achieve excellence at it
    d. The number of patients a hospital must treat in order to avoid harming any

4. What is a definition of unnecessary care?

    a. Care that does not generate any patient benefit
    b. Care that does not generate any physician income
    c. Care that does not generate any hospital income
    d. More expensive care when less expensive care is available

5. What lesson can we learn from Atul Gawande's analysis of cystic fibrosis treatments?

    a. That beneficial medical care is a combination of science, art, human interactions and emotion
    b. That physicians who follow the guidelines most closely generate the best patient outcomes
    c. That physicians who ignore guidelines generate the best patient outcomes
    d. That medicine is almost exclusively a science and the best physicians are those who understand the underlying biological, physiological and anatomical processes the best

6. What does preference-sensitive mean in medical care?

a. That different patients, with the same medical condition, can choose different treatments and all be right
b. That different patients, with the same medical condition, should always choose the same treatment
c. That there is 1 correct treatment for a given medical condition and dozens, perhaps, incorrect treatments
d. That doctors often prefer to give different treatments to similar patients simply to add variety to their professional lives

7. According to this chapter, is the human body a big mechanical device?

a. Yes
b. No. People consist of bodies and minds. The wisest physician understands this and seeks to engage both when prescribing medical care

8. This chapter suggested 3 reasons why physicians prescribe unnecessary and low quality care. Which below is not one of those reasons?

a. Physician hopes and role responsibility, basically thinking 'this treatment *might* benefit my patient and I don't want to withhold any potential benefit'
b. Tort concerns, basically 'I might get sued if I don't do it'
c. The Upton Sinclair insight that 'it's difficult to get a man to believe something when his salary depends on him not believing it.' That's why surgeons tend to recommend surgery, therapists therapy and some providers routinely recommend the most expensive interventions
d. The boredom defense, basically 'I didn't have a lot to do in the hospital that day to I decided to provide some unnecessary care to break up the boredom'

Review Questions

Correct answers in bold

1. What is medical reversal?

    a. **Stop providing medical care when studies show that it doesn't benefit patients**
    b. Save a dying patient. In other words, reverse the biological process
    c. Have a different specialist undo the treatment you previously received
    d. Have a doctor change his/her mind as in 'I thought that Treatment A would help you but I was wrong, so now we'll try Treatment B.'

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Deductibles and Plan Management

Successful and sustainable healthcare cost control programs require that you teach your employees how to identify and avoid unnecessary, ineffective, wasteful and low quality medical care.

Attempts to control expenses with plan design changes or ancillary programs but without this educational component never live up to their billing.

Here's a condensed 50 year history of commercial health insurance:

- Cost sharing or 'major medical' in the 1970s was inflationary so replaced by
- First dollar coverage or HMOs – the opposite of cost sharing - in the 1980s and 90s. People found these plans too restrictive so replaced by
- High deductible plans - the opposite of first dollar coverage - post 2000. People complain about the deductible size and have trouble differentiating necessary and beneficial medical expenditures from unnecessary and wasteful.
- None of these programs integrated the necessary educational component into their fabric. Any would have been far more successful with it.

You've probably tried

- Wide hospital networks figuring more competition leads to lower costs and
- Narrow hospital networks figuring more carrier control leads to lower costs,
- Defined benefit plans to give employers more plan design latitude and
- Defined contribution plans to give employees wider choice, and
- Several other things that didn't work out too well …but never with a fully integrated employee education component.

The unwritten assumptions behind all these plans and design changes: the right financing program will motivate employees either to (a) use better medical care, (b) use less medical care or (c) use less expensive medical care.

History has conclusively shown these assumptions wrong.

Your employees will always find a way to access the medical services that they believe will improve their health whether or not that belief is valid. Attempting to influence their behavior with financing restrictions annoys them, doesn't work and doesn't improve their treatment outcomes or health.

The fundamental axiom
that any effective healthcare financing program honors

Good health is cheaper than bad health. That's universally and patently true.

So is its extension: the more quickly and efficiently you can turn an employee from sick to healthy, the less it costs, especially if you factor in absenteeism and presenteeism.

Better care quality – better outcomes in other words – is cheaper than poorer care. (Yes, I understand that some MRIs cost less than others. But I wonder how many are necessary and actually improve employee health.)

If your employees choose medical care based on likely outcomes, they'll get healthier and you'll save money. It's the best possible win-win.

But if your financing program tries to get them to choose medical care based on other criteria … not so much.

This presents a new focus

I suggest that corporate healthcare programs have as their #1 priority teaching employees how to choose care based on the outcomes they're likely to enjoy.

Design and develop that program first. This book can help. So can my online education program www.TheMedicalGuide.net.

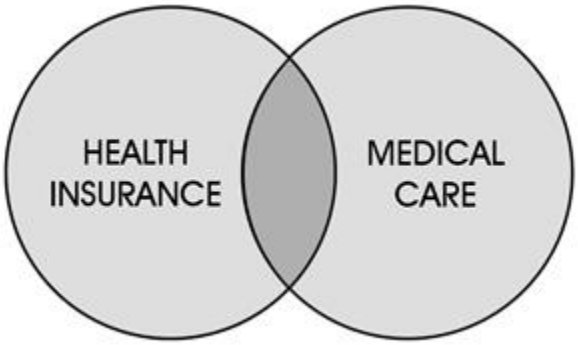
Then design a financing system to enhance and support your educational effort.

Don't do it the other way around.

The Old School approach currently in effect

Corporate engagement programs focus on understanding insurance coverage. Employees ask 'is the service covered?' and often conclude that 'if it's covered, I want it.'

The New School approach proposed in this book



The interesting work takes place in the overlap.

Corporate engagement programs include medical literacy.

Employees learn to ask 'is the service covered, *does it benefit me and do I want it*?'

What this chapter is about

Millions of well insured Americans get too many tests, take too many medications and have too many medical interventions. Our currently in-vogue benefits programs – deductibles, HSAs, wellness programs, etc. – haven't stemmed that tide.

Instead, I'll show you how to identify and avoid unnecessary, excessive, ineffective and low quality medical care.

I'll teach you the Five Most Important Questions to Ask Every Doctor, At Every Appointment, About Every Medical Intervention.

- If you learn, understand and ask these questions, you'll get better medical care with less risk. And you'll save a bunch of money along the way.
- If your company adopts this approach, it will save money and help its employees enjoy better outcomes with less intervention risk.

Too much care – and the wrong care - is bad for your health, both medical and financial. We currently waste according to many, up to $1 trillion annually. That's almost Russia's total GDP!

Consider these estimates.

- David Cordani, CEO of Cigna claims that slippage or 'things that don't work the way they're supposed to' accounts for at least 25% of all medical spending but 'probably much more'.
- Aetna's website says that 'wasteful spending likely accounts for between one-third and one-half of all US healthcare spending'.

- The Dartmouth Atlas, generally considered the bible of healthcare utilization analytics, suggests that up to about 1/3 of all US healthcare spending generates no patient benefit views this ‘as an underestimate given the potential savings even in low cost regions’.

The specifics may shock you. We Americans annually, for example,

- get 36 million prescriptions for a blood pressure lowering medication that doesn’t prevent heart attacks or save lives,
- spend $1 billion on a back procedure that works no better than a placebo,
- spend $3 billion on a knee procedure that can work less well than a placebo,
- spend over $2 billion on a cholesterol lowering drug that has not been shown to prevent heart disease or heart attacks according to its own advertising,
- and much more.

I’ll name names and provide details. I’ll also discuss some common medical procedures and show you that, for example,

- A quarter, maybe more, of the mastectomies in Connecticut generate no patient benefit.
- Half, maybe more, of the back surgeries in Fort Myers Florida generate no patient benefit.
- 30% or maybe even half of the c-sections in Florida, New Jersey and Louisiana provide no patient benefit.

This excess can lead to patient harms caused by medical care. Consider this trend:

- The 1999 Institute of Medicine report ‘To Err is Human’ found that up to 98,000 patients die annually from medical errors.
- Seventeen years later, a 2016 Johns Hopkins study found that over 250,000 Americans die annually from medical errors.

All this leads to a dismal healthcare summary:

- Americans spent $328 billion more for healthcare in 2015 than 2013. That’s about $1000 more per person.
- But we lived slightly less long in 2015. For the first time in decades, our national life expectancy actually fell despite the increased medical spending.

This gross inefficiency puts enormous responsibility on individual patients to choose healthcare wisely.

Step 1 of that process is acknowledging and understanding the problems.

Step 2 is learning how to make wise medical decisions.

How to make a wise medical decision

Follow this process to get better outcomes with less risk and at lower costs:

- First, determine how well the medical intervention works.
- Second, evaluate your treatment options. You almost always have them.
- Third, determine which doctor and hospital generates the best outcomes for your preferred treatment alternative.
- Fourth, if you find two or more equally excellent providers for your preferred option, consider price. But consider price fourth, only after you've completed the first three steps!

Asking the right questions gets you the information necessary for wise decisions.

But asking the wrong questions gets you … something else. Maybe useful information, but maybe just some of the most important information, maybe irrelevant (even if true) facts, maybe impressions, maybe incorrect information, maybe noise, who knows.

Obtaining the relevant information is a skill that most of us lack. In fact, according to the US Department of Health and Human Services, only 12% of Americans are medically literate, meaning they have the skills necessary to assess likely treatment benefits and harms though I suspect the real number – the percentage of people who understand and use the tools described in this book – is actually much lower.

Less medically literate folks have higher hospitalization rates and medical costs, and poorer health outcomes. This medical literacy problem arises because most of us haven't been taught how to approach medical investigations. This book will correct that problem.

The Goldilocks Rule
not too little, not too much, but just right

Too little medical care leads to undertreated patients and poorer-than-optimal outcomes.

Too much medical care leads to overtreated patients, higher-than-necessary treatment risks, higher-than-necessary medical costs and potentially poorer-than-optimal medical outcomes.

Inappropriate medical care leads to suboptimal outcomes, excessive costs, patient dissatisfaction and sometimes lawsuits.

Appropriate medical care minimizes your chance of medical harm but maximizes your chance of medical benefit.

Why can't I simply follow my doctor's advice and skip the rest of this chapter?

You always should consider your doctor's advice! But temper it with our questions for two main reasons:

First, doctors generally worry more about undertesting and undertreating than overtesting and overtreating patients. (This highlights a difference between advice giving and advice receiving, a situation I'll discuss in Question 4.)

- As trainees, they're upbraided for having too little information about their patients not too much information, so learn to overtest.
- As doctors, they're typically paid to do more not less, so may overtreat.
- As caring human beings, they want to do something to relieve your suffering, not nothing.
- As professionals operating in our legal system, they're more likely to be penalized for not doing something than for doing something extra.

One result is that about a third of patients annually receive one or more useless tests or treatments.

- Dr. Atul Gawande, a famous Boston area surgeon, found that 7/8ths of his patients had.
- Millions more, he writes, 'receive drugs that don't help them, operations that don't make them better and scans and tests that do nothing beneficial but often cause harm.'

Second, many doctors assume they know what patients want, their risk / reward tradeoff decisions. But studies show doctors can get this wrong.

- One, for example, showed that most doctors assume breast cancer patients rate 'living as long as possible' as their primary goal. But only 59% of patients agreed. Doctors were wrong about 40% of the time.
- A second showed that 40% of men with benign prostate disease opted against surgery once they were fully informed of surgical risks and benefits.
- A third showed that almost 20% of patients suffering from chest pain diagnosed as stable angina opted against surgery when fully informed of their treatment options and likely outcomes.

A fundamental cause of these problems is 'information asymmetry' or 'your doctor knows more about medical care than you do so thinks he or she understands your treatment goals and preferences too.' Gawande writes

We can recommend care of little or no value because it enhances our incomes, because it's our habit, or because we genuinely but incorrectly believe in it.

Patients often want to do their homework but don't know how. Some attempt to become mini-MDs through online research. That almost certainly won't protect against unnecessary, excessive or inappropriate care; the research is clear.

Instead this book will show you how.

It will put you onto a level (or, at least, a more level) field so you can participate more wisely and effectively in your own medical decision making.

The 5 Question Checklist
Medical Literacy in Practice

*If you **understand** these questions, you're medically literate.*

*If you **ask them**, you're ahead of the curve.*

*If you **get them answered**, you've maximized your chance of benefit and minimized your risk of harm.*

In a typical appointment, you and your doctor discuss a medical problem and your doctor recommends an intervention.

Ask these 5 questions about that recommendation:

- Has it been tested for the outcomes that concern me?
- Out of 100 people like me, how many benefit and how many are harmed?
- Is it overused?
- Would most physicians make the same recommendation or might some suggest something different?
- How many patients like me do you treat annually?

These deceptively simple questions are based on extensive research and analysis. The better you understand them and the more you integrate them into you medical thinking, the better care you'll get.

Ask them of every doctor, at every meeting, about every medical intervention.

You can use this list as a script. Feel free to share it with your doctors.

Question #1
Has it been tested for the outcomes that concern me?

Testing determines how well a medical intervention works in real life, on real people.

When testing, medical researchers typically divide a large group of people in half to make 2 identical smaller groups. They give one group the treatment but not the other.

Then researchers watch both groups for a time period, say 5 years, and note medical differences like the number of heart attacks, deaths or strokes. They attribute any differences to the intervention.

Simple! (Actually not simple at all. Medical research methodology is very complicated and worthy of many books, each much longer than this.)

But what happens if you don't have 5 years available? Say that a new blood pressure lowering drug just came on the market, looks promising and you, a person with high blood pressure, have a doctor's appointment the next day.

Your doctor may say 'this is the newest generation of blood pressure lowering medications and has been configured to reduce the side effects of the old drug. I suggest you try it and see how you tolerate it.'

In theory the new drug works well. But it hasn't been tested yet in real life, on real people, for years.

How well does it work?

Dr. Vinay Prasad, assistant professor of medicine at the Oregon Health and Sciences University, studies that issue. He asks 'how well do medical interventions work if they haven't been tested over long time periods on real people?'

How well, in other words, did medical theory hold up to subsequent testing?

Prasad and his team conducted a fascinating study. They reviewed every article in the New England Journal of Medicine between 2001 and 2010 and pulled out those that studied and tested an established medical practice, one commonly used on patients like intensively lowering blood sugar in Type 2 diabetics to reduce cardiovascular events … interventions, in other words, that made medical sense and that the medical community embraced.

363 studies qualified.

Prasad then asked 'Of those 363 studies, how many affirmed the practice?' i.e. found that it benefited patients.

38% affirmed the practice, 40% negated the practice, (found it ineffective or harmful) and 22% were ambiguous.

Dr. Prasad's research shows that if you base your medical decisions on biology, physiology, anatomy and logic – but not on test results – you are wrong about as often as you are right.

We'll call this Prasad's Law and refer to it throughout this book.

According to Dr. Prasad, rather than focusing on outcomes, patients often

> *gravitate toward the nuts and bolts — what does it do, how does it work?*
>
> *But the real question is: Does it work? What evidence is there that it does what you say it does? What trials show that it actually works?*
>
> *You shouldn't ask how does it work, but whether it works at all.*

Why is this the case?

Our bodies are enormously complicated and our understanding of medical risks, causality and treatment impacts is surprisingly limited. Sometimes (often?) rather than using the most important biological or anatomical factors in our medical theories, we use the most easily accessible and measurable.

Here's an analogy to illustrate:

Assume that our bodies are controlled by a wizard located in our brain, more or less like the fellow behind the curtain in the Wizard of Oz.

The wizard in our brain has a wall of knobs that control body parts and functions - one controls cholesterol levels, another blood pressure, a third bone density, a fourth eye ball pressure, etc.

If each knob is 1 inch in diameter and 1 inch apart (so the wizard can get his fingers around it) the wall is six and a half feet high and half a mile long!

Turning any one knob affects the value of some others, which in turn affect still others.

We simply can't anticipate all the initial effects, rebound effects, interactions and modifications from turning a knob or two.

Medicine rarely works in the simplified 'if A causes B, and B causes C, then A causes C' scenario. That's why we need to test.

Wise patients always ask 'has it been tested for the outcomes that concern me?'

If it has been tested, then your doctor can tell you how well it works. All physicians today can access extensive databases of medical studies…in their offices…in real time so they can answer this question.

If answers exist.

Asking this question may motivate your doctor to refresh his or her memory and look for new studies that have been published since the last time he or she checked.

You and your doctor can then decide if the intervention works well enough for you. I'll show you how in the next section.

But you may learn that the intervention has not been appropriately tested. In that case, you know your chance of benefit is only 50/50. Prasad's Law tells us that.

And even if it benefits you, it might not benefit you very much.

Examples of medical care that should work, but doesn't; Case studies that illustrate the power of asking this question

I'll present 6 case studies to show the power of asking 'has it been tested for the outcomes that concern me?' and why you need to ask this question about every medical intervention:

- Extended release niacin, a 'good cholesterol' boosting drug
- Atenolol, a blood pressure lowering drug
- Ezetimibe, a cholesterol lowering drug
- Vertebroplasty, a back surgery technique
- Arthroscopic knee surgery, a knee osteoarthritis remedy
- Rest after heart surgery, an historical example to tie everything together

Extended release niacin. Niacin, a B vitamin, has been shown in tests to raise good (HDL) cholesterol. More good cholesterol is associated with a lower heart attack risk, so artificially raising it should benefit patients.

Niacin doesn't lower total cholesterol like commonly prescribed statin drugs.

Cardiologists have prescribed various niacin products for years. One, Niaspin manufactured by Abbott Labs, generated about $900 million in 2009 sales.

Then in 2011, the AIM-High trial of niacin effectiveness showed that, while extended release niacin is associated with higher HDL levels and lower triglyceride levels, there was no significant reduction in cardiovascular events.

In 2013, a second study, this time of Merck's niacin drug Tredaptive found the same thing: no difference in coronary event rates between people taking Tredaptive with a statin, and those just taking the statin.

Two studies on two different niacin based drugs arrived at the same conclusion: niacin doesn't reduce rates of heart attacks or strokes.

This is an example of Prasad's Law: interventions that appear to make biological sense and that are adopted before publication of comparative tests are proven ineffective or harmful about half the time when they finally are tested.

Atenolol, a blood pressure lowering drug. High blood pressure is a common condition in which the long-term force of the blood against your artery walls is high

enough that it may eventually cause health problems such as heart disease. High blood pressure can damage the heart and coronary arteries and lead to heart attacks, strokes and death, among other events.

Lowering blood pressure, therefore, should reduce the number of heart attacks, strokes and deaths. So strongly do physicians subscribe to this theory that they write millions of blood pressure lowering medication prescriptions annually, worth billions of dollars, including 36 million prescriptions for Atenolol in 2010.

Atenolol recorded $161 million in 2014 sales.

Unfortunately comparative study hard outcomes do not always support the theory.

Start in 2002 with publication of the LIFE study on two of the most commonly prescribed blood pressure lowering medications called beta blockers, Losartan and Atenolol. Atenolol placed 2nd in preventing heart attacks and strokes.

Was that because Losantan was superior or because Atenolol was actually ineffective?

That question was answered in a 2004 meta review (a compilation that integrates results from several different studies to develop a single conclusion) in the Lancet entitled ‘Atenolol in hypertension: is it a wise choice?’

Those reviewers found that

> there were no outcome differences between Atenolol and placebo in the four studies, comprising 6825 patients, who were followed up for a mean of 4.6 years on all-cause mortality, cardiovascular mortality, or myocardial infarction [heart attacks].

The PubMed abstract summary concludes:

> Our results cast doubts on atenolol as a suitable drug for hypertensive patients.

The theme was then picked up in the March 15, 2005 issue of The American Family Physician, a publication of the American Association of Family Physicians. Dr. Henry Barry’s article ‘Should Atenolol Be Used for Hypertension?’ concluded that, though atenolol did lower blood pressure,

> It does not appear to reduce the rates of cardiovascular mortality or morbidity.

Let’s summarize:

- One major, high quality comparative study in 2002 concluded Atenolol is ‘inefficient’
- A large meta study in 2004 concluded ‘no outcome differences’ as compared to a placebo and cast doubts on Atenolol as a suitable drug for hypertensive patients.

- At least one article in a professional publication in 2005 seriously questioned the use of Atenolol.
- Five years later, docs wrote 36 million Atenolol prescriptions and nine years later Atenolol achieved $161 million in annual sales.

Medically literate folks – the ones who ask the questions in this book – could have saved those millions of dollars by avoiding Atenolol.

Would they have made wise decisions?

In January 2017, Cochrane released an update on beta blocker research. Cochrane researchers reviewed all relevant beta blocker studies published through June 2016, most of which focused on Atenolol. Their conclusions were entirely in line with the research discussed above, specifically that beta-blockers have little to no effect on heart attacks or mortality and are inferior to other anti-hypertension drugs.

I hope you're beginning to understand why you need to ask 'has it been tested for the outcomes that concern me?' about every medication. Even for medications that have been around for a long time.

Ezetimibe, a cholesterol lowering drug. Lower cholesterol is associated with fewer heart attacks. Ezetimibe, typically marketed as Zetia, blocks cholesterol absorption in the small intestine, unlike the more commonly prescribed statins that block absorption in the liver.

- Some patients can't tolerate statins.
- Others might not achieve their desired cholesterol reduction goals with statins and lifestyle changes alone.

Ezetimibe offers benefits to both types of patients. Consider this statement on Zetia's website, zetia.com from about 2011 – 2016.

Adding Zetia to a statin is proven to help reduce cholesterol more than a statin alone.

Zetia's sales exceeded $3 billion annually from 2013 - 2016.

But read the next sentence on Zetia.com, this one in bold:

Unlike some statins, Zetia has not been shown to prevent heart disease or heart attacks.

The New York Times review of Zetia's 2008 clinical trial, for example, concluded that no trial has ever shown that it can reduce heart attacks and strokes.

Note the difference between cholesterol lowering (Zetia has been shown to be good at this) and heart attack prevention (Zetia has not been shown to be good at this).

Then in 2014, the IMPROVE-IT study showed a ‘modest’ though statistically significant benefit of Vytorin (combination of Zetia and Zocor, a statin) over a statin only, but just for a very select group: patients who had already suffered a heart attack or experienced chest pain.

This underscores the need to ask your doctor regularly ‘Has it been tested for the outcomes that concern me?’ Be clear about the outcomes that concern you – heart attack reduction or cholesterol lowering. They’re not necessarily the same.

- Patients who conflated the two and focused on Zetia.com’s first claim that Zetia reduces cholesterol might have opted to take the medication but then only have received the cholesterol lowering benefit, not the heart attack reduction one. On the other hand
- Patients who relied only on the website’s second sentence ‘Zetia has not been shown to prevent heart disease or heart attacks’ - and who had previously had a heart attack - might have missed the heart attack prevention benefit discovered in 2014.

See why being medically literate is so important?

Vertebroplasty to relieve back pain Let’s switch focus now from medications to procedures. Consider vertebroplasty, a procedure to inject medical grade cement into fractured vertebra (back bones) to reduce back pain.

In 2008, the US market for vertebroplasty was $245 million.

Then in 2009 the New England Journal of Medicine published two studies comparing vertebroplasty to a control or placebo group that received lidocaine (a topical skin numbing agent), massage and aromatherapy to reproduce operating room smells.

- The Australian study found ‘no beneficial effect’ of vertebroplasty compared to the control group.
- The Mayo study concluded that patient improvements were similar in the placebo and experimental groups.

Vertebroplasty, in other words, worked as well as, but no better than, the safer and far cheaper placebo.

$245 million on a procedure that works no better than a placebo?

See why asking the ‘has it been subjected to comparative studies?’ question is so important?

Surgery for Knee Osteoarthritis Knee osteoarthritis is a degenerative disease that causes pain, stiffness and decreased knee function.

Arthroscopic surgery, including lavage (removal of particulate material such as cartilage fragments and calcium crystals) and debridement (surgical smoothing of articular surfaces and osteophytes) was the widely used treatment in the early 2000s despite the fact that, according to the New England Journal of Medicine in 2008 ‘scientific evidence to support its efficacy is lacking’.

Estimates of the number of knee arthroscopies performed annually in the US vary, and not all address osteoarthritis so we’ll have to estimate the size of this problem:

- A 2002 New England Journal of Medicine study estimated 650,000 procedures at $5,000 each, creating a $3.25 billion market.
- A 2014 NEJM study estimated the market at 500,000 knee arthroscopies at about $20,000, generating a $10 billion market.
- Vinay Prasad in his 2015 book Ending Medical Reversal estimated the market at 700,000 patients spending $4 billion.

How poorly does the scientific evidence support the efficacy of arthroscopic surgery to treat knee osteoarthritis?

- A 2008 New England Journal of Medicine published study concluded that they ‘failed to show a benefit of arthroscopic surgery for the treatment of osteoarthritis of the knee.’
- This followed a 2002 comparative study which concluded ‘At no point did [the] arthroscopic-intervention group have greater pain relief than the placebo group.’
- The 2002 study concluded ‘This study provides strong evidence that arthroscopic lavage with or without debridement is not better than and appears equal to a placebo procedure in improving knee pain and self-reported function.’

Those disagreeing with these study conclusions present the usual ‘weak study methodology’ case, primarily, I would suggest, to protect their incomes. Even at our lowest market estimate - $3 billion – that’s certainly a big incentive for lots of people to protect their turfs.

These studies raise some uncomfortable questions:

- Why, after the 2002 paper, did doctors continue to prescribe this procedure and patients have it?
- Why after the 2008 study did both parties continue to use it?

This is an extension of Prasad’s Law that says treatments adopted absent testing are proven ineffective or harmful about half the time. Here we have treatments used even after studies showed no patient benefit, underscoring the need for you to ask this question and insist on a clear answer about every medication and procedure.

Asking encourages your doctor to check (again?).

Never hurts but may help.

A lot!

Rest after heart surgery, an historical example to tie all this together.

We'll start in the early 1900s with Dr. James Herrick's advice then fast forward to today's protocols.

Herrick was an extraordinarily influential coronary care researcher who received impressive accolades from both the Association of American Physicians and the American Medical Association.

In his major 1912 paper, Herrick wrote that, after having a heart attack or heart surgery 'the importance of absolute rest in bed for several days is clear'.

Herrick's recommendations were adopted by most hospitals. Over time they extended Herrick's advice of absolute bedrest from several days to a few weeks.

Indeed, thirty four years after Herrick's paper, Dr. Thomas Lewis published his own coronary care textbook Diseases of the Heart and elaborated on Herrick's prescription:

Rest in bed should continue for 4 – 6 weeks to ensure firm cicatrisation of the ventricular wall … Patients have lost their lives … by neglect of these precautions.

Lewis' justification came from pathological studies showing that it can take 6 to 8 weeks for firm scarring of the lesion to occur. Rest for that amount of time was considered necessary to minimize ventricular rupture risks.

Dr. Paul Woods, another coronary care authority, reinforced that message in his textbook Diseases of the Heart and Circulation in 1959, 13 years later, recommending 3 – 6 weeks of bedrest or more depending on the severity of the heart attack.

Thus at least three medical textbooks written between 1912 and 1959 agreed: post heart attack and heart surgery, patients should rest, pretty much for as long as possible.

But by the 1960s medical opinion reversed. Eugene Braunwald, author of his own 2007 cardiology textbook, claims doctors began to realize that

Prolonged bed rest, which had been routine since Herrick's day, could actually be harmful in some patients by leading to venous thrombosis and fatal pulmonary thromboembolism. In uncomplicated cases, the duration of absolute bed rest was shortened to about five days.

Patients who asked 'what do you recommend doc?' in the 1940s and 50s would have received the long bedrest recommendation.

But patients who asked the same questions in the 1960s and 70s would have received the short bedrest advice.

And today, patients are advised to walk every day during the first 6 – 8 weeks post heart surgery, the exact opposite of Herrick's, Lewis's and Woods' recommendations.

How can 'rest' and 'don't rest' both be right? They obviously can't. At least one is wrong. Drs. Herrick, Thomas and Woods offered their best guesses backed up with biological justifications. In effect, they said 'our best guess is that the risk of ventricular rupture exceeds the risk of venous thrombosis and fatal pulmonary thromboembolism.'

Their guesses were really testable propositions which, apparently, weren't actually tested until relatively recently. When tested, they learned that thrombosis risks exceed ventricular rupture risks. Thrombosis and embolism risks are so high in fact that today's patients are advised not even to stand in one place for more than 15 minutes! The exact opposite of Herrick's, Thomas's and Woods' advice.

That's why wise patients don't research why a specific medical recommendation makes sense. Doctors and scientists can justify a wide range of (often conflicting) recommendations, just as we've seen here. Prasad's Law tells us that absent testing for specific outcomes of concern, those recommendations are wrong about half the time.

Instead of relying on theory, wise patients rely on test data, the facts.

The tragedy of this story is that some heart attack recovery patients presumably died in the last century from following the established protocols and textbook advice.

They didn't ask if the recommendations had been tested.

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Dozens, hundreds, perhaps even thousands of other 'makes sense but doesn't work' situations exist. Here are some relatively-easy-to-understand additional examples of Prasad's Law from his book Ending Medical Reversal.

- Estrogen replacement to reduce heart attacks in postmenopausal women. Testing showed no heart attack rate reduction.
- Coronary stent insertion to prevent heart attacks in patients with stable angina. Testing showed no impact on heart attack rates over time.
- Prophylactic antibiotics for people with persistent Lyme disease symptoms and a history of Lyme disease. Testing showed no symptom reduction.
- Lowering diabetic's blood sugar (A1c) below 7% to prevent heart attacks with an intensive drug regimen. Testing showed an increase in mortality rates.
- Calcium plus vitamin D to reduce the risk of hip fractures. Testing showed no hip fracture rate reduction but an increase in kidney stone risk.
- Withholding birth control pills for women with lupus to reduce the rate of lupus flares. Testing showed no increase in flares.

- Saw palmetto for benign prostatic hyperplasia. Testing showed no benefit measuring multiple outcomes despite more than 2 million men using it.

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ChoosingWisely, a program organized by the American Board of Internal Medicine Foundation to combat wasteful, unnecessary and harmful medical care lists 300+ more examples of medical practices that, according to testing, should not be used. ChoosingWisely is a wonderful resource for well informed patients. Here are a few examples for illustration purposes.

Don't automatically use CT scans to evaluate children's minor head injuries.

Avoid doing stress tests using echocardiographic images to assess cardiovascular risk in persons who have no symptoms and a low risk of having coronary disease.

Don't perform EEGs (electroencephalography) on patients with recurrent headaches.

Don't routinely treat acid reflux in infants with acid suppression therapy.

Don't recommend prolonged or frequent use of over-¬the-¬counter (OTC) pain medications for headache.

Don't routinely prescribe antibiotics for inflamed epidermal cysts.

Don't use systemic (oral or injected) corticosteroids as a long-term treatment for dermatitis.

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When you ask 'has it been tested for the outcomes that concern me?' you may learn how well it works. In that case you and your doctor can determine if the benefits are substantial enough, and risks low enough, for you to have the treatment. I'll show you how in the next section.

But you may learn that the treatment has not been tested in real life, on real people.

In that case, remember Prasad's Law.

Applying Prasad's Law to long term medication use

Some medications may have been tested for 1 year, say, but be prescribed for longer. What are the 8, 15 or 20 year effects, both positive and negative? We often don't know.

This is a version of Prasad's Law. In this case, the untested treatment is the time horizon. A medication with few side effects over 6 months may have major side effects over 10 years.

You can rephrase the testing question to 'Has it been tested for the length of time that I'm likely to be on it?'

Summary of Question 1
What We Have Learned So Far

Comparative tests tell us how well medical interventions work.

Wise patients ask ‘Has it been tested for the outcomes that concern me?’ and base their medical decisions on comparative test results. I’ll show you how in the next section.

Importantly, we also learned that interventions that make biological and anatomical sense are shown to be ineffective or harmful about half the time in comparative tests.

Patients who base their medical decisions on biology and logic – but not test results – are wrong about as often as they’re right.

Question #2
Out of 100 people like me, how many benefit and are harmed?

Determining how well care works from medical tests

Once you learn that a treatment has been tested, you and your doctor can discuss the impact. Use this phrasing:

- Out of 100 people like me, how many benefit? And
- Out of 100 people like me, how many are harmed?

This tells you how well the treatment works in testing circumstances. We’ll discuss how well it may work in real life circumstances in the next chapter.

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Ask ‘out of 100’ to get a number for your answer. ‘16’ conveys more information than ‘some’, ‘many’, ‘a few’ or ‘quite a few’.

Some patients may decide that 16 people benefiting is good enough to have the treatment while others say ‘only 16? That’s not very many.’ Different people can reasonably disagree.

Statements like ‘this treatment cuts your risk by 36%’ don’t answer the question! 36% of what? Percentage answers may confuse more than they illuminate.

Remember that Prasad’s Law applies if your doctor can’t answer the ‘of what’ question above.

Ask about ‘people like me’ because treatments can have different impacts on different demographic groups. Consider these examples.

Age: The American Academy of Pediatrics recommends against prescribing cough and cold medications for respiratory illnesses in children under 4 saying ‘these products

offer little benefit to young children and can have potentially serious side effects'. They're apparently fine for 6 or 8 year olds though.

… out of 100 people … these medications work, but

… like me … not if you're under 4 years old

Gender: In 2014, the Food and Drug Administration cut the recommended dose of Ambien, a sleep aid, in half for women after determining that men and women metabolize it differently. Women, it turns out, have more of the drug in their bodies the next morning, putting them at higher risk of impaired driving.

… out of 100 people … the medication works, but

… like me … not so well for women

Other patient differences exist but we don't always know how frequently. You and your doctor may have to estimate the impact on people like you.

Identify the benefits of interest to you. If you take a heart attack prevention medication ask 'out of 100 people like me, how many avoid a heart attack by taking this medication?'

- Remember our discussion of Atenolol and Zetia in the last section.

If you want to reduce your back pain, ask 'out of 100 people like me, how many enjoy less back pain as a result of this procedure?'

- Remember our discussion of vertebroplasty and knee surgery in the last section.

Beware of listing 'lower my cholesterol' or 'lower my blood pressure' as the benefit you hope to achieve. We discussed earlier how these 'test benefits' may or may not correlate closely to 'patient' or 'event' benefits. Focus on the benefits you hope to achieve.

And be as specific as possible.

Some case studies to indicate the power of asking this question

Out of 100 people like me, how many benefit and are harmed?

Consider antibiotics to treat pediatric ear infections, a quite common childhood problem. Ear infections can be painful to the child and frightening to the parents who, not unreasonably, want to do something to help.

Ear aches are sometimes viral and sometimes bacterial. Doctors often prescribe antibiotics.

This intervention – antibiotics to treat pediatric ear aches - has been studied so Prasad's Law doesn't apply.

A meta review – that's a compendium of several individual studies – of 15 studies on 4100 kids concluded that 6 in 100 who took antibiotics reported less ear pain after 2 – 7 days; 94 in 100 did not enjoy less ear pain as a result of the antibiotics. Most had a complete recovery within 2 – 7 days without the medication.

But 11 in 100 who took antibiotics suffered uncomfortable side effects like diarrhea.

- Out of 100 kids who take antibiotics to treat ear infections, how many benefit by enjoying less ear pain in 2 – 7 days? 6
- Out of 100 kids who take antibiotics to treat ear infections, how many are harmed by diarrhea or other uncomfortable side effects? 11

Now you have sufficient information to discuss this intervention with your pediatrician. Does it work well enough for your child? Some parents may decide yes, others no.

But in both cases, it's an informed decision made by a parent in light of the facts.

Dozens of similar cases exist. One website www.TheNNT.com lists about a hundred. ChoosingWisely www.ChoosingWisely.org takes a slightly different approach and lists hundreds more. Both sites will provide good information for you to discuss with your doctor.

Out of 100 people like me how many benefit and are harmed?

We already discussed how age and gender can impact outcomes. I'd like to explore a different, infrequently discussed but vitally important like me category: social status.

I'll define social status ambiguously as a combination of wealth, income and sense of control over your life, analogous to the way former US Supreme Court Justice Potter Stewart defined pornography: you know it when you see it.

The Whitehall studies in Britain first identified and quantified social status' impact on health. These studies tracked disease and death rates by job and rank in the British civil service and their conclusions have been reproduced in other studies, in other countries.

Whitehall found that low social status folks had higher disease and death rates than high status folks. Surprisingly – and this is the big deal - this was not only due to measureable factors like cholesterol, blood pressure, blood sugar, smoking, obesity or exercise rates.

After correcting for those factors, the lowest status folks were about twice as likely to have heart attacks, develop other diseases and die as the highest status ones.

Whitehall also found a gradient: the higher you are on the social status scale, the lower your disease and death rates and the reverse, the lower you are on the social scale, the higher your disease and death rates.

Over and above specific disease risk factors, Whitehall concluded, there is something about social status independently that impacts people's health. Harvard School of Public Health Professor Nancy Kreiger, whose own work affirms Whitehall's conclusions, put it this way:

> An individual's health can't be torn from context and history. We are both social and biological beings—and the social is every bit as "real" as the biological.

In line with this analysis, a major 2016 study in JAMA, the Journal of the American Medical Association found that the life expectancy gap

between the richest 1% of Americans and the poorest was about 12 years on a gradient similar to Whitehall's. In an accompanying editorial, Nobel laureate Angus Deaton emphasized the impact of income and social status on health and castigated traditional medical thinking:

The finding that income predicts mortality has a long history… the mortality gradient by income is found wherever and whenever it is sought…but the medical mainstream emphasizes biology, genetic factors, specific diseases, individual behavior, health care, and health insurance.

Consider the medical impacts of your own social status. Imagine your doctor says 'your cholesterol level is slightly high. The guidelines suggest lowering it. I'll prescribe a medication.'

- If you're a low status person (thus facing higher than average heart attack risks) you may be undermedicated, leaving you exposed to disease harms.
- But if you're a high status person (thus facing lower than average heart attack risks) you may be overmedicated, exposing you unnecessarily to medication harms.

Try to include social status factors in your 'like me' discussions with your doctor along with age, gender, general health status, family history etc. One good information source is the 2004 report 'Work, Stress and Health: The Whitehall II Study'. Share it with your doctor. It's surprisingly easy to read and it may change the way you think about medical care.

It certainly did for me.

'Out of 100 people like me…' or 'The guidelines say…'
Case study of hypertension

The American Heart Association recommends that people over 60 years old begin treatment for high blood pressure when their readings exceed 150/90.

But out of 100 people like that, how many benefit by following those guidelines?

Some answers come from a 2009 Cochrane report that summarized 15 trials totaling 25,000 subjects over age 60 with moderate to acute hypertension followed for average 4.5 years.

Out of 100 people over 60 years old with moderate to acute hypertension, how many avoid cardiovascular disease or death over 4.5 years?

Answer: About 4

Here are Cochran's numbers:

- Risk of cardiovascular death or disease without taking hypertensive medication: 14.9/hundred. This is the control group.
- Risk of cardiovascular death or disease among patients taking hypertensive medications: 10.6/hundred. This is the test group.
- Medication benefit: 4.3 fewer deaths or diseased patients/hundred (4.3%)

I don't know how many, if any, were harmed by the medication.

Which question gives you the best information and best helps you make the wisest decision: 'Out of 100 people like me, how many benefit?' or 'What do the guidelines say?'

It's your call.

Summary of Question 2
What We Have Learned So Far

Question 2 builds upon the lessons of Question 1.

Question 1 was 'Has it been tested for the outcomes that concern me?' We learned that comparative tests identify the benefits and harms of a medical intervention.

- Importantly, we also learned that medical interventions that have not been subjected to comparative testing are ineffective or harmful about half the time. We called this Prasad's Law.

Question 2 showed how to quantify the benefit and harm impacts. We learned to ask

- Out of 100 people like me, how many benefit? And
- Out of 100 people like me, how many are harmed?

We also learned

- Why to ask ‘out of 100’ and not to accept answers like ‘this treatment reduces you risk by 36%’.
- Why to ask about ‘people like me’, including about people in your socio-economic demographic.
- Why ‘patient outcomes’ always matter but ‘test outcomes’ may not.

Question #3
Is it overused?

Sometimes beneficial care is overused so may not benefit you

This question acts as a yellow warning light to wise patients: proceed but proceed cautiously.

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Testing sometimes shows that a treatment works well on a narrowly specified group of patients but, in the real world, doctors may offer it more widely, perhaps hoping to benefit even more patients.

Examples include mastectomies, back surgery, c-sections (I’ll discuss these three in some detail below), tonsillectomies, antibiotic prescription, prostate surgery, MRI use, coronary angioplasty and many more.

This results in treatment variation meaning that different doctors may treat similar patients differently.

Vast amounts of research into this phenomenon have identified three significant issues.

First, about 85% of the time, two or more treatments can generate the same patient outcomes.

Mastectomy or lumpectomy for early stage breast cancer, surgery or physical therapy for back pain, injections or physical therapy for frozen shoulder, etc. Though the outcomes may be the same, the process, pain, risk, recovery period, family impact and cost can vary widely.

Second, when faced with care options, many patients delegate decision making to their doctors. This forces the doctor’s preferences, not the patient’s, to define the treatment decisions and doesn’t always serve the patient’s best interests.

We’ll explore some implications in Question 4, the next section.

Third, the higher the supply of medical services in a region, the more frequently patients access those services: the more hospital beds, the more hospitalizations, the more MRI units, the more MRI tests, the more orthopedic specialists, the more orthopedic surgeries etc.

We'll discuss some implications in this section.

Excessive utilization raises costs and risks but doesn't improve patient outcomes. It may even worsen them since patients expose themselves only to potential treatment harms, not benefits.

We'll explore three case studies of treatment variation. Two are based on Dartmouth Atlas of Healthcare information: early stage breast cancer treatment in Massachusetts and Connecticut and back surgery in southwestern and southeastern Florida. The third is hospital baby delivery patterns, specifically c-section rates.

These are 3 of dozens I could have chosen. As you read them, consider how patients who have the more aggressive, excessive and overused treatments may actually end up worse off.

Case Study: Mastectomy Rates in Massachusetts and Connecticut

Female Medicare beneficiaries in Connecticut, using Connecticut hospitals, get about 40% more mastectomies per 100,000 than do similar women in Massachusetts. This has been roughly constant since 2008.

How can we determine if these surgical rate differences are driven by patient health differences or physician treatment orientation differences?

We'll first consider patient differences. The American Cancer Society tracks cancer incidence and mortality rates by state. They show that the breast cancer incidence rates for 2011 per 100,000 women are virtually identical in both states:

Based on breast cancer incidence rates alone the treatment variation appears driven by physician orientation, not patient disease rate differences.

Did the Connecticut women benefit from more mastectomies?

The American Cancer Society also tracks breast cancer mortality rates in each state. That's the rate at which women die of breast cancer. Again, they're virtually identical in both states.

If the higher rate of mastectomies in Connecticut from 2008 – 2011 generated patient benefit, we would expect to see lower Connecticut breast cancer mortality rates in 2011-2012 than in Massachusetts. That didn't happen.

Women asking the standard treatment questions – is this a good treatment? Do you get good results? Would you recommend this treatment for your wife, daughter or sister? – would get the same answers in Massachusetts and Connecticut.

But the Connecticut women wouldn't avoid those additional mastectomies.

The higher mastectomy rate in Connecticut generates no patient mortality reduction benefit. It only raises patient risks and costs.

Asking the ‘is it overused in this hospital or region’ question would help motivate physicians and well informed patients to review these kinds of data.

Follow up with ‘out of 100 women like me, how many benefit and are harmed by mastectomies?’

Really well informed women might also ask ‘would most physicians make the same treatment recommendation or might some suggest something different?’ I’ll introduce that question in the next chapter.

Case Study: Back Surgery in Florida

Medicare beneficiaries in southeastern Florida, around Miami, are about half as likely to have back surgery as Medicare beneficiaries in southwestern Florida, around Fort Myers.

Are retirees in Miami medically different from retirees in Fort Myers? John Wennberg, founder of the Dartmouth Atlas and professor emeritus at the Geisel School of Medicine at Dartmouth, answers with a resounding ‘no’ saying

There is no epidemiologic evidence that illness rates vary as sharply from one health care region to another as does surgery.

Do retirees in Miami prefer more aggressive care than retirees in Fort Myers? In other words, do Miami patients routinely ask for physical therapy for their back pain while Fort Myers patients typically ask for surgery?

Again ‘no’ but this time from Dr. James Weinstein, former Chairman of the Orthopedics Department at Dartmouth’s Geisel School of Medicine who has studied treatment variation for years:

It's highly improbable that Medicare retirees living in Fort Myers prefer back surgery two times as often as residents of Miami.

What causes the treatment variation? Wennberg again provides the answer:

Doctors decide who needs health care, what kind, and how much.

And the key patient benefit question: Do retirees in Fort Myers benefit from the extra back surgeries? In other words, do Miami retirees suffer unnecessarily from receiving too few back surgeries?

Though I was unable to find solid academic studies that specifically answer this question (!), Dr. Elliott Fisher and his Dartmouth colleagues addressed this issue in general in their massive 2003 study, ‘The Implications of Regional Variations in Medicare Spending’. One observation, paraphrased for readability here:

For every 10% increase in medical spending, the relative risk of death increased.

In none of the regions studied did the higher per capita expenditures lead to a statistically significant mortality decrease.

In other words more care, or care above the minimum available in any US region, led to more harm not more benefit.

Wise patients don't stop their questioning when they learn that a treatment is beneficial, as spinal surgery and mastectomy sometimes are.

Wise patients want to ensure that the treatment provides benefit to them. That takes additional questioning.

Acceptable and Unacceptable Answers to 'Is it overused?'

Acceptable answers include 'yes', 'no' and 'I don't know'. All can lead to a useful, additional discussion.

Unacceptable answers include 'we never perform unnecessary back surgery.' Fort Myers orthopedists and Miami orthopedists would say this about as frequently!

So would Connecticut and Massachusetts oncologists.

See the somewhat-famous-party-trick discussion coming up for further explanation.

Case study: C-section delivery rates at different hospitals

C-section rates vary tremendously among hospitals and regions. Some hospitals routinely deliver 40% or more of babies by c-section while others deliver 20% or less.

Similarly some states exhibit far higher average c-section rates than others.

We'll start our analysis with a 2011 New Hampshire Insurance Department study 'A commercial study of vaginal delivery and cesarean section rates at New Hampshire hospitals' that showed c-section rates varied between 15% and 47% of deliveries by New Hampshire hospital. That study concluded

There are no obvious reasons that explain why c-section rates are higher at one NH hospital than another …

there does not appear to be a relationship between c-section rates and health status among hospitals …

statistics show essentially no relationship between hospital population health and health status and c-section rates.

The NH study did not note outcome differences among hospitals suggesting similarity. (Major outcome differences would have been headline news and almost certainly included in this study.)

That raises the question: Do hospitals that perform more c-sections on similar populations generate healthier babies?

A second 2011 study addressed that, this time of 30,000 births at 10 upstate New York hospitals without specialized neo-natal intensive care units but with varying c-section rates. It found no difference in outcomes for babies born in the hospitals with the highest c-section rates and those with the lowest when outcomes are measured by Apgar scores, need for assisted ventilation, or need to move to intensive care hospitals.

Two studies, both showing different c-section rates by hospital without apparent patient health reasons or outcome differences.

Fast forward to 2013 and consider the conclusion of a Harvard School of Public Health study of 228,000 births in 49 different Massachusetts hospitals:

The same woman would have a different chance of undergoing a c-section based on the hospital she chooses …

Certain hospitals' high rates of cesarean births have more to do with characteristics of the hospitals themselves than with characteristics of their patients.

Harvard goes on to issue this caution:

While c-sections can be a lifesaving procedure for an infant in distress, or when there are multiple births or other labor complications, c-sections that are not medically necessary can put mothers and babies at avoidable risk of infection, extend hospital stays and recoveries, and increase health costs.

Again a beneficial medical intervention is overused and when 'not medically necessary' (Harvard's words) puts patients at unnecessary risk.

The same year, 2013, a different study by Dr. Katy Kozhimannil and others of 817,000 births in 593 hospitals nationally arrived at the same general conclusion. Kozhimannil found that c-section rates varied from 7 to 70 percent of all deliveries by hospital and suggested that provider practice patterns were a key driver of this rate variation.

Surgical variation rates were not, according to Kozhimannil, explained by hospital size, geographic location or teaching status…

The scale of this variation signals potential quality issues that should be quite alarming to women, clinicians, hospitals and policymakers.

More or less like the New Hampshire study, the New York study and the Harvard study.

Four different studies arrived at the same conclusion: c-sections benefit some patients but are overused so may not benefit – and may even harm – others.

To summarize:

- The hospital that you choose has a significant impact on your likelihood of delivering by c-section.
- Hospitals with the highest c-section rates don't necessarily serve the sickest, most at-risk populations.
- C-section rates vary significantly even among low risk mothers.
- Hospitals performing the highest rates of c-sections do not generate better outcomes than hospitals performing lower rates.

These treatment variation situations get replayed for dozens of procedures including

- tonsillectomies
- coronary stent insertions
- heart valve replacements
- referrals for CT scans
- hip replacements
- radical prostatectomies, and others.

Dartmouth researchers estimate that if you add all the excesses above the minimum, for lots and lots of procedures, you'll arrive at about 1/3 of all medical spending. I'd recommend that anyone interested in this topic visit the Dartmouth Atlas website and click around. It's packed with fascinating, potentially life-saving information.

A somewhat famous medical party trick story
showing that even great doctors in great hospitals practice differently

John Wennberg, more or less the godfather of treatment variation analytics in this country, performed a party trick of sorts to show how doctors practicing at highly regarded hospitals can treat similar patients differently.

He used Boston, home to Harvard Medical School affiliated teaching hospitals, and New Haven, home to Yale Medical School affiliated hospitals, as his case study.

Wennberg learned that Boston area patients spent about 40% more time in the hospital:

- A Boston patient suffering from gallstones would be 40% more likely to be hospitalized than a similar patient in New Haven.
- A patient hospitalized for surgery that required 1 night in a New Haven hospital would often have spent 2 nights in a Boston hospital.

He wondered if the New Haven docs felt they undertreated patients or if Boston docs thought they overtreated. When asked, doctors in both cities claimed to treat patients appropriately.

Which were right? They can't both be.

To answer that question, Wennberg presented his findings at New Haven and Boston medical conferences, but he accidently-on-purpose switched the data!

He showed the Boston docs that their patients spent 40% less time in the hospital and therefore received less care than New Haven patients, and vice versa, and asked for explanations.

- The Boston docs came up with lots of reasons why the New Haven ones erred by overtreating their patients, admitting too many to hospitals and therefore exposing them to unnecessary treatment risks and financial costs.
- The New Haven docs explained why the Boston ones erred by undertreating their patients, admitting too few to hospitals and therefore exposing them to unnecessary disease risks.

Wennberg then admitted his data mistake and went through the (presumably uncomfortable) analysis of the doctors' faulty reasoning.

The bottom line: though doctors all want to treat appropriately – and claim to - they are often unaware of their own assumptions and treatment patterns.

That's why wise patients always ask our questions and demand answers…

Even from the most experienced doctors who graduated from the most famous medical schools and work at the most prestigious hospitals!

Summary of Question 3
What We Have Learned So Far

Question 3 builds upon the lessons of Questions 1 and 2.

Question 1 was 'Has it been tested for the outcomes that concern me?' We learned that comparative tests identify the benefits and harms of a medical intervention.

- Importantly, we also learned that medical interventions that have not been subjected to comparative testing are ineffective or harmful about half the time. We called this Prasad's Law.

Question 2 showed how to quantify the benefit and harm impacts. We learned to ask

- Out of 100 people like me, how many benefit? And
- Out of 100 people like me, how many are harmed?

Question 3 moved us out of the laboratory and into the real world. We learned that sometimes beneficial medical interventions are overused. We learned to ask

- Is it overused?

Appropriate answers include ‘yes’, ‘no’ and ‘I don’t know’.

Inappropriate answers include ‘we never perform excessive or unnecessary treatments.’

We’ll move now to Question 4 ‘Would most physicians make the same recommendation or might some suggest something different?’ This helps you identify your treatment options.

While always important to ask, this question is particularly critical for patients who learn that the answer to Question 3 is ‘yes, we sometimes perform this procedure too often’.

Question #4
Would most physicians make the same recommendation or might some suggest something different?

How to get and evaluate a second opinion

We learned earlier that patients have care options about 85% of the time. Often two or more treatment processes generate the same patient outcomes.

But the treatment processes can involve quite different pain levels, family impacts, recovery periods, costs and other factors.

Researchers have learned that, for the 85% of care that allows for choice, wise and well informed patients may prefer treatments different from that recommended by their doctors.

And two different patients with the same medical problem can choose different treatments and both be right.

Unfortunately, since patients today often delegate decision making to doctors, physician preference rather than patient preference often determines which treatment patients ultimately receive. That’s not always such a good thing.

Preference-sensitive decision making among patients with access to good information

Various studies have assessed the impact of patient education on preference-sensitive decision making and have generally arrived at the same conclusion: when provided with good information about both outcomes and processes, patients tend to prefer less invasive and lower risk care.

The general trend is about a 20 – 25% shift.

Coincidentally, less invasive / lower risk care tends to be less expensive.

One 2012 study in Washington State found that patients who went through a thorough treatment comparison process had 26% fewer hip replacement surgeries, 38% fewer knee replacements and cost about 15% less than patients who did not go through the same process.

Other studies have indicated

- 20% fewer stent insertions
- 40% fewer prostate removal surgeries
- 40% fewer spinal fusion surgeries for herniated disks

These studies and others suggest that physicians need to diagnose both the medical condition and the patient to prescribe the appropriate intervention. A classic analysis, Patient Preferences Matter, written by two medical school professors and one business school prof, highlights the impact:

> Health care may be the only industry in which giving customers what they really want would save money.
>
> Well-informed patients consume less medicine – and not just a little bit less, but much less.
>
> When doctors accurately diagnose patient preferences, an enormous source of waste – the delivery of unwanted services – is eliminated.

In other words, when doctors assume they know which treatment process a patient wants, they substitute their own preferences for the patient's.

That's not always wise because there's a huge difference between advice giving and advice receiving. The advice recipient may or may not agree with the advice giver.

Here's a list of some potential preference-sensitive considerations that affect physician 'advice givers' differently from patient 'advice receivers'. It's not exhaustive. I didn't include 'success' since it's obviously the most important consideration of both doctors and patients.

Some physician issues and concerns	**Some patient issues and concerns**
Regulations and guidelines	Pain
Fear of lawsuit	Recovery period
Local / regional / hospital norms	Family impact
Income	Self image
Experience with treatment alternatives	Personal preference (e.g. religious)
Avoid feeling guilty	Cost

The question ‘what would you do if you were me, doc?’ is unfair. The physician-advice-giver can’t remove him or herself entirely from the constraints imposed by that role.

How to proceed after getting a second (or even third) opinion

Once you’ve had a second (or third) physician make treatment recommendations, use this chart to compare benefits and harms. Try to fill in as many boxes as possible. Include Treatments C and D as appropriate

	Treatment A	Treatment B
Benefits and harms at intervention		
Benefits and harms over the short term		
Benefits and harms over the long term		

Each patient can define benefits and harms as those most important to him or her, as well as the short and long term. Typically short term means the first few months and long term 3 – 5 years, though you can modify these definitions as you see fit.

Here are some issues in a hypothetical comparison of surgery and physical therapy for illustration purposes only. You may have different concerns.

First, benefits and harms of the intervention.

Surgery	Physical therapy
How long will I be hospitalized?	How many sessions will I need?
How much pain will I feel and for how long?	How much pain is associated with the therapy process?
How much work will I miss?	When will I know if the therapy is working?
How long will I be incapacitated?	
How likely is an infection or complication?	

Second, benefits and harms over the short term.

Surgery	Physical therapy
How long before I regain my strength and range of motion?	How often do patients report satisfaction at 3 and 12 months?
How many patients report satisfaction with the outcomes at 3 and 12 months?	How many patients quit PT and opt for surgery in the short term?
How often do patients need a second surgery?	

Third, benefits and harms over the long term

Surgery	Physical therapy
How many patients need a second surgery within 48 months?	How many patients report satisfaction with the PT outcome at 48 months?
How many patients report satisfaction with the outcome at 48 months?	How many patients who start with PT ultimately end up with surgery within 48 months?

This comparative process isn't limited to surgery and PT: you can use it to compare any medical interventions, though the specific questions in each box may differ.

Try to format your treatment comparisons this way. It will help you focus on the most critical issues and streamline your decision making process.

Feel free to show a chart like this but with your own questions to your doctor. It may facilitate your discussions.

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Case Study: How John decided on physical therapy for his torn rotator cuff

John, a 69 year old insurance broker, walked up to me in a lecture hall one day with his arms high in the air, smiling and saying 'my shoulder feels fine'.

Odd behavior and greeting in a professional setting. I hadn't seen or talked with him in the previous year or two.

His right shoulder had been so weak, he said, that he couldn't shift gears in his pick-up: he had to reach over the steering wheel with his left hand to shift.

His scans clearly showed a torn right rotator cuff and his orthopedic surgeon recommended surgery. All fairly routine.

But his story then took a surprising turn. I'll quote him:

'I probably would have said yes to surgery prior to hearing your lectures. Instead I asked your questions and decided to try PT first.

I regained 95%+ range of motion without pain in same time period as surgical recovery.

Same outcome as surgery at far lower cost, risk and hassle.'

The key questions:

Out of 100 people like me, how many benefit from, and are harmed by, rotator cuff surgery?

Would most physicians recommend rotator cuff surgery or might some suggest something different?

Interestingly John, a well-educated, knowledgeable, regular attendee at insurance seminars, wouldn't have asked those questions absent specific instruction and a script.

I suspect a similar situation exists for most patients like the Fort Myers back surgery folks and Connecticut mastectomy women we discussed earlier.

They all might have made different choices had they simply been taught to ask the right questions.

****

Another patient's experience asking the 'out of 100 people like me' and the 'would most physicians agree' questions.

'Preference-sensitive' applies to physicians too!

A fellow called me with this poignant story one day, completely out of the blue. He had attended a lecture and read my book Transparency Metrics.

I have a good relationship with my cardiologist, so I felt comfortable asking your 'out of 100 people like me' questions. So I did.

He put down his pen, looked at me and said 'no one has ever asked me that. I don't know the answer. Let's figure it out' and he started typing on his computer.

The process of finding answers got me involved and I ended up feeling more comfortable with his treatment recommendations as a result. I feel like I now have an even better working relationship with him than I did before.

I'm also more inclined to comply with his recommendations.

I asked a few questions then he announced 'now I have to tell you about my next experience'.

I asked my dermatologist the same questions including 'would most physicians agree with your recommendation?'

His response: 'you come into my house and ask me those questions? If you don't trust my judgment, I think you should get another dermatologist.'

Different doctors for different patients.

Preference sensitive works for physician choice also.

Choose the doctor whose style and professional demeanor work for you.

Summary of Question 4:
What We Have Learned So Far

Question 4 builds upon the lessons of Questions 1, 2 and 3.

Question 1 was 'Has it been tested for the outcomes that concern me?' We learned that comparative tests identify the benefits and harms of a medical intervention.

- Importantly, we also learned that medical interventions that have not been subjected to comparative testing are ineffective or harmful about half the time. We called this Prasad's Law.

Question 2 showed how to quantify the benefit and harm impacts. We learned to ask

- Out of 100 people like me, how many benefit? And
- Out of 100 people like me, how many are harmed?

Question 3 moved us out of the laboratory and into the real world. We learned that sometimes beneficial medical interventions are overused and learned to ask

- Is it overused?

The answer helps identify at least one critical reason for asking Question 4 'Would most physicians make the same recommendation or might some suggestion something different?'

There are several additional reasons for posing this question to your physician including:

- It helps you get a second opinion that differs from the first thus exposing you to a range of treatment options.
- It helps you differentiate personal preferences from medical imperatives.

Once you identify the treatment option that you prefer, you'll want to identify the physician and hospital that does it the best. Ask Question 5 'How many patients like me do you treat annually?'

Question #5:
How Many Patients Like Me Do You Treat Annually?

The more experience a specialist or hospital has treating patients with your medical condition, the better your likely outcomes

Research has identified a pretty strong (but not perfect!) correlation between the volume of similar patients treated by a specialist or hospital and the outcomes for those patients: The higher the volume, the better your chances.

This is not a perfect predictor but it's about the best predictor currently available.

One classic study on the impact of hospital volume on mortality rates was published by Dr. John Birkmeyer of the Dartmouth-Hitchcock Health System and his colleagues. They analyzed the impact of hospital volume on mortality rates for 2.5 million patients who underwent 14 different medical procedures over a 5 year period.

Patients, they concluded, can significantly reduce their operative mortality risk by choosing a high volume hospital. Though the specific mortality rate reduction varied by procedure, Birkmeyer and his colleagues identified a surgical quality gap between high and low volume hospitals.

They concluded three things about this gap:

First, it is large enough to concern patients.

Second, it is consistent across different medical specialties and research studies, and

Third, it makes sense. High volume hospitals, they reason, tend to have more consistent processes for postoperative care, better-staffed intensive care units, and greater resources for dealing with postoperative complications.

Other research pretty strongly supports Birkmeyer's conclusions:

A 2011 study of heart failure patients estimated that 20,000 lives could be saved annually if patients at low volume hospitals switched to high volume hospitals.

A study of bariatric surgery found that hospitals treating more than 100 patients annually had shorter lengths of stay, lower mortality rates and decreased costs. In particular, bariatric surgical mortality rates at low volume hospitals were up to 3x higher than at high volume hospitals for patients over 55 years old.

A 2013 study of high risk patients found those undergoing aortic valve replacement at high volume hospitals enjoyed better outcomes.

Studies of breast cancer treatment, knee surgery and other medical care finds pretty much the same things.

By contrast, studies comparing patient outcomes from newer vs. older technologies, or from academic medical centers vs. other hospitals, do not always find such a gap.

One such newer vs. older technology study found that physicians need to perform 1600 robotic assisted prostate removal surgeries to achieve excellence. Experience with the technology, often more than the technology itself, correlates with quality outcomes.

We find the same thing for surgeons – the higher their volume of a particular type of surgery, the better their outcomes. Dr. Paul Ruggieri summarized the literature on this topic in Chapter 5 of his book The Cost of Cutting:

> The message is becoming clearer with each published study. High volume surgeons operating out of high volume hospitals give patients the best chance for quality outcomes.

Based on the data, the high volume surgeon part of the equation seems to be the most important factor.

Ruggieri, a surgeon, might be slightly biased.

But Birkmeyer, the Dartmouth physician, agrees with Ruggieri's assessment, concluding that patients can improve their chances of survival substantially, even at high volume hospitals, by choosing high volume surgeons.

Thresholds

Some organizations publish 'thresholds' or recommendations for the minimum experience a surgeon or hospital needs to achieve excellence. Treating fewer than the threshold number of patients tends to increase mortality rates but treating more doesn't decrease those risks.

The Leapfroggroup, for example, has developed hospital threshold recommendations for several procedures such as

- Coronary artery bypass graft, minimum 450 procedures/year.
- Abdominal aortic aneurysm repair, minimum 50 procedures/year.
- Percutaneous coronary intervention, minimum 400 procedures/year.

Johns Hopkins, Dartmouth-Hitchcock and the University of Michigan go one step further and have developed minimum hospital and surgeon requirements for their affiliated hospitals including

- At least 20 pancreatic cancer surgeries per hospital per year, and at least 5 for each surgeon.
- At least 50 knee or hip replacements per hospital per year, and at least 25 per surgeon.
- At least 10 carotid stent insertions per hospital per year, and at least 5 per surgeon.

John Birkmeyer, the leader of the Dartmouth effort, suggests the impact. If all US hospitals adopted this standard, he says, about half the hospitals that perform many of these procedures would be prohibited from continuing to do them.

Wise patients choose specialists and hospitals working at or above the recommended threshold.

Why is experience so important?

The common sense answer that 'practice makes perfect' is only part of the reason, and the least important part. Physicians learn the process of cutting, suturing, etc. relatively quickly. Though these mechanical skills may improve slightly over time, this doesn't address the significant mortality reduction evidenced by high volume surgeons and hospitals. Few patients, it seems, die from faulty incisions.

Instead, I suggest that the true benefit of dealing with high volume surgeons and hospitals comes from their ability to identify patients who are 'out of bounds' more quickly and address their problems more appropriately. With volume a surgeon can sense, almost even without testing, that something is wrong.

Without the experience that volume brings, the surgeon is unsure if the patient's blood loss or reactions are within the normal range. This applies at a systemic level to hospitals also: nurses and technicians can develop the same sense from experience.

Atul Gawande wrote insightfully about this process in his article 'The Computer and the Hernia Factory', a study of Shouldice Hernia Hospital in Canada. Shouldice only performs hernia surgeries. Each Shouldice surgeon performs about 700 annually or, over their medical career, perhaps 20,000 similar surgeries. Gawande estimated, in 2002, that Shouldice's hernia surgery failure rate was 'an astonishing 1.0%.' He revised that figure in 2008 to 'closer to 0.1%'.

By comparison, some studies suggest an average 10-year hernia repair failure rate outside of Souldice at around 11%.

With repetition, Gawande found, 'a lot of mental functioning becomes automatic and effortless, as when you drive a car'. This allows experienced practitioners to focus on novel or abnormal situations and essentially ignore all that is normal and routine. A surgeon, he writes, for which most activities become automatic has a significant advantage.

He described a Shouldice operation:

- The surgeon performed each step ‘almost absently’
- The assistant knew ‘precisely which issues to retract’
- The nurse handed over ‘exactly the right instruments; instructions were completely unnecessary’
- The doctor slowed down only once, to check ‘meticulously’ for another hernia. He found one that ‘if it had been missed, would almost certainly have caused a recurrence’

This ‘almost absent attention to routine features’ but intense focus on potential abnormalities comes only from experience. That’s why higher volumes identify better quality surgeons and hospitals.

Just like why more experienced drivers have fewer car accidents!

When you consider hiring a specialist or using a hospital, be sure to ask the volume question. It just may save your life.

Summary

Let’s review what we’ve learned:

Patients who follow the Goldilocks principle enjoy better outcomes than patients who do not.

- Too little medical care can expose you unnecessarily to disease harms
- Too much medical care can expose you unnecessarily to treatment harms
- Inappropriate medical care can expose you to more risks, higher costs and lower satisfaction than optimal

We introduced 5 questions to ask all doctors about all medical interventions.

- Has it been tested for the outcomes that concern me?
- Out of 100 people like me, how many benefit and are harmed?
- Is it overused?
- Would most physicians make the same recommendation or might some suggest something different?
- How many patients like me do you treat annually?

You can, of course, ask plenty of your own questions too: you may have specific concerns about pain, cost, time off from work, impact on your family, etc.

But I hope you ask the questions listed here. They'll help you differentiate better from poorer care, reduce your chance of receiving unnecessary and non-beneficial care and increase your likelihood of satisfaction with your own medical care.

Review Questions

Answers on next page

1. What is a comparative study?

    a. A study that compares two very similar groups of people, one of which gets the medical intervention and the other of which does not
    b. A study that looks at only 1 group of people
    c. A study that predicts outcomes based on biological theory
    d. A study that compares the biological and physiological make up of different people

2. What is a well informed patient according to the medical definition of ‘well informed’?

    a. Understanding how well care works, what treatment options exist and which provider generates the best outcomes
    b. Understanding deductibles, insurance regulations and prices
    c. Understanding the biological processes in each treatment option
    d. Someone who reads lots of articles online

3. Which do doctors generally worry about the most?

    a. Performing too few tests and undertreating patients
    b. Having patients wait longer in their waiting rooms
    c. Providing interesting magazines for patients to read
    d. Performing too many tests and overtreating patients

4. Which is the cheapest?

    a. Good health
    b. The lowest cost knee surgeon
    c. A hospital-based MRI
    d. A free-standing MRI

5. Which strategy is generally the cheapest after factoring in all costs including patient out-of-pocket, deductibles, insurance premiums, time off of work, productivity losses and rehab expenses?

    a. Getting the best treatment outcomes
    b. Getting care from the lowest cost surgeon
    c. Paying cash for your treatment
    d. Negotiating the best deal you can with each provider

6. Why would a wise patient ask a physician if a proposed treatment has been subjected to comparative testing?

    a. Because treatments that have not been subjected to comparative testing are ineffective or harmful about half the time

b. Because it makes you sound smart to your doctor
c. Because you want to show your doctor who's really running the meeting
d. Because you want to waste time before making an important decision

7. What is Prasad's Law?

a. Medical treatments that have not been subjected to comparative testing are ineffective or harmful about half the time
b. A hospital room built is a hospital room occupied
c. The most expensive surgeon is the best
d. The most expensive hospital generates the best patient outcomes

8. Which benefits more people?

a. A treatment that prevents heart attacks 3 out of 100 people
b. A treatment that cuts the heart attack rate by 25%
c. A treatment that reduces total cholesterol levels by 10 points
d. We have insufficient information in (a), (b) and (c) above to answer the question

9. Which benefit interests a wise patient the most?

a. A reduction in heart attacks
b. A reduction in cholesterol levels
c. A reduction in blood pressure levels
d. An improvement in blood oxidation rates

10. This chapter suggests that patients who base their medical decisions on biology, physiology, anatomy and logic – but not comparative studies – are what?

a. Wrong about as often as they are right
b. Wise and thoughtful
c. Using the best possible information
d. Likely to enjoy the best outcomes

11. As the number of medical services in a community – like MRI machines, vascular surgeons or hospital beds – rises, what tends to happen?

a. More patients use those services
b. Fewer patients use those services
c. Service prices tend to fall
d. Care quality tends to decline

12. Wise patients sometimes ask if a particular treatment is overused. Which below in an inappropriate answer to that question?

a. Yes
b. No

c. I don’t know
d. I never provide unnecessary care

13. What is a ‘preference sensitive’ medical decision?

a. A decision that’s right *for you*. Different patients with the same medical condition can choose different treatments and all be right.
b. A decision that your doctor would prefer that you make, not him or her
c. Delegating your decisions to your doctor
d. Delegating your care decisions to your hospital

14. What is the general trend among patients who explore their treatment options?

a. They tend to choose less risky, less invasive and consequently less expensive care by about 25 – 30%
b. They get confused
c. They ultimately do what their doctor tells them to do
d. They cost the most

15. What is the main purpose of second opinions?

a. Expose patients to a range of treatment alternatives
b. Waste time
c. Increase physician billing opportunities
d. Confuse patients

16. Which surgeon generally generates the best patient outcomes?

a. The surgeon who does a specific type of surgery most frequently
b. The surgeon who graduated from the most prestigious medical school
c. The surgeon who charges the most
d. The surgeon who uses the newest technology

Review Questions

Correct answers in bold

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Price transparency and CDH Plans

Dr. Clifton Meador, former dean of the University of Alabama Medical School, issued this caution about the role of financing and prices in American medicine: (references available offline)

> Solutions to the high costs of medical care are almost exclusively financial or payment based [but] the underlying causes are based on misdirected clinical and diagnostic thinking

In other words, Meador cautions us about using financial tools like price lists to address clinical problems.

Dr. Andy Lazris, geriatrician and author of Curing Medicare, agrees, decrying our medical care system that

> pushes the most aggressive care, often despite a paucity of evidence to support that approach …as little as 15% of what doctors do is backed up by valid evidence

Prices can vary dramatically for the same service throughout our healthcare system. 'Transparency' means 'making prices public so people can choose the most economical alternative'. Some say this increases systemic value.

I'm not so sure.

Some pricing examples

Here are some graphic examples of price differences within a relatively small geographic region for the same services. These prices come from the New Hampshire medical price website, nhhealthcost.org, downloaded in 2013 for arthroscopic knee surgery. I chose this website because it was public and easy to use.

Facility	**Total Cost**
Concord Ambulatory Surgery Center	$3,431
Franklin Regional Hospital	$5,118
Cheshire Medical Center	$6,644
Parkland Medical Center	$7,717
Weeks Medical Center	$9,873

Pretty wide variation for the same service. Here are some prices for a pelvic MRI, same website.

Facility	**Total Cost**
Derry Imaging Center	$1,486
St Joseph Hospital	$2,574
Exeter Hospital	$2,758
Speare Memorial Hospital	$3,381
Monadnock Community Hospital	$3,868

Impressive differences. The same situation occurs for dozens of tests and treatments throughout our healthcare system.

Why prices matter (a lot)

Paying too much for a test, medication or treatment *directly* affects two groups of people: individuals / families with high deductible health plans and self insured companies. Both, in an economic sense, function the same way – they spend their own money on medical care. Each dollar saved drops directly to their own bottom line.

Paying too much *indirectly* affects us all by raising overall costs and therefore health insurance premiums.

Thus, the argument goes, considering price generates benefits for us both individually and collectively.

Why prices don't matter (much)

Prices do not tell us

- If we will benefit from the medical care
- If we will be harmed by the medical care
- If we use excellent, average or mediocre providers and treatments.

In short, shopping for medical care primarily based on price can lead patients to cheaper unnecessary or poor quality medical care. And, since it's cheaper, perhaps to *more* unnecessary or poor quality care.

How much unnecessary and poor quality care exists in the US?

The standard estimate of unnecessary care quantity in our healthcare system today is about 1/3. That comes from the Dartmouth Atlas of Healthcare and is based on the amount of geographic treatment variation identified by studying Medicare intensity levels by geographic region. Some regions routinely provide more care to residents while others routinely provide less. The Dartmouth researchers added up all the differences and concluded that the variation equaled about 1/3 of all medical spending.

With our total healthcare expenditures approaching $3 trillion annually, this '1/3' estimate accounts for about $700 billion annually and perhaps as much as $900 billion. Aetna claims the actual amount is at least $765 billion.

But I think this a low estimate, and perhaps a very low one based on two analyses that we'll discuss in some detail later in this chapter.

- First, Dr. Vinay Prasad and his team from the National Cancer Institute and National Institutes of Health, in a very rigorous, detailed study, estimated that about half of all established treatments are ineffective or harmful.[175]

  If we cut geographic 'low intensity' utilization rates by about half to account for Prasad's findings, **we might double the Dartmouth waste estimate to $1.5 trillion *or more***…potentially well over half of all medical spending.

- Second, Dr. Al Mulley and his team from Dartmouth Medical School estimated the potential systemic savings from incorporating patient preferences into treatment designs at about 20%.[176] Mulley's insight, along with others who have studied the same phenomenon, was that patients who understood their options tended to choose less medical care – both a lower number of procedures and less intense / aggressive / expensive ones.

  If we cut geographic 'low intensity' utilization rates by 20% to account for Mulley's findings, **we increase the Dartmouth waste estimate to about 40% of all medical spending.**

Add the Prasad and Mulley numbers to Dartmouth's original waste estimate and you get a very large number. I think a perfectly reasonable, even conservative estimate is 40% of all medical spending.

But I won't argue with higher estimates.

Overestimating treatment benefits

[175] Prasad, A decade of reversal, Mayo Clinic Proceedings, August 2013

[176] Mulley, Patient Preferences Matter, The King's Fund, 2012 http://www.kingsfund.org.uk/sites/files/kf/field/field_publication_file/patients-preferences-matter-may-2012.pdf

Patients typically overestimate the benefits of medical care and underestimate the risks. Sometimes they think all the tests, drugs and treatments are crucial to maintaining their health. Other times they discount the risk and side effect warnings. Still other times they think the care quality is all equally good from all providers.

In general, patients seem to think that medical care is always – or, at least *almost* always - beneficial and necessary.

But patients often miss on their benefit estimates and overstate them by quite a bit. One study, for example, found that women without the BRCA genetic mutation overestimated their cancer risk reduction benefit from prophylactic bilateral (double) mastectomy 4 fold or more. [177]

- The average estimated risk reduction was 65%. Most women in the study group estimated their chance of developing breast cancer *without* surgery at 76%, and their chance of still developing breast cancer *with* the double mastectomy at 11%.
- Meanwhile, the real risk of developing breast cancer without surgery was 17%. Whatever the prophylactic mastectomy benefits, they were no greater than 17%, far less than the estimated 65% risk reduction anticipated by most patients.

Another study found that 80% of patients overestimated the benefit of hip fracture prevention medications, 90% overestimated the benefits of breast cancer screening and 94% the benefits of bowel cancer screening.

Clifton Leaf, assistant managing editor of Fortune magazine, makes pretty much the same point in his upsettingly insightful analysis of the war on cancer, The Truth in Small Doses. Most patients seem to believe that 'the newest cancer fighting drug, or at least the next one after this one, will certainly provide terrific treatment benefits, so I have to have it.'

Unfortunately, as Leaf shows in almost excruciating detail, those apparent benefits are often illusory or statistical manipulations. Take our war on breast cancer, for example, and consider all the 'newest and greatest' drugs developed since 1970, then see the impact on both our ***actual*** number of female breast cancer deaths and our national breast cancer death rate per 100,000 women: [178]

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[177] These examples come from If Patients Only Knew How Often Treatments Could Harm Them, Austin Frakt, New York Times, March 2, 2015. Frakt summarizes 30+ studies of patient expectations of medical care benefits, based largely on Patient's Expectations of the Benefits and Harms of Treatments, Screening and Tests by Hoffman and Del Mar, JAMA Internal Medicine, Feb 2015

[178] Leaf, The Truth in Small Doses, page 127. Data from the National Center for Health Statistics (CDC) and National Vital Statistics System

Year	Actual Number of Breast Cancer Deaths	Crude Breast Cancer Death Rate (deaths per 100,000 women)
1970	29,652	28.4
1975	32,158	29.4
1980	35,641	30.6
1985	40,093	32.8
1990	43,391	34.0
1995	43,844	32.2
2000	41,872	29.2
2005	41,116	27.3
2010	40,996	26.1

I did my own 'back of the envelope' analysis of breast cancer mortality gains over the past 20 or so years and found equally unimpressive improvements. I learned that from the mid-1990s to 2006 our national age of breast cancer death remained the same: 68, despite improved technologies, treatments, access and more widespread screening.

	Mid-1990s	2010 [179]
Average age of breast cancer diagnosis	62 [180]	61
Average age of breast cancer death	68 [181]	68
Number of survival years post-diagnosis	6	7

[179] 2006 data from National Cancer Inst, SEER Stat Fact Sheet: Breast downloaded Oct 2012

[180] Glockler, Cancer survival and incidence, The Oncologist, Dec 2003

[181] Saenz, Trends in Breast Cancer Mortality, Population Reference Bureau, Dec 2009

My concern: frightened patients may, under the influence of myth, ads, hope or hype, make unwise medical care choices, 'unwise' in the sense that the care probably won't benefit them much and may harm them some. But they may justify their choices based on relative prices: 'it cost $5,000 from Supplier A and only $1,000 from Supplier B. I'll give it a try. Saves me / my employer / my HSA $4,000!'

Would they have 'given it a try' for $5000?

We often think, as behavioral economists like to point out, in relative, not absolute terms. That $4,000 savings seems pretty good, a motivation to buy. That's why so many consumer products advertise '$500 off this weekend only' without telling the actual price. It's a good deal *relatively*, perhaps especially appealing to scared patient consumers.

That's why I find studies that indicate patients would opt for less, or at least very different care if they had better information about the likely benefits and harms, critically important. [182]

With these types of benefit overestimates and harm underestimates in mind, I'd like to propose a 4-Step Decision Making paradigm.[183] I suggest that patients who follow this process will make better medical decisions, end up more satisfied with their outcomes and save some money along the way.

Perhaps quite a bit of money.

How to make a wise medical decision

I suggest that wise patients use the following decision criteria when considering and accessing medical care. Price considerations are 4th on this list of 4, meaning they're relevant but that other factors are far more important.

First decide if medical care will help you**.** You can learn this from comparative studies of patient outcomes.

Care may not benefit you for a two main reasons.

- You may not be 'sick' even though some indicator or other shows you to be 'at risk'. Our sickness indicators change overtime, with some becoming more expansive and others more restrictive. Someone, for example, with blood sugar of 130 mg/dl was 'not sick' prior to 1997 but 'was sick' after, when a new threshold definition was adopted.

[182] Frakt, op cit

[183] This is the 2nd or 3rd time I discuss this in this book. My excuse: seems like a pretty worthwhile approach to medical decision making. Hope repetition serves to reinforce the message rather than bore readers.

Similarly, a 65 year old with blood pressure of 145/90 'was sick' prior to new definitions adopted in 2013, but was 'not sick' after. [184]

As a general rule, medical care cannot improve your health if you're not sick.

- You may be sick but treatments may not work. We learn from comparative studies which treatments work most of the time, which some of the time and which infrequently.

  Sometimes simply waiting for the 'sickness' to heal itself is the best strategy. This seems the case for pediatric ear aches - the NNT of antibiotics to reduce pain caused by Otitis Media in the first 7 days is 20, for example [185] - and most back pain. ChoosingWisely states that 'back-pain sufferers who had an MRI in the first month were eight times more likely to have surgery, and had a five-fold increase in medical expenses—but didn't recover faster.' [186]

  In your own case, unfortunately even if you're sick, medical care may not be able to help you.

Once you determine that medical care can help you - *if* that's what you determine and *if* you determine that it can help you *enough* - then **second**, decide which care *process* you prefer. You almost always have options: mastectomy or lumpectomy for early stage breast cancer, spinal fusion surgery or physical therapy for back pain, acupuncture or injections for a sore shoulder and many others.

- The various options sometimes (often?) generate similar outcomes though the treatment, risk and recovery processes may differ significantly.
- There's often no one 'right' answer for everyone, only 'right' answers for each individual

Once you decide which process you prefer, then, **third**, determine which medical provider gets the best outcomes.

- One spinal surgeon, for example, may generate far better patient outcomes than another so, if you've already decided you prefer spinal fusion surgery to physical therapy, choose the better surgeon. Ditto for hospitals.
- A good indicator of likely outcomes is the annual volume of patients like you that each physician and hospital treats. Though this is not foolproof – far from it, in

[184] http://www.webmd.com/hypertension-high-blood-pressure/news/20131218/new-blood-pressure-guidelines-raise-the-bar-for-taking-medications

[185] See Otitis Media evaluation on www.TheNNT.com

[186] Imaging tests for low back pain on www.ChoosingWisely.org

fact – it's about the best indicator we currently have to predict likely patient outcomes.

Finally, **fourth,** *after* you determine that medical care can benefit you, and *after* you decide which treatment process you prefer, and *after* you decide which provider gets the best results for patients like you, consider prices.

- You may find that two equally good providers charge different prices for your preferred treatment process. In that case and ***only in that case***, the wise patient chooses the low cost provider.

Be sure to follow these steps in order and rigorously. That will ensure you get the best outcomes, from the process you prefer, at the lowest cost. Don't short circuit this decision tree or you risk getting sub-optimal outcomes, from a process you really don't like, from a provider who's not very good and perhaps overpaying along the way.

Why this decision making process is so important Part 1
The story and legacy of J. Alison Glover: physicians rely on hunches too much

Dr. Glover was a British physician and researcher, perhaps the first to identify the role that physician 'hunches' had in medical care. Glover studied tonsillectomy procedure rates and impacts in the 1920s – 30s. [187] He learned that in Scotland between 1931 and 1935, 60 people died from enlarged tonsils and 513 from tonsil removal including 369 children under 15 years old.

- In this case, even though people were sick, the available medical care couldn't help them much.
- Had they applied Step 1 above, many would have opted against having tonsillectomies and, perhaps, lived as a result.
- Had they applied Step 4 only, the dismal results would have been the same, but some people would have saved money in the process, a Pyrrhic victory if ever there was one.

The US healthcare system, during the same years, was expanding its rate of tonsillectomies in children. Knowing the Scottish experience, however, the Americans tried a different approach, radiation to treat tonsillitis between the 1930s and 50s. This was both unnecessary and ubiquitous, according to the Chicago Tribune's 2004 analysis. [188] The treatments led to increases in thyroid, salivary gland and jaw cancer.

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[187] See In pursuit of the Glover phenomenon http://the-141.blogspot.com/2012/05/in-pursuit-of-glover-phenomenon-what.html and John Wennberg A debt of gratitude to J. Alison Glover http://ije.oxfordjournals.org/content/37/1/26.long

[188] Goldman, Radiation Babies, Chicago Tribune, Nov 14, 2004

- Patients rigorously using our 4-step process above would, again, have learned in Step 1 that medical care would possibly generate more harm than good.
- They may also have determined in Step 1 that they really were not sick. As such, medical treatments could not make them ‘better’. See below.
- They might also have determined, in Step 2, that tonsillectomies were less risky than radiation.

Glover hypothesized that physician preferences, rather than patient need, drove tonsillectomy rates. He tested this hypothesis by reviewing tonsillectomy rates at the Hornsey Borough School in north London, in the late 1920s.

British children in those days got their medical care through the local school with the school physician acting, more or less, like a Primary Care Physician does today in the US, while sometimes even performing surgeries like an American specialist would. As such it was the school’s responsibility to diagnose and treat tonsillitis, along with lots of other illnesses.

Glover found that in 1928, an unnamed Hornsey school physician performed 186 tonsillectomies. A new doctor named Garrow arrived in 1929 and the number of tonsillectomies fell to 12.

- The average number of tonsillectomies per year from the previous physician, 1921 – 1928: 169
- The average number of tonsillectomies per year after Garrow took over, 1929 – 1933: 13
- The percent of apparently unnecessary tonsillectomies between 1921 and 1928: about 92%.

Glover identified no outcome differences or population changes during this time. It appeared, though, that some 156 children received unnecessary tonsillectomies annually from the previous doctor. They were not, in our terms, ‘sick’.

- Again, to tie this back to our price transparency discussion, wise Hornsey parents would have determined whether or not tonsillectomies provided benefit first and then considered price (if that was a factor in 1929 Britain. I’m not sure it was.)
- Unwise parents would have assumed something about the procedure benefits then jumped to our Step 4 and compared prices from available providers.

OK, one might say. The Hornsey situation happened a long time ago, in a country far away. It doesn’t apply to American medicine today.

John Wennberg follows in Glover’s footsteps

Wennberg, then a young researcher at Dartmouth Medical School, built on Glover's ideas and tracked tonsillectomy rates in Vermont in the 1970s. He found exactly the same thing as Glover did in Hornsey:

- 7% of children under age 16 had tonsillectomies in Middlebury Vermont, while
- 70% did in Morrisville, despite these two communities being demographically similar.

Wennberg identified a similar treatment variation rate when comparing Waterbury Vermont to next door Stowe, again two socio-economically and demographically similar towns (among the full time residents though not necessarily the ski vacationers who didn't generally have tonsillectomies there anyhow).

Parents choosing the cheapest tonsillectomy provider in Morrisville or Stowe would have received less expensive though still unnecessary care about 80% of the time. Not a vast improvement over the 92% unnecessary rate discovered by Glover in Hornsey, years before.

'Too long ago' you still might say. 'My doctor uses the most up-to-date technology, so this wouldn't happen to me. Those Vermont studies are 50 years old.'

In 2013, Wennberg, now an elderly senior researcher and his colleagues at Dartmouth published a tonsillectomy rate analysis among kids in Northern New England during the period 2007 – 2010. Here's what they found in each Pediatric Surgery Area, per 1000 children:

Rates per 1000 children by Pediatric Surgery Area		Surveys of New Hampshire, Vermont and Maine by Dartmouth affiliated researchers	
Middlebury, Vt	**5.6**	Burlington, Vt	**2.9**
Berlin, NH	**10.4**	Lewiston, Maine	5**.2**
York, Maine	**7.3**	Portland, Maine	**4.0**
Presque Isle, Maine	**5.8**	Bangor, Maine	**2.7**
Dover, NH	**8.1**	Waterville, Maine	**3.6**
Manchester, NH	**8.1**	Ellsworth, Maine	**3.8**
Exeter, NH	**8.4**		

The average rate in Burlington Vermont and Bangor Maine was about 3 tonsillectomies per 1000 children while the average rate throughout New Hampshire was about 9, a 3-fold rate difference. The unnecessary tonsillectomy rate in New Hampshire between 2007 and 2010: about 68%, better than Glover's Hornsey example 80 years before but still awfully high.

The Dartmouth researchers could not identify population health differences that explained this treatment rate difference, just as Glover had been unable to in Hornsey. Nor could they identify population health gains from the excessive tonsillectomies.

Throughout this story, the treatment rate differences appear due to physician preferences, not patient need.

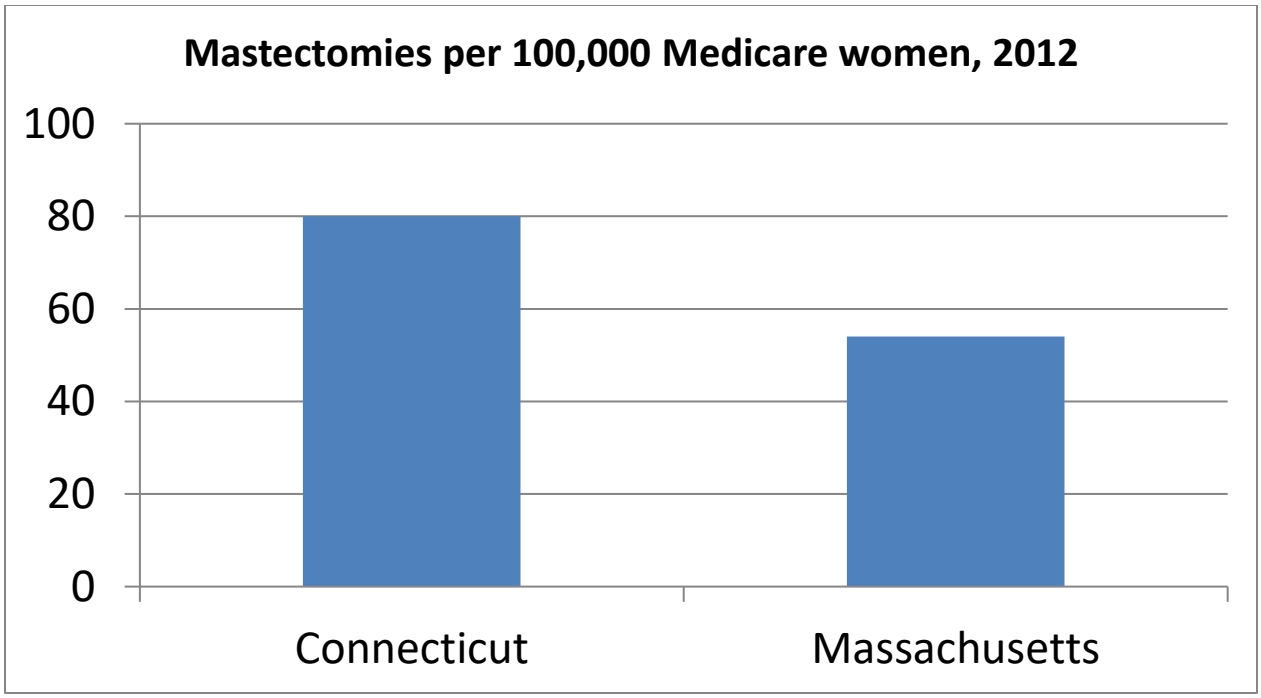
- The appropriate mechanism to avoid unnecessary care remains consumer education and use of our 4-Step Program, not price lists and not google searches.
- Parents choosing the cheapest tonsillectomy providers in New Hampshire would have received less expensive unnecessary care for their children 2/3 of the time…just like the parents in Stowe or Morrisville 50 years earlier or Hornsey 80 years before. Not much systemic evolution over the years.

Physicians appear, according to Wennberg, to rely on ‘hunches’ too often, rather than data and scientific outcome evidence from comparative studies when making treatment recommendations to patients, just as they did in Hornsey and Morrisville many years before.

But perhaps the most shocking treatment variation example comes in the mastectomy rate differences among Massachusetts and Connecticut Medicare beneficiaries. Note that both Massachusetts and Connecticut patients have access to outstanding medical care in facilities affiliated with Harvard and Yale medical schools respectively. It just doesn’t get any better than that!

I say ‘most shocking’ because in this breast cancer treatment case we have disease incidence rates, disease treatment rates and patient outcome rates. This puts to bed the ‘population difference’ justification for treatment variation rates.

Here’s a chart showing mastectomy rates in both Massachusetts and Connecticut, per 100,000 Medicare beneficiaries, from the Dartmouth Atlas of Healthcare, 2012.



Connecticut women are about 50% more likely to have mastectomies than Massachusetts women.

This raises the 'sickness' question: are Connecticut women sicker than Massachusetts women? Do they get breast cancer 50% more frequently?

The answer is no, according to breast cancer incidence rate data from the American Cancer Society. [189] The breast cancer rates are virtually identical.

Breast cancer incidence rates per 100,000 women

	Non Hispanic White	African American	Hispanic
Connecticut	139	113	127
Massachusetts	137	109	104

Now, if women in both states were equally sick but received different treatments, did Connecticut women benefit from the additional mastectomies?

Again the answer is no. Breast cancer mortality rates are almost identical in both states. [190]

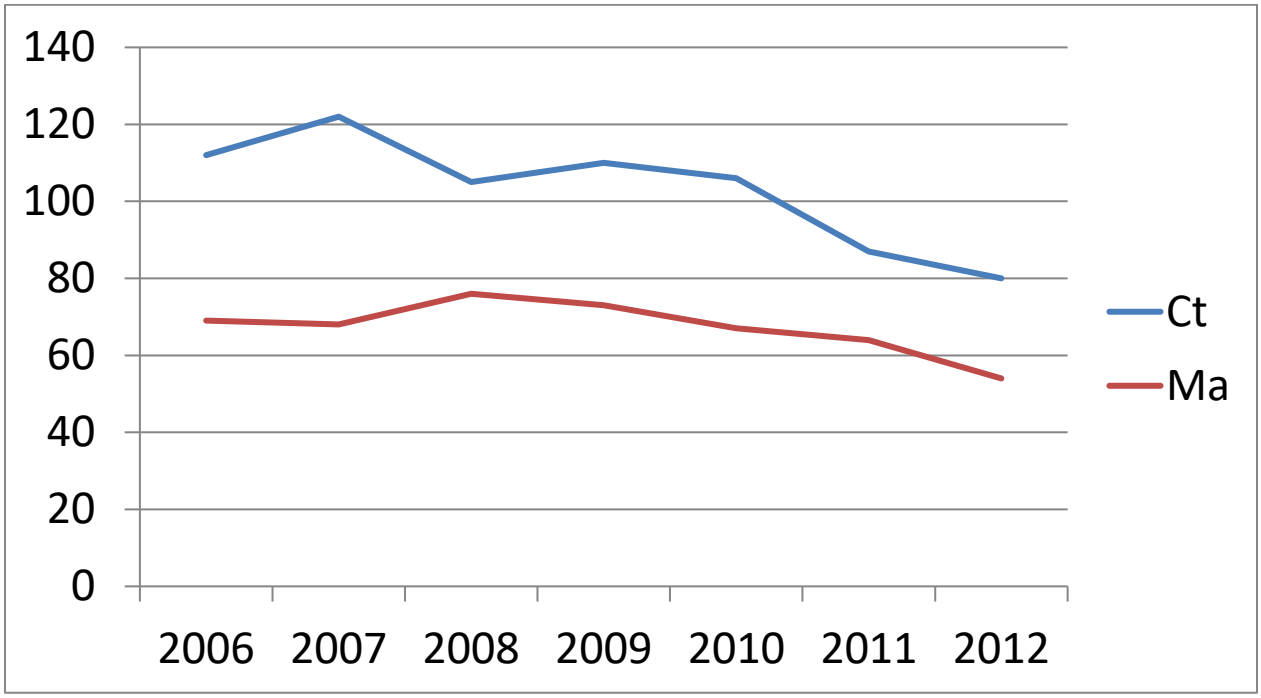
[189] American Cancer Society, Cancer Facts and Figures, 2011-2012

[190] http://www.cancer.org/acs/groups/content/@epidemiologysurveilance/documents/document/acspc-030975.pdf

Breast cancer mortality rates per 100,000 women

	Non-Hispanic White	African American	Hispanic
Connecticut	24.0	27.4	12.1
Massachusetts	23.5	27.3	12.1

This treatment variation situation has existed for years. Connecticut always has more, per thousand women. Here are the rates from 2005 – 2012, again using data from the Dartmouth Atlas:



That 50% more in Connecticut rate has existed for many years.

If the additional mastectomies Connecticut women received over time had any benefit, then we would see breast cancer mortality rate differences that approximate the treatment differences. That is not the case.

Rate discrepancies like these exist for dozens of medical tests and treatments.

These situations – tonsillectomy rates in Vermont in the 1970s and northern New England from 2007 – 2010, and mastectomy rates in Massachusetts and Connecticut in the 2000s – are exactly the same as Glover identified in Hornsey in the late 1920s.

- Knowing treatment prices would no more help a Connecticut women in 2010 avoid an unnecessary mastectomy – or a Scot in the 1920s avoid dying from a

botched procedure or an American in the 1940s avoid radiation-induced thyroid cancer - than a Hornsey child in 1928 avoid an unnecessary tonsillectomy.

- Most likely, price transparency would only have helped that Hornsey child or Connecticut women get cheaper unnecessary care.

An underlying cause of this problem, according to many who have studied it: physicians like to use the newest available technology [191] and patients generally believe that more medical care is better medical care. Wennberg put it this way: [192]

- Few surgeons are hesitant believers in the efficacy of the operations they perform, nor do they doubt their clinical necessity.
- Most patients are convinced that the benefits of surgery exceed the risks by a wide margin.

Yet, as we have just seen, these two certainties do not add up to patient benefit as often as either doctors or patients would like. Knowing prices adds nothing to the patient's chance of benefit.

Why this decision making process is so important Part 2
The impact of Vinay Prasad's research: half of established medical interventions are found to be useless or harmful when subjected to comparative studies

Dr. Prasad, Senior Fellow at the National Cancer Institute and National Institutes of Health, was lead author in an extraordinary, though little discussed, study published in the Mayo Clinic Proceedings in 2013, *A Decade of Reversal*. [193] Prasad and his team reviewed every article published in the New England Journal of Medicine between 2001 and 2010 and found that 363 studied an 'established' medical practice, meaning a commonly used medical protocol.

Of those, 146 studies or 40% reversed the practice.

In other words, 40% of comparative studies on existing, established, routine medical practices showed those practices were ineffective or harmful. The actual percentage is probably closer to 50% being ineffective or harmful when Prasad's 'inconclusive' group, 139 practices or 22% is included.

Stated differently, about half of what doctors do doesn't work. As Prasad told the New York Times

[191] See Dr. Lazris's comment at the beginning of this chapter.

[192] http://ije.oxfordjournals.org/content/37/1/26.long

[193] http://www.mayoclinicproceedings.org/article/S0025-6196%2813%2900405-9/abstract

> They all sound good if you talk about the mechanisms… the nuts and bolts, what does it do, how does it work….but the real question is: Does it work? [194]

Or, as he said in his fascinating You Tube summary: [195]

> Of all those things we're doing currently that lack good evidence, probably about half of them are incorrect.
>
> Patients who are embarking on procedures, screening tests, diagnostic tests should really try to ascertain whether or not those are based on good evidence. By good evidence, I mean randomized controlled trials powered for hard endpoints such as mortality or morbidity and not surrogate endpoints.
>
> Consequences of medical reversal are quite dire. All the people who were subject to the intervention during the years it fell in favor… in retrospect, we realize, received no benefits
>
> These are practices that should never have been instituted, that were instituted in error…even for things that make perfect sense.
>
> The take away message from our paper is that a large proportion of medical practices which are based on little to no evidence are probably incorrect. Their continued use jeopardizes patient health and wastes limited healthcare resources.

Remember Prasad's definition of *evidence*: randomized controlled studies powered for hard endpoints, not biological, anatomical or physiological explanations of why some intervention makes sense. Wise patients discuss outcome evidence with their doctors; unwise discuss anatomy and physiology. Prasad clearly explains why the latter approach doesn't work.

Here are some of Prasad's examples of medical reversals. You can find the entire list on the Mayo Clinic Proceeding website. As you review this list, ask yourself if you would like to have the *cheapest* of the reversed procedure or test. My guess: you don't want it at all, regardless the price.

I tried to choose relatively non-technical discussions. Many of Prasad's 146 reversals are very technical, specialized interventions and his discussions are often aimed at a medically trained audience.

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[194] http://well.blogs.nytimes.com/2013/07/26/medical-procedures-may-be-useless-or-worse/

[195] https://www.youtube.com/watch?v=fB1qEoDO2nE

Intensive Blood Glucose Control and Vascular Outcomes in Patient with Type 2 Diabetes	A target A1C of 7.0% or less was the guideline for most patients with diabetes. However data were inconsistent how glucose control played a role in vascular disease. In the Action in Diabetes and Vascular Disease (ADVANCE) trial, the effects of glucose control on major vascular outcomes were evaluated. There was no evidence of reduction in macrovascular events and intensive glucose control was associated with increased risk of severe hypoglycemia and increased rate of hospitalization.
A Randomized Trial of Arthroscopic Surgery for Osteoarthritis of the Knee	Arthroscopic surgery is widely used for osteoarthritis of the knee even in the face of scant evidence of its efficacy. This failed to show a benefit of arthroscopic surgery for treatment of osteoarthritis of the knee as assessed by WOMAC scores
Effects of Combination Lipid Therapy in Type 2 Diabetes Mellitus	Fibrate therapy has long been used in the treatment of dyslipidemia in type II diabetes. Though statins are considered primary therapy to reduce the risk of cardiovascular events, rates remain elevated despite use. Two large previous studies of fibrate therapy in type II diabetics conflicted with regard to their effect on cardiovascular events. The Action to Control Cardiovascular Risk in Diabetes (ACCORD) Lipid study demonstrated here that statin and fibrate combination therapy did not differ in outcomes compared with statin therapy alone at similar levels of serum lipids.
Two Controlled Trials of Antibiotic Treatment in Patients with Persistent Symptoms and a History of Lyme Disease	Many patients with persistent symptoms of Lyme disease receive prolonged courses of antibiotics, although the effectiveness of this practice remains unknown. This randomized, placebo-controlled, double-blinded trial failed to show any significant improvement in

	symptoms after a prolonged 90- day course of antibiotics in patients with persistent symptoms.
Calcium plus Vitamin D Supplementation and the Risk of Fractures	Observational evidence and data from randomized clinical trials suggested that calcium or vitamin D supplements or both may slow bone loss and reduce the risk of falls. However, in this randomized clinical trial involving 36,000 postmenopausal women, calcium with vitamin D supplementation did not significantly reduce hip fracture, and increased the risk of kidney stones

Consider our mastectomy data from Connecticut and Massachusetts above. Rates are down in both states, more dramatically in Connecticut, even though Medicare enrollment is up. Does this mean 20 or 30% of the Connecticut mastectomies performed in 2006 – 2010 (and earlier – I didn't include those data to keep the above chart easy-to-read) were performed in error (Prasad's term)?

That's in addition to the rate discrepancy between Connecticut and Massachusetts.

Why this decision making process is so important Part 3
Al Mulley and the problem of patient preference misdiagnosis: well informed patients often prefer treatments that differ from what their doctor thought they would want

Dr. Albert Mulley and his team from Dartmouth's Geisel School of Medicine evaluated the phenomenon and impact of physician attempts to diagnoses patient treatment preferences. [196] Patients who learn of all their treatment options, it turns out, often choose very differently from their physicians, or indeed, from what their physicians would expect them to choose.

Mulley summarizes his conclusion this way:

> Well-informed patients consume less medicine – and not just a little bit less, but much less. When doctors accurately diagnose patient preferences, an enormous source of waste – the delivery of unwanted services – is eliminated. It is particularly notable that when doctors accurately diagnose the preferences of patients struggling with long-term conditions, those patients are far more likely to

[196] http://www.kingsfund.org.uk/sites/files/kf/field/field_publication_file/patients-preferences-matter-may-2012.pdf . See especially page 9, source of quote in the next paragraph

keep their conditions under control, leading to fewer hospitalizations and emergency department visits.

But rushed doctors treat as *they think* the patient wants. This 'silent misdiagnosis' harms both patients and the system:

- It harms patients by providing care to them that they would not have chosen had they been better informed. Patients, according to Mulley, can suffer just as much from a missed *preference* diagnosis as from a missed *medical* one.
- It harms the entire system when doctors select more aggressive, invasive and expensive treatments than the patients themselves would, thus increasing overall costs. 'Patients choose fewer treatments when fully informed' according to Mulley, a conclusion reached in other studies. [197]

  This echoes Wennberg's suggestion above about specialist enthusiasm for surgery and Lazris's about the system promoting the more aggressive care far too often.

Mulley estimated the overall system savings from better patient preference diagnoses at 15 – 20%, but this comes with a huge caveat. He and his team evaluated the impact of improved patient preference diagnosis in the Britain's National Health Service. The UK averages spending less than half per capita on healthcare as we do, about $3,400 per person compared to over $9,000 per American. The potential savings for our healthcare system is enormous, possibly well over that 20% estimate.

Dr. Sandeep Jauhar, cardiologist and author of 'Doctored' agrees with Mulley's thesis, suggesting that healthcare reforms

> will have to focus less on payment models and more on education…better-informed patients might be the most potent restraint on overutilization …Shared decision making would be more likely to get patients the treatments they want [while helping them avoid unnecessary or inappropriate care]

Adding to this whole line of thinking, Atul Gawande, one of the key thought-leaders in this field, suggests a new role for doctors that builds on Glover, Wennberg, Prasad, Mulley and Jauhar's thinking:

> **the ideal modern doctor should be neither paternalistic nor informative but rather interpretive, helping patients determine their priorities and achieve them** [198]

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[197] See the Dartmouth Atlas of Healthcare, sections on Preference-Sensitive Care and Reflections on Variation

[198] Sheri Fink, New York Times Book Review of Gawande's Being Mortal, November 6, 2014

I think this is a brilliant summary of the doctor's role. But it takes time to 'help patients determine their priorities and achieve them'; it's not a role one can play in a time compressed environment.

What this means for price transparency

Step 1 of our 4 step 'how to make a wise medical care decision' really matters. This step, in case you forgot, is 'determine that medical care can benefit you'.

That, I think, is where our medical care system should point patients first. Prices are where our medical care system should point patients last.

Dr. Andy Lazris summarizes the problem nicely:

> an idea has blossomed within our medical thinking that equates aggressive, specialized care with good care … with enough perseverance, our healthcare delivery system is capable of virtually anything…the perception that science and technology can cure everything …[but] as little as 15% of what doctors do is backed up by valid evidence … [instead] technology is king
>
> the public – from patients and their families to doctors and experts and politicians and journalists – perceive that more is better [199]

Knowing prices does nothing to fix this problem.

When I think of the various healthcare problems we face, and of price transparency as the solution, I am reminded of a quote I heard at a convention some years ago – sorry, can't remember exactly where or when – about healthcare: Never have so many bright and talented people worked so incredibly hard to achieve so little.

That quote and the energetic price transparency movement also remind me of Ronald Reagan's famous campaign response to a tried-and-failed political initiative of an opponent: *There you go again*.

In healthcare *'there you go again'* means yet another attempt to solve clinical problems with financial tools. It never works. Dr. Meador told us that in the beginning of this chapter.

The problems raised by attempting to solve clinical problems with financial tools

Our healthcare financing tools, commonly called 'health insurance', focus almost exclusively on 'financing' and almost totally disregard 'health'. David Dranove of Northwestern University summarized the impact of this fallacy in his book The

[199] Lazris, Curing Medicare, page xviii

Economic Evolution of Managed Care on cost control reforms in the 1980s and 90s: they 'utterly failed, on all accounts'.

Though there are many reasons for this, I think the two fundamental are:

- A primary financial focus almost inevitably reduces the ***amount of time*** each physician has for each patient. Time is the physician's primary inventory, one which he or she must use wisely to maximize his or her income. As the payment for each inventory unit – i.e. each minute – decreases, physicians need to maximize their income per unit. Hence, they see more patients per hour or day.

  Michael Porter, Harvard Business School's great business strategy professor, put this succinctly in his 2006 book Redefining Healthcare: Without the discipline of value-based competition on results, carriers have incentive to reduce the time physicians spend with patients. [200]

  Price lists and price transparency programs take us exactly where Porter warned we don't want to go. We need to focus on outcomes, not prices, to improve outcomes. We cannot improve value (outcomes per dollar spent) otherwise and we'll probably end up decreasing it.

- Financial / price based solutions lead to 'simplistic actions such as across-the-board cuts in expensive services, staff compensation, and head count' according to Porter. [201] More succinctly, he says,

  'It is a well-known management axiom that what is not measured cannot be managed or improved' [202] meaning financial solutions to clinical problems may lead to cuts that negatively impact care quality. Rather than managing some critical but unquantifiable care components, market pressures may lead to across the board cuts.

  That was, more or less, our experience with HMOs in the late 1990s and early 2000s: fairly brutal cuts and cost controls that led, among other things, to the Patient's Bill of Rights. Might we simply re-create the same experience, only this time motivated by price lists?

I'll let some physicians express all this in their own words.

Dr. Vikas Siani, President of the Lown Institute, suggests that publishing prices lists will put more pressure on clinicians to improve their efficiency. This will limit the amount of

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[200] I wrote this quote in my notes while reading Porter and Teisberg's Redefining Healthcare, but can't find the exact reference. This article in the Harvard Business Review says pretty much the same thing. https://hbr.org/2011/09/how-to-solve-the-cost-crisis-in-health-care

[201] Ibid

[202] https://hbr.org/2011/09/how-to-solve-the-cost-crisis-in-health-care

time for each patient's care and serve to erode, not enhance, the doctor-patient relationship.[203]

Dr. Joshua Fenton of UC Davis Medical School, lead author of a study that concluded ''Patient satisfaction is linked to higher healthcare expenses and mortality, study of 50,000 people over 7 years' claims [204]

> Doctors may order requested tests or treatments to satisfy patients rather than out of medical necessity, which may expose patients to risks without benefits. A better approach is to explain carefully why a test or treatment isn't needed, but that takes time, which is in short supply…

…and which may decrease in supply under the increased billing pressures that result from excessive price considerations.

Publishing prices absent the critical and, as yet poorly developed quality metrics may make this situation worse, not better. The net result may be *more* unnecessary tests and treatments, not fewer according to Dr. Jauhar who says

> There is no more wasteful entity in medicine than a rushed doctor.[205]

To save time, he says, doctors order more tests or refer to more specialists. This adds costs and risks; it doesn't decrease them.

Time compressed physicians have less time to develop personal relationships with each patient. This leads, according to a study of 20,000 diabetics and their care givers, to less empathy for patients and poorer outcomes. [206]

- Patients of high empathy doctors had about 35% fewer metabolic complications like hyperglycemia or diabetic comas.
- Empathy means sharing feelings with other people, not belittling, undermining or judging, according to Dr. Rana Awdish, a critical care physician at Henry Ford Hospital who's involved in hospital's empathy program. These skills can be taught and practiced, she says, but this requires emotional availability on part of physician, something he or she needs time with patients to develop.

[203] http://www.doconomics.com/blog/?p=4647

[204] http://www.ucdmc.ucdavis.edu/publish/news/newsroom/6223

[205] Jauhar, New York Times, 7/20/14

[206] Bakalar, NY Times, Doctor Empathy a Factor in Diabetes Care

- Dr. Jauhar addresses the empathy issue from a typical physician's point of view: 'Among my colleagues I see an emotional emptiness created by the relentless consideration of money.' [207]

Kaplan and Haas, in their 2014 Harvard Business Review article 'How Not to Cut Health Costs' give an example:

- Starting kidney dialysis with a fistula (a surgical procedure to connect to an artery or vein) rather than catheter generates better outcomes, meaning longer lives with fewer complications.
- Patients starting at optimal times in their disease progression cost tens of thousands of dollars less per year than otherwise.
- One nephrologist said that spending 30 minutes more per patient with advanced kidney disease could dramatically improve rate of fistula or graft starts, *but there was no time or compensation for the discussion*.
- Publishing nephrology office price lists will, suggest these authors, take us in the wrong direction, generate more patient harm and ultimately cost our system more.

Actions like helping patients choose doctors based on price destroys healthcare system value.

But actions that (1) increase the amount of time physicians have with patients and that (2) enhance the doctor-patient relationship, that (3) help doctors diagnose preferences better and that (4) help patients choose effective care based on their preference and high quality outcome studies, add value.

How to turn price transparency from value-destroying to value-creating

Our definition of value includes two components: costs and outcomes, value being measured as outcomes per dollar spent. Focusing only on spending will probably decrease systemic value by reducing outcomes, for all the reasons above.

Including critical outcome factors along with prices can turn this positive, into a value creating exercise. I'll list some components below as examples. The chapter on Decision Aids goes into this in much more detail.

Consider first **birthing**, about 10% of non-Medicare hospital income. Along with price lists by hospital, an informed patient would need to know

- Infant mortality rates by hospital

[207] Jauhar, Doctored, page 170

- Infant and maternal readmission rates
- C-section rates
- Plus have some indication of whether or not each hospital's catchment area population was abnormal in some critical respect.

For **preventive care**, a wise patient would need to know

- Mortality and morbidity rates both with and without the preventive care
- Harm rates from the preventive care such as false positives and test and treatment harms
- Plus have an ability to understand what all these numbers and statistics really mean.

For **hospital choice**, patients need to know

- Infection rates
- 30 and 60 day readmission rates
- Tendency / process information by hospital per 1000 people in each hospital's catchment area, similar to Dartmouth Atlas information
- Volume of similar patients treated annually. Though an imprecise metric, care quality correlates relatively well with care quantity, and the hospitals performing the highest number of similar surgeries annually tend to generate the best patient outcomes.

For **surgeon choice**, patients need to understand

- Infection rates, complication rates, mortality rates, return-to-operating room rates and hospital readmission rates by surgeon / by procedure
- It does not seem fair that hospitals should be privy to this important information while prospective patients, whose health could be influenced by it are not, says Dr. Paul Ruggieri, general surgeon and former clinical instructor at Harvard Medical School. [208]
- Absent that information, patients need volume rates by surgeon. 'Patients can improve their chances of survival substantially – even at hospitals with high volumes of a procedure - by selecting surgeons who perform the operations frequently,' according to Dr. John Birkmeyer, former Chief of General Surgery at Dartmouth – Hitchcock Medical Center in New Hampshire.

[208] Ruggieri, The Cost of Cutting, page 127

For **pharmaceuticals**, note that the Americans average about 13 prescriptions / capita / year, double other OECD countries that generate similar or better population statistics.

- Several new Decision Aid reference sources provide useful drug information though in different forms. I particularly like Number Needed to Treat and Harm analyses. I'll discuss much more of this in the chapter on Decision Aids

Patients who know this quality information can use their doctors as 'interpreters' (Gawande's term) to help them determine which care they really want and which process they prefer. Prices can have a role in those discussions but, I suggest, probably a relatively limited one.

Conclusion

Good health is cheaper than poor health. That's both axiomatic and true.

Activities that get patients healthier are almost always less expensive than activities that either keep people unhealthier or do not positively impact health.

Well informed patients who understand their options tend to cost less than poorly informed patients. Well informed patients who use our 4-Step Decision Process will chose care wisely by balancing the likely benefits against the likely harms. They will use outcome data from comparative studies to help them make their decisions, consult with their physicians about options and alternatives and ultimately end up healthier.

Poorly informed patients assume that more medical care is better medical care, tend to assume higher likelihoods of benefit and lower of risk than are true, and are ultimately somewhat less likely to end up in good health.

Turning patients from poorly informed to well informed saves money. Shopping by price, especially for medical interventions that do not benefit patients, does not.

I conclude that Price Transparency is value-creation neutral:

- Listing prices alone, absent the critical quality indicators discussed above and in detail elsewhere in this book, probably destroys value.
- But listing prices *along with* those critical quality metrics, and using prices to engage patients in a discussion of care quality can increase system value.

It's too early in this process to know where this is headed and to issue a definitive conclusion.

[1] Richard Harris, Rigo Mortis and John Wennberg, Tracking Medicine for example.

[1] See the Dartmouth Atlas of Healthcare for example on this.

[1] State of Washington 2018 report First Do No Harm. I used this source for the other examples in this section also.

[1] Wennberg, Tracking Medicine. He estimates that patients have options about 85% of the time.

[1] See the Dartmouth Atlas of Healthcare and various research papers from the Dartmouth Institute for Health Policy and Clinical Practice, for example. Also David Cutler's estimate in The Quality Cure, page 20.

[1] See Wennberg, Tracking Medicine, Chapter 1

[1] HHS, Quick Guide to Health Literacy, https://health.gov/communication/literacy/quickguide/factsbasic.htm

[1] Mulley, et al, Patient Preferences Matter, Kings Fund and the Dartmouth Center for Health Care Delivery Science, 2012, page 9

Review Questions

Answers on next page

1. Do prices among vendors vary much for the same medical service?

    a. Yes
    b. No
    c. Only in New Hampshire
    d. Rarely in New Hampshire

2. Can you determine which vendor provides the highest quality medical services from price lists?

    a. Yes
    b. No
    c. Only in New Hampshire
    d. Rarely in New Hampshire

3. Can a patient determine if he or she will benefit from a specific medical service by learning its price?

    a. Yes
    b. No
    c. Only in New Hampshire
    d. Rarely in New Hampshire

4. About how much ineffective or harmful medical care exists in this country?

    a. About 2% of medical care is ineffective or wasteful
    b. About 40 – 50% of medical care is ineffective or wasteful
    c. About 97.8% of medical care is ineffective or wasteful
    d. Well over 100% of medical care is ineffective or wasteful

5. This text suggested 3 reasons that explain why medical care is sometimes ineffective or wasteful. Which below is NOT one of those reasons?

    a. Physicians rely on hunches, not science, too often
    b. Medical care that has not been subjected to comparative studies is proven ineffective or harmful about half the time when subjected to those studies
    c. Physicians too frequently treat patients according to physician preference, not patient preferences
    d. Doctors are poorly trained in this country

6. This text suggested a Four Step Process for making wise medical care decisions. Which below is Step 1 of that process?

    a. Determine if medical care provides more benefits than harms or than doing nothing

b. Pray
c. Ask a trusted friend or relative what to do
d. Learn as much as you possibly can about the anatomical and physiological causes of your medical problem

7. Which below is NOT an element of the Four Step Process?

a. Determine which treatment process you prefer
b. Determine which doctor and hospital generates the best outcomes for your preferred process
c. If two providers generate the same outcomes from your preferred process, consider prices
d. Pray

8. Which, below, is *most likely* to happen if medical prices become widely known to patients?

a. Doctors will spend less time with each patient
b. Our national 30 day hospital readmission rate will drop
c. Our infant mortality rate will drop
d. Americans will live longer

9. Which, below, is *least likely* to happen if medical prices become widely known to patients?

a. Care quality will improve
b. Prices for many ineffective treatments will fall
c. Doctors will advertise the prices of their (often ineffective or harmful) services
d. Hospitals will advertise the prices of their (often ineffective or harmful) services

10. Americans seem to perceive that more medical care is better and that higher technology care is better than lower. How will posting prices affect these perceptions?

a. It won't
b. It may reduce moral hazard when people understand what care costs
c. It may induce more moral hazard when people learn true care costs
d. It may incent people to drop insurance coverage

Review Questions

Correct answers in bold

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Why Private Sector Healthcare Reforms Always Fail to Control Costs

We have a 40+ year history of healthcare system reform, and a 40+ year history of reform failures to control costs. Harvard Business School Professor Michael Porter explains why:

> With the wrong diagnosis, the attempts to treat the system have addressed the wrong issues or offered piecemeal, ultimately ineffective solutions aimed at symptoms rather than causes. [1]

Harvard Business School's Michael Porter, along with his colleague Elizabeth Teisberg, have written the Big Book About Healthcare, 400+ pages, titled **Redefining Healthcare**. Chapter 2 provides a litany of competitive dyfunctionalities. We'll use some of Porter and Teisberg's categories to articulate why we have expensive, fragmented, inappropriate and dysfunctional forms of healthcare competition.

Note when reading this: Porter is a business school professor, primarily interested in improving healthcare value. 'Value' for Porter means 'outcomes per dollar spent'. Good surgical outcomes at low cost are high value medical services, for example, while similar outcomes at higher costs represent less value.

Porter and Teisberg see as dysfunctional many healthcare regulations because these are designed to treat healthcare purchasing as different from purchasing other goods and services in our economy. **The clash between appropriate business strategies to promote patient value, and inappropriate regulations to control competition, comes through quite clearly.**

Dysfunctional Competition in the Wrong Geographic Market

We know that some hospitals provide better value than others. The Cleveland Clinic, for example, is nationally recognized as an outstanding cardiac center, and the Mayo Clinic wins accolades for its patient care. Both provide outstanding patient value – excellent outcomes at moderate prices. From Porter's point of view, we could increase overall American patient value by allowing more patients to access these, and similar, outstanding medical facilities.

But regulations often prohibit people insured in one state from getting treatment in another state, at least, without paying hefty 'out of network' costs (essentially fines). A Massachusetts small group employee, for example, who has Massachusetts based health insurance, must pay this fine – in the form of out-of-network costs - to access the Cleveland Clinics' outstanding care.

This makes no sense. We don't do this in other economic arenas. We are not restricted from purchasing cars made in other states, or computers, or food, or clothing. That's one reason why we have a history of quality improvements and cost reductions in these products.

But in healthcare, we charge patients **more** to get better care – meaning often quicker and cheaper care.

What would happen if, for example, Massachusetts insureds could use out of state facilities without these extra charges? The short answer: it would be a win-win for the carrier, employer and employee:

- The carrier would save money;
- The employer would thus have reduced premiums;
- The employee would save money and – as an added bonus – receive better care.

The only losers – perhaps – are the Massachusetts providers who lose a patient to an out-of-state competitor. (I say lose 'perhaps' because competitive pressures from out-of-state providers might actually improve the value at Massachusetts hospitals, so they will get more insureds from other states than they lose. Inter-state competition might reward them with more patients.)

This type of geographic restriction may make no sense to people who believe that purchasing healthcare is the same as purchasing other goods and services.

But it may make perfect sense to folks who believe that purchasing healthcare is **different** from purchasing other goods and services. These people may see the state as a protector of its citizens.

Massachusetts, for example, may have significantly more stringent licensing requirements than some other states. As such, it's the Massachusetts state regulator's responsibility to dissuade its citizens from leaving the state to receive – potentially – inferior care. Yes, some people may not be able to access the Cleveland Clinic. But they are protected from receiving shoddy care in lots of other states.

Regulators, thus, may restrict people from getting the **upside** of out-of-state providers, but they also save people from getting the **downside** – shoddy treatment. That, apparently, is the justification.
Are they right? Are they wrong? The answer depends on how you define healthcare. If it's like other goods and services, then the regulators interfere with market competition to the detriment of us all. But it it's unlike other goods and services, then regulators provide a valuable function.

Regulators think that purchasing healthcare is different from purchasing other goods and services, so they regulate accordingly.

Whether or not we agree with them, we all pay the price in the form of higher costs than any other advanced industrialized country.

Dysfunctional Competition over the Wrong Time Horizon

We know that most diseases, especially the chronics ones, last longer than 1 year. Lupus, multiple sclerosis and cystic fibrosis, for example, last a lifetime. Yet we finance healthcare treatments with one year health insurance policies.

These policies, underwritten by different carriers, may have different provider networks, different drug formularies and different approval criteria for various medical treatments. A patient may need to change physician, hospital, medications and treatment protocol when the employer decides to change plan.

Conceivably some patients may need to change provider, medication and treatment protocol annually. This makes no medical treatment sense - people with chronic conditions need, above all, continuity of care. This allows the treaters to monitor progress, tweek protocols as necessary and take a long term view of patient improvement.

But short term health insurance policies – i.e. 1 year plans - incent carriers and providers to seek quick hits, like eliminating certain expensive drugs or failing to invest in world-class hospital IT systems. This can be counter-productive: a patient responding to one drug may develop problems when that drug is discontinued due to a formulary difference.

Some drugs may, for example, be more expensive in the short term but reduce long term costs significantly. The VA has found this sometimes to be true. Our 1 year policy horizon and associated restrictions, however, may dissuade physicians from using the better / lower-long-term cost medication. The patient may receive sub-optimal care and the total disease treatment costs may ultimately increase.

Yet we allow, and indeed require, 1 year long insurance policies because of our weird employer based funding system. Employers, loath to take on appreciating long term liabilities, balk at committing to longer term insurance policies.

This short term funding mechanism treats healthcare purchasing as **different from** other goods and services. Your employer doesn't buy your food or auto insurance, for example. We don't subject other products designed for long term use – like automobiles – to the same short term financial review. Imagine if we purchased cars using the same 1 year time horizon as we use when purchasing healthcare!

The historical quirks that led to our employer based insurance system have generated many regulations that protect employers from potentially harmful financial obligations…sometimes to the detriment of patients, and often to the detriment of employer's own long term financial interests.

In the meantime, we choose our health insurance policies based largely on premium price. We shop for health insurance like we shop for other goods and services. But we finance healthcare very differently, using this artificially imposed 1 year time horizon.

Thus we have a financing system absurdly designed to treat healthcare purchases as **different** from other goods and services, while we try to apply routine business practices to medical treatments – restricting costs to remain within a budget, for example. This is a huge disconnect.

Dysfunctional Competition over the Wrong Unit of Measure

We currently shop for providers, when we shop at all, seeking the 'best' doctor, the 'best' surgeon or the 'best' hospital. We typically have no clear definition of 'best'.

Some people define the best hospital as the name hospital, the research facility associated with a famous university. Some define the best doctor as the head of a department or research institute, or a graduate of a famous medical school. Others define the best surgeon as the one most frequently recommended by other doctors.

None of these definitions, typically, includes a quantification of outcomes, as in 'Dr. Smith is the best surgeon because 97% of his patients fully recover within 30 days'. We typically lack this data.

But there's a more insidious underlying issue here. Dr. Smith is but one component of a large team that provides care to a patient. The team consists of diagnosticians, nurses, pre-op professionals, surgeons, assistants, post-op professionals, rehab professionals, IT specialists, therapists, psychologists, etc. Good patient outcomes require the entire team to work together as a well oiled machine for a failure of any one component may doom the patient.

In other words, the appropriate unit of measure for medical care is **the medical condition itself** – not the individual surgeon or hospital. A great surgeon with a poor rehab team may generate poor results.
A specific hospital may be outstanding at orthopedic care, but lousy at cardiac. Or the hospital may be outstanding at certain surgical procedures but poor at chronic care. Or have a poor IT system that fails to follow patients post-discharge, leading to a high readmission rate. Or perhaps have poor post-op patient counseling that fails to prevent self destructive behavior.

A brilliant surgeon with a poor post-discharge team may generate outcomes as poor as those from a crummy surgeon with an excellent post-discharge team.

We need cost and outcome information **by medical condition** for competing hospitals in order to make wise purchasing decisions. We also need this information to make wise healthcare reform decisions. Yet this information is virtually nonexistent.

The costs and value of each individual treatment component cannot be assessed in isolation, as each component is but a part of the larger team effort. Our attempts to control a portion of the treatment costs – surgical costs, for example, or rehab therapy costs – backfire as a result.

Healthcare reforms that consider any unit of measure other than the specific medical condition will almost certainly also fail.

Dysfunctional Competition to Amass Wealth

Our various medical care providers – primary care physicians, specialists, hospitals, diagnosticians, allied medical professionals, etc – all share a client who is not their patient. Their real client: the insurance carrier who pays the bills!

I have no doubt that medical care professionals would each, personally, like to help their patient's get better. Many went into the profession to help people.

But I equally have no doubt that medical professionals also seek to maximize their incomes, as do all rational business people in a capitalist environment. In the healthcare field, we call this 'supply induced demand'. It correlates with moral hazard – the healthcare problem we discussed in Chapter 8. Here's how it works:

Physicians know that someone besides the patient – i.e. an insurer - will ultimately pay the bill. The physician also knows the criteria that each insurer uses to approve payments. It's a simple step – and probably unconscious for most medical professionals - then, to design a treatment plan that generates the highest payments.

Take this process one step further. Each hospital has an economic self interest in providing the most reimbursable treatment to each patient. Providers also have economic interests in not referring that patient out. This would mean that another provider benefits economically.
Providers – both specialists and hospitals - compete to provide the most care to each patient and refrain from referring patients to other providers. Again, probably not even consciously.

Now add one more step. Providers assemble themselves in networks, often affiliated with hospital systems. When referrals are necessary, they refer 'in-network'. Not to the 'best' specialist or, necessarily, to the cheapest. Instead, to an in-network affiliate, to keep the carrier's payments within their group. Compensation, bonuses, etc may rest on physicians' abilities to keep patients in-network.

And add a final step. Provider groups negotiate rates against carriers. The carriers want to pay less; the providers want to earn more. The larger and more powerful the provider group, the higher the rates.

Rates become a function of negotiating power, not of outcomes, not of efficiency, and not of patient satisfaction.

Providers thus compete with carriers and with each other to amass wealth. Whether or not patients get good treatment or enjoy good outcomes becomes a side issue in the compensation competition.

Hospitals typically do not support their claim for higher payments with data showing that their 30-day readmission rate is lower than another's. Nor do they show that their diabetic patients reduce their blood sugar levels more in a given time period. They generally don't argue that they should get paid more because their treatment quality is better.

Instead, they threaten not to accept a carrier's payment schedule. Here's Rick Weisblatt, Senior Vice President for Health Services at Harvard Pilgrim Health Care in Massachusetts, describing how geographically isolated hospitals (for example, on an island) negotiate fees. They use their geographic monopoly

> To leverage higher reimbursement. The employers in that community generally want that hospital in the network. And the hospitals are not shy about threatening termination [of the carrier's contract] [1]

The competition is to amass wealth, not provide better value.

Healthcare competition is <u>like</u> competition in other arena where the parties negotiate fees and prices to maximize their wealth. But it is <u>different from</u> other goods and services which compete on value – in our case, cost per patient outcome.

Instead, in healthcare, the parties compete simply via power relationships.

Dysfunctional Competition over the Wrong Hospital Strategies

Most American hospitals are General Hospitals, providing all medical services from ER to cancer treatment to open heart surgery, to all patients in a geographic area. These broadline general hospitals compete with each other.

Yet numerous studies have demonstrated that specialty hospitals – orthopedic, cardiac, etc – generate better outcomes at lower prices. The literature is full of case studies of this. [1]

Indeed, Harvard Business School Professor Regina Herzlinger – who has taught accounting to budding MBAs for years – claims bluntly:

> Specialty hospitals generally provide better, cheaper healthcare than the everything-for-everybody general hospital. [1]

General hospitals, rather than competing with specialty hospitals on **value** (best outcomes per dollar spent) instead obtain political redress.

Some states – about 35 currently – have Certificate of Need regulations on the books. CON laws restrict hospital expansion or construction unless the hospitals can demonstrate a 'need' for the additional services to government regulators – at a public hearing. A new specialty hospital looking to enter a market must similarly face this requirement.

Imagine the hearing. I, for example, want to open Gary's Coronary Hospital, perhaps in conjunction with an out-of-state hospital (or even, heaven forbid, a foreign hospital). I think I can provide better value – better outcomes at lower costs – than the current hospitals in my region. I'm willing to invest my money in this venture.

I make my proposal at the public hearing. 'Why,' I wonder, 'do I need to convince regulators about the validity of my proposal? I wouldn't have to go through this if I wanted to open or expand a shoe store. Or if I was a university president and wanted to expand my business school or chemistry department. I'm looking for the same tax treatment as the university, but I have a far more difficult regulatory hurdle to overcome.'

After I outline my business plan, the local incumbents speak in turn. They all explain to the regulators that there is no 'need' for my new coronary facility. They all, it turns out, have sufficient capacity to cover all the cases that I'm hoping to get. They try to convince regulators that there is no need for my services.

I, in this case, see purchasing healthcare as **like** purchasing other goods and services. I'll invest my money and take my chances. If I'm wrong about the need for my service, I'll fail and go out of business. I'm willing to take that risk.

But the regulators see purchasing healthcare as **different from** most other economic activities. They perceive a need to avoid wasting resources – potential tax losses from another non-profit entity, perhaps. They may want to avoid generating excess expensive medical capacity, so seek to protect hospitals from themselves. They may want to prohibit me from 'cherry-picking' profitable services from existing broadline general hospitals, using the totally fallacious argument that hospitals need the profitable patients to subsidize the unprofitable ones. [1]

Regulators may also perceive a need to protect the local incumbents, perhaps on the theory that 'they do such good work' for the local community - even if this raises medical costs to state inhabitants. In Michael Porter's terms, CON laws serve to

> Protect local incumbents from competition that could drive improvements in the diagnosis and treatment of specific medical conditions. [1]

Hospital systems tend to be very large local employers, often the largest or second largest in a local market. Physician and hospital campaign contributions are also

generally quite significant, especially at the local level. One wonders the impact of this electoral and campaign contribution clout in the Certificate of Need decisions.

This situation played out at the national level in, for example, the Medicare Modernization Law of 2003. That Law prohibited establishment of new specialty hospitals for 18 months. Congress passed a second 6-month ban in 2005.

Now that's a good way to stifle competition!

Note the tension between those who see healthcare as like, and unlike, other economic activities. Contrast the regulations governing private hospital expansion with the regulations governing private college expansion. A private college (also generally a non-profit, like a hospital) can open a new department or expand an existing one without receiving state permission. But a hospital cannot….to our cost disadvantage.

Dysfunctional Competition Based on the Wrong Information

Wise shoppers need quality information – both price and outcomes – about the products they're considering. Neither is available in healthcare.

Contrast the purchase of a tennis racquet with the purchase of any medical service, even one as simple as an MRI.

You can comparison shop for tennis racquets. You can determine price, weight, color, string tension, hand grip size and construction material. You might even – depending on where you purchase – hit a few balls with it. You can get all this information about a product that costs a couple hundred dollars and plays a minor or inconsequential role in most people's lives.

Contrast this with available medical provider information. We'll use an MRI example, because this is a relatively straight-forward, discrete test.

You can't determine the MRI price – it's a function of carrier discounts, which in turn are a product of power negotiations. You can't determine radiologist quality. You can't learn how many misdiagnoses have been generated from this facility – either false positives or false negatives. You can't determine if this particular machine is the most current incarnation of MRI. You can't even learn how many people with your medical condition have used this radiological facility.

In short, you can't learn anything about this procedure's cost or quality, even though it may have life impacting consequences for you.

Not only is this type of quality information unavailable to shoppers, but it's also typically unavailable to physicians. Indeed, according to Porter, 'most physicians lack any objective evidence of whether their results are average, above average or below average…they generally lack information on their own efficiency.' [1]

Imagine lacking quality feedback about your own competence and outcomes in other profession! Porter goes even further:

> The information that is available – health plan overviews, subscriber satisfaction surveys, and reputation surveys…has modest value. Much more relevant is information about…results.[1]

The hospital rankings currently available, in, for example, US News and World Report or Money magazine 'fall far short of the types of information really needed to support comparisons of value'. [1]

This differs, of course, from auto, food or other product information.

Why is medical information so unavailable? One short answer: government regulators treat healthcare differently from the way they treat providers of other goods and services. They don't require it.

We require auto manufacturers to publish lots of information about their products, including crash test ratings. But not hospitals. Why?

Some claim that hospital lobbies are too powerful. This seems an unsatisfactory answer, for the auto industry also has lobbyists, is also powerful and would probably be delighted to avoid publicizing crash test ratings and other comparative information that might cast them in a poor light. Ditto for the food industry.

Instead, I think, regulators see medical service provision as essentially different from provision of other goods and services, and thus subject to a different set of rules. They allow medical providers to withhold comparative information from the public, apparently with the justification that ordinary people would not be able to understand this data. (OK, political pressures and lobbying are a consideration here also.)

Interestingly, regulators have no problem mandating certain kinds of services for sick people – minimum nursing staffing ratios, for example, or mental health parity. They do this because they believe that the market alone will not provide adequate services to sick people. They typically regulate based on political influences – the nurses lobby, for example, demanding certain minimum staffing rates – rather than on rigorous, extensive studies comparing various nurse-to-patient ratios and patient outcomes.

But regulators balk at requiring price and outcome transparency. They require it for autos, but not for healthcare. They require it for food products, but not for healthcare. They require it for financial services, but not for healthcare. They even require it, more or less, for life, homeowners and auto insurance – but not for healthcare.

The best way to understand these discrepancies? Understand that many regulators see healthcare as essentially different from other goods and services.

This conflict – between regulations based on one set of assumptions, and competition based on another – leads to dysfunctional competition that raises medical service prices without simultaneously improving patient outcomes.
Porter and Teisberg note several other kinds of inappropriate and dysfunctional competition in the healthcare arena. We've presented enough above to make our underlying point: our lack of consensus about whether healthcare is like or not like other goods and services leads to a poor regulatory framework and dysfunctional, costly competition.

Our Lack of Consensus Is Expensive

As our medical providers compete for business in this poorly regulated, dysfunctional marketplace, we have more and more people ***administering*** our healthcare. In 2006, for example, we had some 470,000 health insurance employees – that's 1 for every 2 physicians! [1]

These numbers don't include the number of hospital and physician office employees who coordinate with these insurance employees. Surveys find that both doctors and nurses spend between one-third and one-half of their time on paperwork and that health insurance administration alone is a staggering 30% of all healthcare spending. [1]

Why are these costs so astonishingly high? Because we lack a consensus on whether healthcare is like or dislike other goods and services. As a result, we have an overly complicated, confused and often internally contradictory regulatory and administrative system.

We could reduce administrative costs, complications and confusion if we all agreed that healthcare is like other goods and services – or dislike.

If, for example, we let the market alone dictate healthcare system evolution, then we could eliminate many mandates and healthcare access restrictions, referral costs and requirements and inappropriate geographical competition. We could probably eliminate the expensive and inappropriate medical arms race by focusing on outcomes per dollar.

Alternatively, if we agreed that healthcare is a government function – not a market function – then we could eliminate many of our current costly types of provider competition, like individual underwriting and pre-existing condition exclusions and network restrictions. We could also eliminate the massive private insurance overheads that serve no useful economic function in a public healthcare system.

But since we lack consensus, we have the worst of both worlds. We have expensive private insurance overhead. We have expensive provider overheads whose only function is to deal with the various insurance carriers and complications. Yet we don't have the benefits of true market competition that would lower costs and improve outcomes.

Indeed, our current convoluted healthcare billing system is so complex and confusing that carrier and provider *billing offices themselves* often cannot understand the process. Errors and double billing abound. [1] Partially as a result, insurers find reasons to reject up to 30% of all the bills they receive from physicians and hospitals [1] – leading to more administrative time and expense to straighten all this out.

Our lack of consensus about how to treat healthcare – is it like or dislike other goods and services? – is hugely expensive for all of us.

Overview of Health Insurance Reforms Since 2000

The US has enjoyed spurts of health insurance reforms for the past 60 years at least. Medicare and Medicaid, the first major public health insurance programs since World War II, passed Congress in the 1960s. Nixon's HMO Act of 1973 followed, presenting a major private sector reform about 6 years later. Both dramatically changed our health insurance landscape for years to come.

After 3 decade major healthcare reform lull, the W. Bush administration passed the Medicare Modernization Act in 2003 and the Obama administration the Affordable Care Act 7 years later. Both also dramatically changed our health insurance landscape for years to come.

But did either the MMA or Aca have the impacts their authors desired? Did either improve the health status of Americans? Did either cut medical costs? Did either dramatically expand coverage? This chapter will address those questions and propose some startling and perhaps unsettling answers. It will then suggest some changes to our healthcare system, already in the works, that *could* have the dramatic systemic impacts that the healthcare reformers had hoped to have.

The Two Major Healthcare Reforms Since 2000

The Medicare Modernization Act of 2003, passed by the George W. Bush administration, represented the ***market based*** reformers vision of an improved healthcare system. Among its key components, this legislation enhanced the so-called 'consumerism' movement in American health insurance by codifying Health Savings Accounts and Health Reimbursement Accounts into our income tax and health insurance systems.

- Health Savings Accounts (HSAs) allow insured folks to invest tax deductible money into special accounts called Health Savings Accounts that they own personally. This money grows tax free until needed, when it can be withdrawn tax free to spend on medical care. HSAs are the only triple tax free investments available under the IRS code; they're tax deductible when initiated, grow tax free and are not taxed when withdrawn for qualified medical expenses.
  HSAs have grown tremendously, totaling over $80 billion by 2022 with some individual accounts reaching $100,000 or more.

  Health Savings Accounts are closely tied into high deductible health plans, both legislatively and economically. Insured people could originally only invest an amount equal to their annual health insurance deductible into their HSA. Overtime, this requirement has changed; in 2021, the contribution limits were $3600 for an individual plan and $7200 for a family plan.

  Economically and philosophically, these accounts were designed to help medical care consumers think of medical payments as being made with their own money.

The Medicare Modernization Act authors hoped that this change in consumer attitude – from thinking of medical payments as someone else's money (the health insurance company's) to thinking of medical payments as their own money – would motivate patients to shop more wisely for medical care, compare prices and choose the least expensive care, in other words, act like purchasers of other consumer products. This consumer driven movement would, in turn, force medical providers to cut prices and therefore reduce healthcare spending by billions of dollars.

That, at least, was the theory.

- Health Reimbursement Accounts (HRAs) are funded by employers. These were designed, originally, to cushion the impact of high deductible plans on employees by covering all or part of the deductible. Operationally, the employee pays for a medical treatment, then submits a receipt to his / her employer for reimbursement. Overtime this became mechanically simpler, with employees paying for medical services with their HRA card.
  HRA payments are tax deductible to the employer and tax free to the employee.

  HSAs and HRAs have become integrated into our health insurance landscape since 2003 and have also become far more complicated and intricate than outlined here. My purpose in this chapter is simply to introduce them as components of the Medicare Modernization Act of 2003.

The Medicare Modernization Act also introduced Parts C and D of Medicare.

Medicare Part C, often called Medicare Advantage, operates like an old-fashioned HMO. These plans are offered by private insurance companies under Medicare's guidance and with Medicare's approval. Medicare pays a fixed amount to the companies that offer Medicare Advantage Plans. These companies must follow rules set by Medicare. However, each Medicare Advantage Plan can charge different out-of-pocket costs, have different rules for how to get services like specialist referrals or specific hospital and physician networks, and sometimes include additional benefits. That introduces additional consumerism into the marketplace; different Medicare beneficiaries can choose different Part C plans according to their own different insurance plan preferences.

The MMA authors hoped that competition among health insurers – the folks who actually offer various Part C plans – would force prices down. Part C subscribers would, again in theory, choose the lowest cost / most attractive insurance options. As these plans grew in popularity, the offering insurance companies could negotiate lower and lower prices with participating doctors and hospitals.

Again, in theory.

- Medicare Part D covers outpatient prescription drugs, previously not covered by Medicare.

Our purpose in this chapter is less to describe components of the Medicare Modernization Act or, later, the Affordable Care Act, but more to discuss their impacts on the American healthcare system. To that end, we'll move now to commentaries on the state of American healthcare post-MMA. I'll use summarizes from well known academics representing various disciplines – medicine, business, economics and public policy – to make my points.

In 2005 – two years after passage of the MMA – two Harvard Medical School professors, Jules Richmond and Rashi Fein representing for our purposes the medical school perspective, called our healthcare system a 'mess' in the title of their lengthy book on the state of American healthcare entitled 'The Healthcare Mess'. Interestingly Richmond was a former US Surgeon General and exceptionally well placed to understand the issues he discussed.

In 2010 – seven years after passage of the MMA – Regina Herzslinger, a well known Harvard Business School professor and, for our purposes representing the business school perspective, called our healthcare system 'insane'. That was at a Boston area lecture I attended, though my notes are somewhat confusing on this point; she may have called our system 'stupid'. The distinction doesn't matter.

Others from various academic disciplines offered similar commentaries.

Seven years after passing the Medicare Modernization Act and seeing an obvious need to correct some perceived fatal flaws in our healthcare system, the Obama administration passed the Affordable Care Act, a set of government based health insurance reforms. These differed markedly from the market based reforms encompassed in the 2003 Medicare Modernization Act. The ACA's primary goal was to expand insurance coverage, not to enhance consumer / patient power. Among the key ACA provisions, it

- Introduced income based subsidies for health insurance premiums, so lower income folks could afford to purchase private plans,
- Introduced health insurance exchanges or online marketplaces, where consumers could view all health insurance plans available in their area and comparison shop based on price and benefits,
- Introduced employer mandates, requiring employers to offer health insurance to their employees under various circumstances and conditions,
- Introduced an individual mandate, requiring everyone to have health insurance, again under various circumstances and conditions,
- Introduced community rating, so everyone in the same area paid the same amount for health insurance with some minor condition differences, like age and smoking status. This ended 'individual underwriting' where the insurance carrier priced policies differently based on a host of individual risk factors. Individual

underwriting made health insurance unaffordable to very sick people, a situation the Obama administration wanted to avoid.

- Eliminated annual or lifetime policy payment ‘caps’ or amounts of money a person could receive in insurance payments per year or per lifetime. Caps protected insurance carriers from extremely high payouts but, again according to ACA authors, did not serve severely sick patient interests as well.
- Medicaid expansion in which the Feds paid states to cover more low income people.

The commentators continued.

In 2014 – four years after passing the ACA and 11 after passing the Medicare Modernization Act, Ezekiel Emanuel, perhaps the primary author of the ACA and brother of President Obama’s Chief of Staff Rahm Emanuel, called our healthcare system “terribly complex, blatantly unjust, outrageously expensive, grossly inefficient and error prone”. Remember – this summary came from a supporter of healthcare reform.

In 2016 – six years after passing the ACA and 13 after passing the MMA, Jonathan Engle from Columbia University’s School of Public Heath called our system “uniquely dysfunctional”.

In 2020 – ten years after passing the ACA and 17 after passing the MMA, Angus Deaton and Anne Case, two Princeton economics professors, called our system a “calamity”. Deaton won the Nobel Prize for Economics in 2015 for his work in this field.

Other academics and healthcare commentators chimed in along the same general lines.

The summary of our selected healthcare commentaries above, described US healthcare system evolutions through 2 major reforms – the Medicare Modernization Act of 2003 and the Affordable Care Act of 2010 – as moving from a ‘mess’ to a ‘dysfunction calamity’. Not a ringing success by any means.

Interestingly, this fiasco (my word) is taxpayer subsidized since employer paid premiums are tax deductible to the employer and not taxable to the employee - the biggest tax break allowed by the IRS. This raises questions to me, at least, about the purpose of our healthcare system. Is it designed to get people healthy? Is it designed to be benefit sick people? Or is it primarily a jobs program designed to keep well educated, well compensated people happy? Read on and decide for yourself.

Success and failure defined and demonstrated

Let’s now define healthcare reform success and failure. Success in any business, economic, or public policy reform means better products at lower cost and with wider access. This applies to activities ranging from internet expansion to educational reforms, from air conditioning utilization to automobile safety and emission standards and from cell phone use to consumer product sales: better products at lower cost and

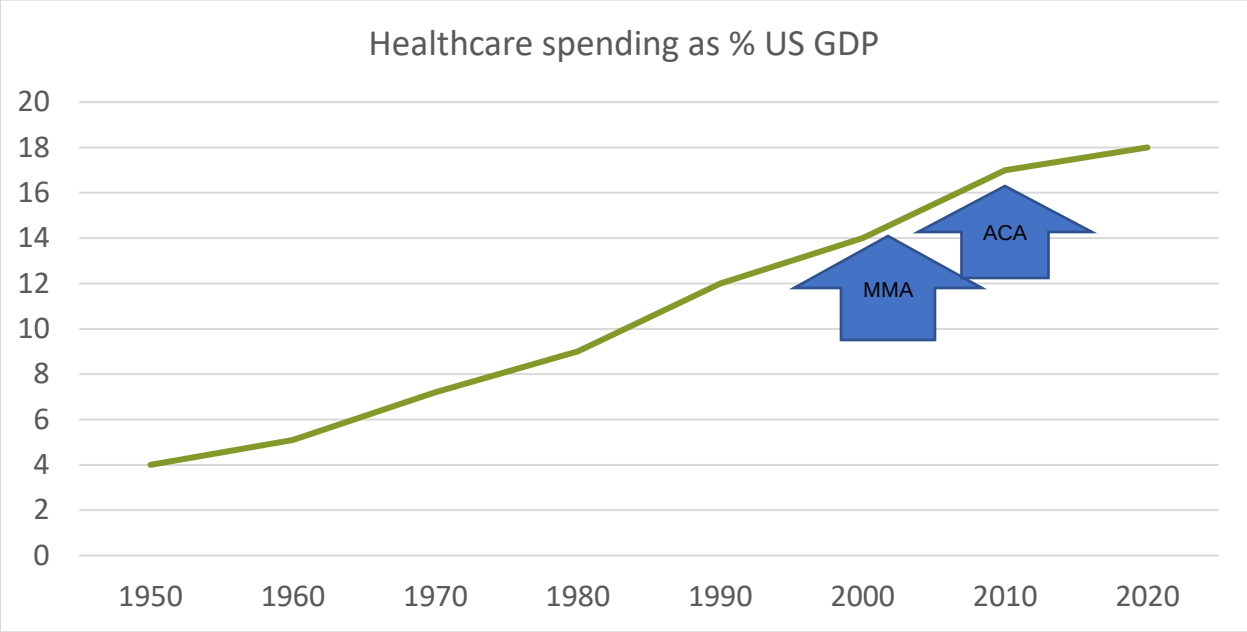
with wider access. By this definition, we can see internet success as an example – many more people have internet access today, at higher speeds, greater reliability and lower costs, than in 2003. Ditto cell phone use and automobile evolution and a host of other services and products.

> A quick note on car costs as an economic cost methodology example: we'll use the same approach to healthcare costs in a few pages.
>
> The average new car cost $24,770 in 2003, the average hourly wage then was $13 so the average person, working at the average wage, had to work 1905 hours to purchase a new car. (People generally financed new cars over time.)
>
> But in 2022, the average new car cost $47,150, the average hourly wage was $32 so the average person, working at the average wage, had to work only 1468 hours to purchase a new car. The 2022 new cars had a host of features that the 2003 cars lacked, including back up cameras, voice activated controls, onboard navigation, Wi-Fi and, increasingly, electric motors.
>
> Thus, despite the higher 2022 sticker price, the average 2022 new car, with all those additional safety and other features, cost less economically than the 2003 ones.

In healthcare, our reform definition means better health outcomes at lower costs for more people. Failure is the opposite: healthcare costs more, doesn't work any better than in the past and remains inaccessible to many.

How have we done on these metrics since 2003?

Healthcare spending as a percent of our total economy has risen since 1950 at about a constant rate. See the chart below. As healthcare spending grows, it consumes more and more of our economic resources. It inflates, in other words, more quickly than the economy as a whole. You can see that the Medicare Modernization Act had no impact on the rate of healthcare spending growth, while the Affordable Care Act has a minor impact. After both reforms, healthcare spending continues to grow faster than the overall economy and continues to consume more and more of our economic resources.



As a side note, ‘consume more and more of our economic resources’ means that we have fewer resources to invest in other parts of our economy as a percentage of our economy. Thus, as healthcare spending grows, other sectors – education, national defense, infrastructure development, etc. – have fewer resources available, again as a percentage of our total economy.

Phrased differently. this means that, as healthcare spending grows, we either spend less in these other sectors or borrow more to fund them fully.

Healthcare outcome improvements, though, do not demonstrate this same growth. See the chart below showing average life expectancy since 1950. I use life expectancy as the care quality metric since the fundamental function of a healthcare system is to keep people alive.

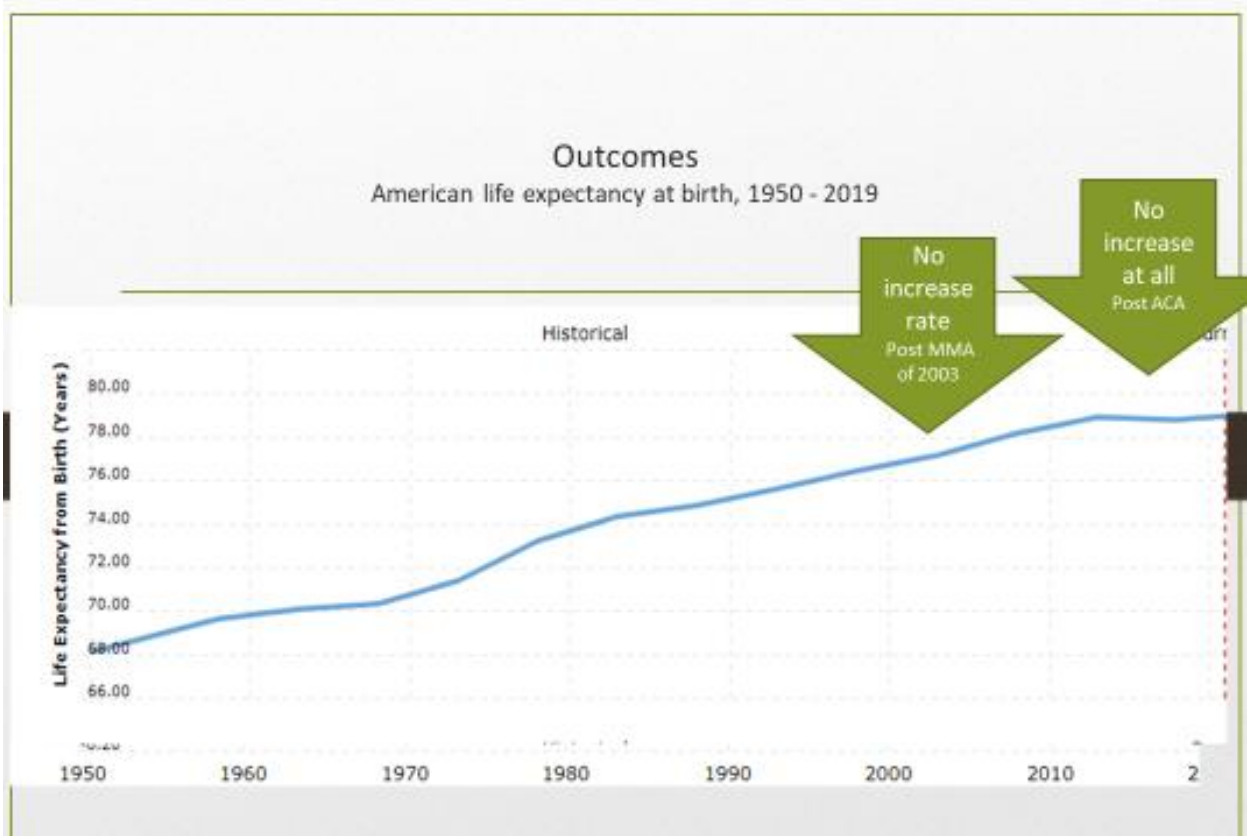
In economic / public policy terms, if our healthcare system keeps people alive longer, then it is arguably worth more funding; but if it does not, then I question whether the additional costs provide any value.

> Yes, I know that factors outside the healthcare system can impact longevity: wars, pollution, genetics, individual behaviors...a long list. But my point is that a healthcare system exists to keep people healthy and alive for longer. If a society identifies harms that limit longevity, then a good healthcare system will adapt and develop programs and treatments to ameliorate those harms. Take smoking, for example. Once identified as a cancer causing / life limiting agent, our healthcare system developed treatments – surgeries, early disease identification programs etc. – and preventive measures – patient education, smoking session programs,

medications to reduce smoker cravings, etc.- to combat smoking's negative effects. That's how a good healthcare system works.

A poor healthcare system limits the definition of 'healthcare' to functions it can perform well – knee surgeries and cataract removals for example - focuses on those, and claims that life extension is someone else's problem. A good healthcare system adapts and extends life. Is our healthcare system, post 2 reforms and by this definition, 'poor' or 'good'? See below.

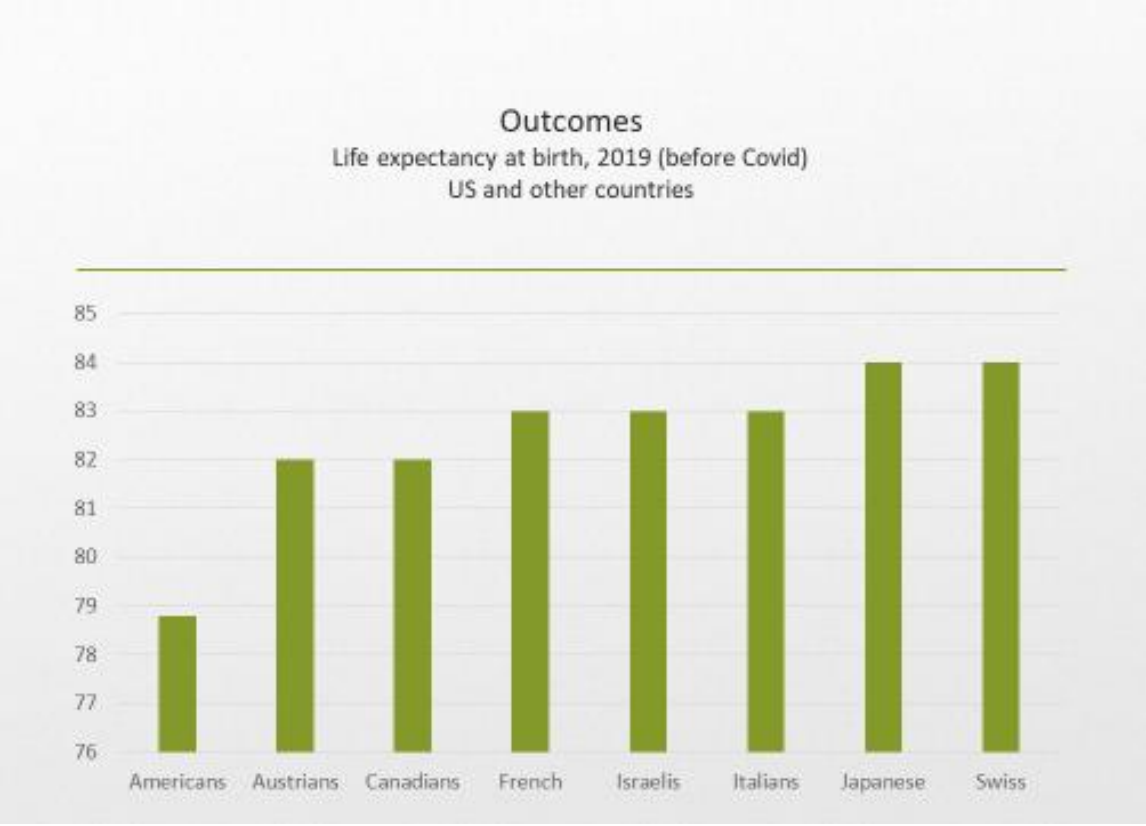
The chart below showing American average longevity at birth ends in 2019 on purpose: I did not want any Covid issues to interfere.



Four things to note here: first, the life expectancy annual increase is basically linear; we gained about as many life years in the 1950s as in the 1990s. Second, the biggest life expectancy gains occurred in the 1970s when we passed various public health measures like the Clean Water and Clean Air Acts. Third, the Medicare Modernization

Act had no impact on the rate of life expectancy growth; it was irrelevant. Fourth, interestingly and for some reason that I cannot explain, we saw no life expectancy growth post passage of the Affordable Care Act, again irrelevant.

In 2019, the last full year before Covid struck and all these metrics became murkier and more confusing, Americans lived less long than people in many (most?) other developed countries. See the chart below, generated **16 years** after passing the Medicare Modernization Act and **9** after passing the Affordable Care Act.



Neither the Medicare Modernization Act nor the Affordable Care Act impacted American's longevity. The underlying tends that existed when those healthcare reforms passed simply continued. The trillions of additional healthcare spending dollars encompassed in those legislations were irrelevant from a longevity perspective.

> Let's look at post-reform healthcare costs and outcomes as economists again, just like we looked at auto costs and quality a few pages ago. We'll use two different methodologies.
>
> First, the methodology we used in auto costs a few pages ago. In 2003, the US spent about $5,700 per capita on healthcare. The 2003 average hourly wage was about $13 so the average person, earning the average wage had to work 438 hours to pay for healthcare.

In 2019, the year before Covid hit, the US spent an average of about $11,500 per capita on healthcare. The 2019 the average hourly wage was about $15.35, so the average person, earning the average wage had to work 749 hours to pay for healthcare.

The analysis above shows that healthcare was much more expensive in 2022. It doesn't tell us if the more expensive healthcare system in 2019 worked better than the 2003 version like in the auto example above, where today's cars are better and safer than the 2003 versions.

So our second approach to thinking as economists will incorporate a productivity and quality indicator to measure healthcare system improvement (or lack thereof) over time. We'll divide average per capita healthcare spending per year by average longevity and compare that number in 2003 – the last year before passage of the Medicare Modernization Act - and 2019, the last year before Covid.

In 2003, again, the US spent about $5,700 per capita, we lived, on average, about 77 years, so our ratio of per capita spending to expected life years was 74. That doesn't mean anything in a vacuum but allows us to compare systemic quality and productivity over time.

In 2019, again, 16 years after passing the Medicare Modernization Act and 9 after passing the Affordable Care Act, we spent about $11,500 per capita and lived, on average, about 79 years. Our 2019 ratio of per capita spending to expected life years was 147, about 73 points higher than our 2003 indicator.

Could this increase be due to overall inflation? One online inflation calculator suggests that $1 in 2002 was equal to $1.42 in 2019.[209] Applying this factor, our healthcare efficiency metric of 74 in 2003 would reasonably be expected to rise to 105 in 2019 due to inflation, a rise of only 31. But it increased by 75. More than half the increase in our metric was something other than inflation.

What was it? My presumptive answer: healthcare system inefficiency, defined as outcomes per dollar spent. Leaving inflation out, we spent far more for each life year in 2019 than in 2003. I'll suggest 4 types of inefficiency or system value reductions.

- One type revolves around prices. Healthcare providers, pharmaceutical companies, medical device manufacturers etc. raised prices far more than at average overall inflation rates because they could – an indicator of market strength. We'll discuss market consolidation later in this chapter.

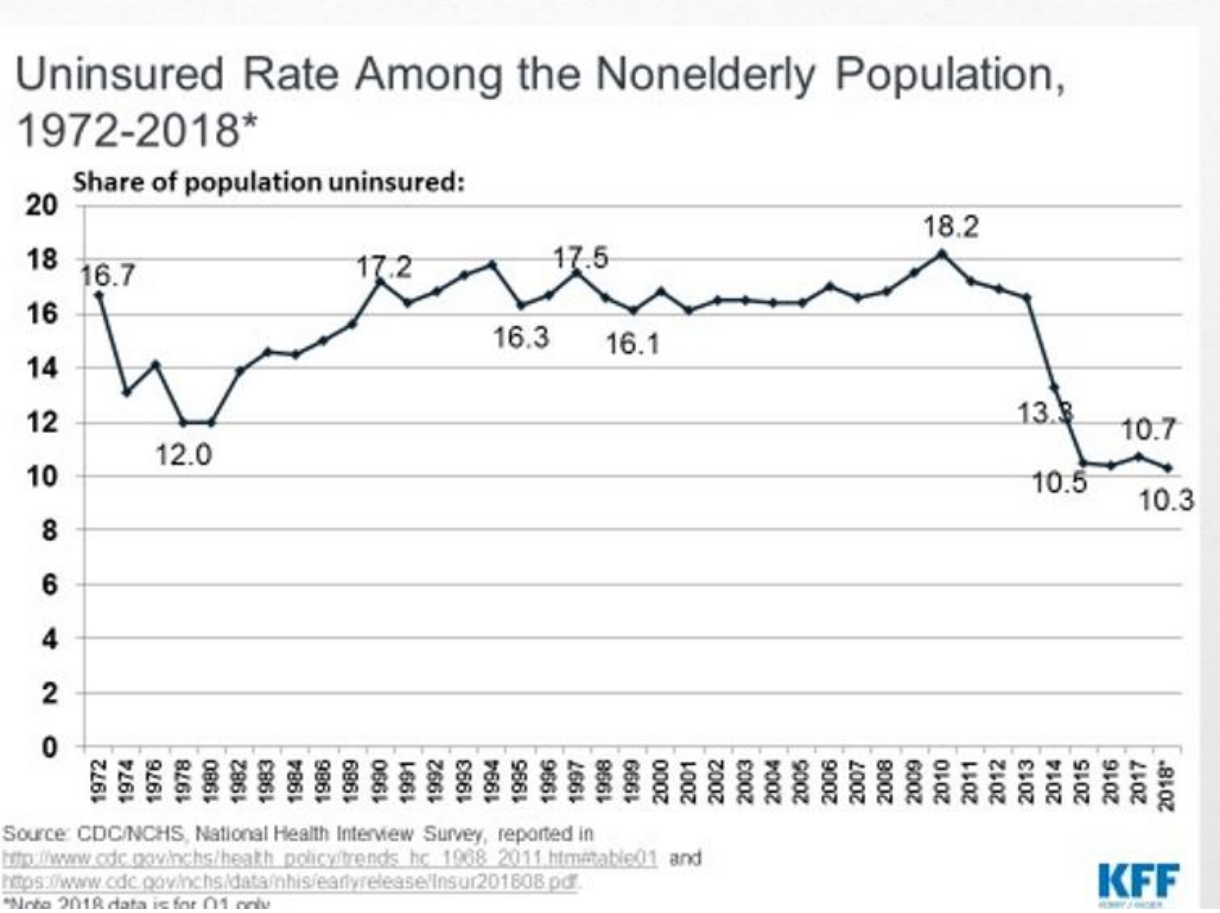
[209] CPI inflation calculator https://www.in2013dollars.com/us/inflation/2002?endYear=2019&amount=1

- A second type of inefficiency comes from patient coding. According to the HHS inspector general, “hospitals increasingly billed for inpatient stays at the most expensive level from FY2014 to FY2019…these stays are vulnerable to…upcoding.”[210] Upcoding means labelling a patient as sicker for financial and reimbursement purposes.
- A third type of inefficiency comes from the mix of medical services provided in 2019 vs. 2003. Providers in 2019 sometimes (often?) opted for more expensive treatments when less expensive ones existed, or new drugs that worked no better than older ones might dominate the marketplace, or new devices that worked no better than older ones.
- A fourth type of inefficiency might come from a changed patient population needing medical care. The 2019 folks might be older, sicker or more obese than the 2003 group.

There is good evidence that all 4 factors combined in 2019 to describe that increase in our healthcare efficiency metric. We’ll discuss some of this below. Regardless, though, of the exact cause, my underlying point here is that neither healthcare reform package – the 2003 Medicare Modernization Act nor the 2010 Affordable Care Act, nor both together – created a more efficient healthcare system that provided better outcomes at lower costs. Both reforms failed on that efficiency scale.

Let’s turn now to coverage expansion, one of the 3 goals of any economic reform program. Post-Medicare Modernization Act – the legislation that was supposed to reduce healthcare costs and thus stimulate higher coverage rates due to the lower costs of health insurance – our **national uninsured rate** did not decrease. But post-Affordable Care Act the national uninsured rate did decrease, from about 18 to 10% of our total non-elderly population, or from about 50 to 30 million people. See the chart below.

[210] HHS Inspector General Data Brief, **February 2021** OEI-01-18-00380



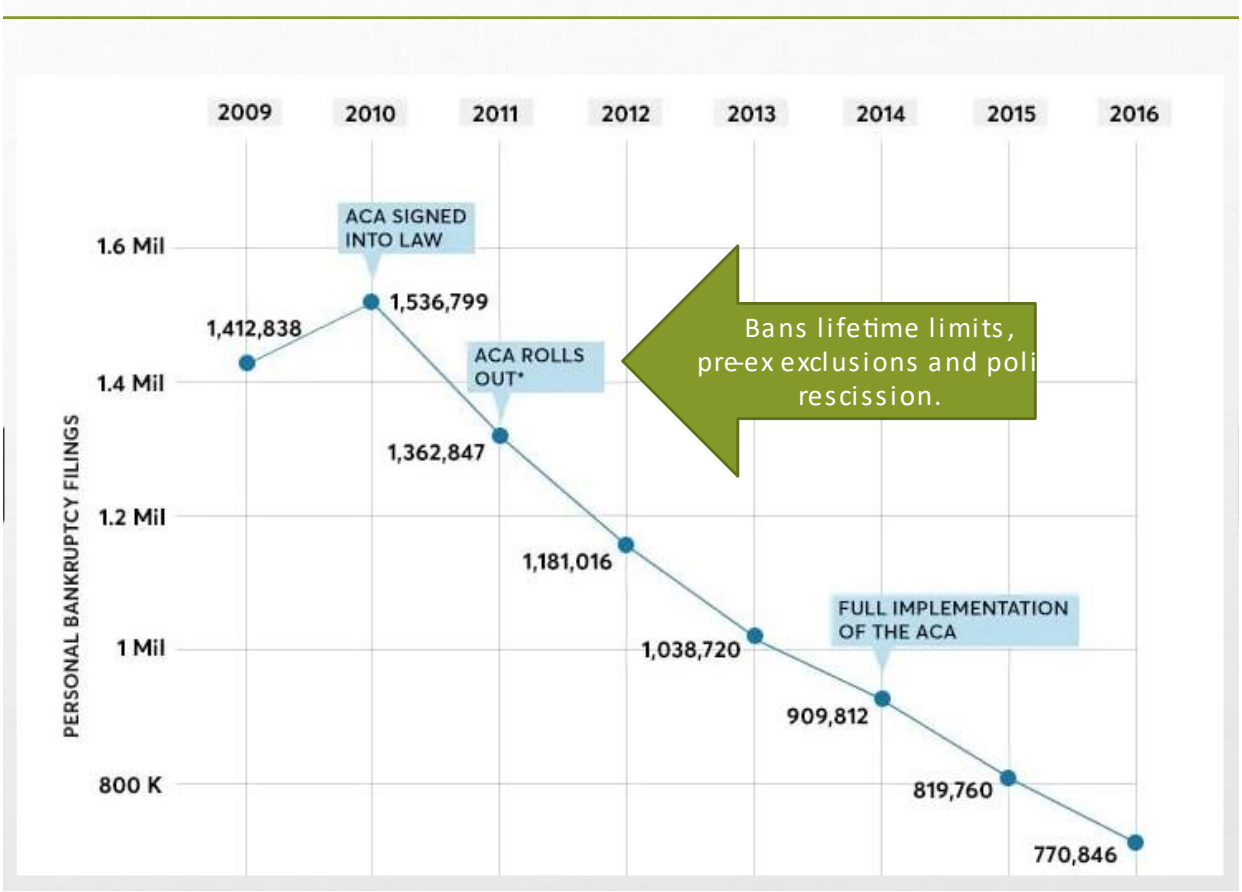
Wider health insurance coverage post-Affordable Care Act but no life expectancy gain. We'll discuss why below, but this initial analysis raises an interesting question: should we grade healthcare reforms *only* on coverage rates? After all, coverage rates are something we can control fairly easily (nothing in healthcare is easy but expanding coverage is mainly a political issue while extending longevity includes medical, economic, social, genetic, educational, behavioral and other issues.)

Some people say 'yes', that the government's role should only be to ensure coverage while the private sector – doctors, hospitals, pharmaceutical companies etc. - should focus on care quality and cost. The government's role is only to promote access; the private sector's is to promote quality. Thus 'good healthcare reform' by this definition, brings down the uninsured rate. Period.

> I find this a strange argument. Extending it to the logical conclusion, it makes the Canadian or British healthcare systems better than ours. After all, they cover everyone while we only mange to insure about 90% of Americans. Few brokers, in my experience, and fewer politicians I suspect, would embrace that conclusion.

All this supports my skeptical position about healthcare reform, that Americans have no clear national vision of what a good healthcare system actually is. Yet each of us, working in the healthcare arena, claims to using our own, parochial one: a good healthcare system is one that pays me well. Odd but, unfortunately I suspect, true.

There is, though, one unequivocal, clear winner from healthcare reforms since 2000 – people declaring bankruptcy from medical expenses. Our national bankruptcy rate has fallen by about half since passage of the Affordable Care Act, from about 1.5 million to 750,000 annually. See the chart below. Many, if not most bankruptcies in the US are caused by medical bills.



While reducing the number of personal bankruptcies is clearly a good thing, I wonder if there might be alternative strategies available to accomplish this goal – other, that is, than revamping the entire US healthcare system. Nonetheless, I take this as a healthcare reform win, the only one I see.

Healthcare reform tools

Let's now consider the tools available to healthcare reformers.

Market based reforms, like the Medicare Modernization Act, focus on so-called 'bottom up' or consumer driven incentives. These market based folks like to deregulate so the market, i.e. the interactions between medical care suppliers and medical care purchasers, takes place as efficiently as possible. Market based reformers dislike mandates and requirements, seeing these are obstacles coming between clinicians and patients. They dislike, in other words, things like insurance coverage requirements or minimum benefit packages that, in their eyes, raise prices unnecessarily. The marketplace, they argue, would differentiate 'good' from 'bad' insurance policies more efficiently.

> Classical economic theory holds that an unencumbered buyer with access to all available information, will choose the highest quality / lowest cost products available. The market based reform team tries to apply this economic principle to healthcare.

Market based reformers like competition, figuring that more competition will force medical care suppliers (providers, clinicians, physicians, pharmaceutical companies and insurers) to find better / less expensive ways to treat sick patients. This becomes, they hope, a virtuous circle in which each product improvement / price reduction move stimulates others in the same direction.

Market based reformers like association health plans, seeing them as competition to large insurance companies. They like price lists and reference pricing figuring that patients will use price as a choice consideration, purchase lower priced care and therefore exert downward pressure on medical prices.

> Reference pricing means that an employer or insurance policy will pay a stipulated amount for a specific treatment, say $5000 for knee surgery for example. If the patient wants the $6000 treatment, or prefers the $6000 surgeon, then he or she pays the additional $1000. In theory, reference price lists reflect the lowest priced medical providers in an area, thus stimulating other providers to lower their own prices to compete.

Market based reformers like Health Savings Accounts and HRAs, both of which put money into patient hands, on the theory that patients will spend their money more wisely than a huge, bureaucratic, bulky insurance carrier.

Government based reforms, on the other hand, use more top-down tools. This team likes regulations that force medical providers and carriers to act in certain ways. They don't trust the market to work its magic in healthcare. These folks like mandates, for example, that require employers to provide health insurance to employees. They like

the individual mandate that requires everyone to have health insurance, this to avoid so-called ‘insurance death spirals’ in which only sick people purchase insurance.

> Insurance death spirals occur when healthier people don’t purchase health insurance, but sicker people do. This drives up premiums, so ‘slightly sicker’ people stop purchasing and only the sickest remain on the insurance books. This makes premiums too expensive for most people, uninsured rates skyrocket and the system collapses.
>
> Insurance operates on the law-of-large-numbers principle and needs lots of healthy people enrolled to counter the costs of sick people. That is why the Affordable Care Act instituted the individual mandate.

Government based reformers also like a required minimum set of benefits in any ACA compliant policies. They worry that carriers might lower their policy prices by leaving out important benefits. Policy holders, either unsophisticated purchasers or victims of unscrupulous sales tactics, might not learn of the benefit gaps until they get a bill, potentially a huge one. In other words, government based reformers see a minimum benefit requirement as consumer protection far less than inflationary. Our market based reform friends, discussed above, see the situation very differently.

The Affordable Care Act created health insurance exchanges, or online marketplaces where individuals could shop for health insurance. Exchanges list all available policy options from all available carriers in a region, encouraging consumers to compare prices and coverages before purchasing. By and large, exchange offered plans cover similar benefits but with different cost sharing.

> Cost sharing means that the policy holder and insurance company each pay a portion of the premium and medical costs. Some policies might cost less but force the insured to pay more at the point of service; others might cost more but have a lower annual deductible.

Which team of healthcare reformers is right - the market based or government based folks? Which approach will reduce healthcare spending, extend life expectancy and provide universal insurance coverage? The unsatisfactory answer is that no one knows for sure, but both teams are convinced of their own infallibility with almost religious zeal. The Medicare Modernization Act passed the Senate in 2003 with 45 Republican votes and only 9 Democrats; the Affordable Care Act passed with 60 Democrats and no Republicans. Given that neither reform reduced costs, extended life expectancy or provided universal insurance coverage, I suspect that the real purpose of healthcare reform is to fight the good fight, raise money from political supporters and stay in office rather than actually to solve any of our myriad healthcare system problems.

But that’s just my own point of view.

Why reforms always fail to reduce costs, extend longevity and provide universal access?

I would argue that all our healthcare reforms since 2003 have ignored the 3 elephants in the room: obesity, industry consolidation and so-called 'diseases of despair' a new term to describe suicide, alcoholism and drug abuse. Any one of these 3 elephants would have made true healthcare reform difficult; all three together make healthcare reform impossible and generate the dismal results we see today. Let's address each elephant in turn and do so in the classical economic terms of supply and demand. But in our case, we'll go in reverse order, demand and supply because this makes our story flow somewhat more logically.

Obesity on the demand side of our 'supply and demand' equation, suggests why Americans need so much medical care. High national obesity rates work in opposition to our 3 healthcare reform goals: obesity decreases life expectancy, increases healthcare costs and therefore exacerbates our uninsured problems.

As I researched the obesity data for this lecture, I found three examples of obesity costs that surprised even me, and I study this stuff for a living. First, as people become more obese, their need for knee surgery rises dramatically. For this analysis, remember that a normal or healthy Body Mass Index tops out at 25.

> Body Mass Index or BMI is our standard weight and obesity metric. It divides someone's weight in kilograms by their height in meters squared. You can find lots of online BMI calculators. A BMI between 18.5 and 24.9 is considered healthy. Below 18.5 is considered underweight, above 25 overweight. A BMI above 30 is labelled obese. The chart below shows BMI rates for a 6 foot tall person at different weights, simply as an example:
>
> - At 147.5 pounds, the 6 foot tall person has a BMI of 20
> - At 184 pounds, the 6 foot tall person has a BMI of 25
> - At 221 pounds, the 6 foot tall person has a BMI of 30
> - At 258 pounds, the 6 foot tall person has a BMI of 35
> - At 295 pounds, the 6 foot tall person has a BMI of 40

As the BMI increases, the need for knee surgery increases proportionally more. Here are estimates from the American Academy of Orthopedic Surgeons for the rate of total knee arthroscopy by BMI. Compared to a normal weight person,

- Someone with a BMI of 30 is 8.5 times more likely to need knee surgery;
- Someone with a BMI of 35 is 18.7 times more likely, and
- Someone with a BMI of 40 is 32.7 times more likely.

We'll label that example 'surprising cost impacts of obesity #1'.

Next, consider the need for bariatric surgery, or surgery to remove part of your stomach to reduce your weight. People generally opt for this procedure after diets and other

lifestyle changes have failed. The US annually spends about $180 billion on bariatric surgery and related medical procedures, that approximation in 2020 dollars.

Compare that to our annual cancer treatment expenditures of around 200 billion or so. Almost as much. But note that virtually everyone in American who gets diagnosed with cancer gets treated. By contrast only about 1% of the eligible obese population has so far had bariatric surgery. That's a huge population appropriate for and needing the procedure. We'll label this 'surprising cost impacts of obesity #2'.

And third, consider the additional Covid costs of obesity, including more severe symptoms, longer hospitalizations, more costly treatments and poorer outcomes. (This section was written in early 2022. Over time Covid treatments have evolved so some of this might be out-of-date when you read it.) According to Dr. Dariush Mozaffarian, dean of the Tufts Friedman School of Nutrition Science and Policy, as quoted in the Boston Globe on November 22, 2021 in an article The Obesity Pandemic Has Made Covid Much More Deadly, "64 percent of all the hospitalizations from COVID could have been prevented, if we had a metabolically healthy population, without the rates of obesity and diabetes and hypertension that we have now."

Let's try to calculate the obesity costs of Covid using Dr. Mozaffarian's estimate above. First, we'll assume the average hospital cost of treating a Covid patient at $100,000. Admittedly rough, this comes from the Becker's Hospital Review analysis by state.[211] To simplify, the average Massachusetts hospital costs of treating a complex Covid patient in 2020 – 2021 were $209,200; the average Massachusetts hospital cost of treating a non-complex patient were $62,900. Other states are basically in the same ballpark. $100,000 per patient is 'not obviously absurd' to quote one of my old grad school professor's mantra.

Meanwhile, the American Hospital Association estimates over 80 million Covid cases and 4.6 million hospitalizations.[212] Multiplying those 4.6 million hospitalizations times $100,000 per hospitalization comes to a whopping $460 billion. Dr. Mozaffarian's 64% of Covid hospitalizations attributable to obesity is almost $300 billion.

That's a huge cost! We'll label this 'surprising cost impact of obesity #3'.

I hope I've made the basic point that obesity is a key driver of healthcare spending and adds a huge amount to our healthcare costs. Which raises the critical question of how well we have done on the obesity front since we reformed healthcare 2003. Presumably

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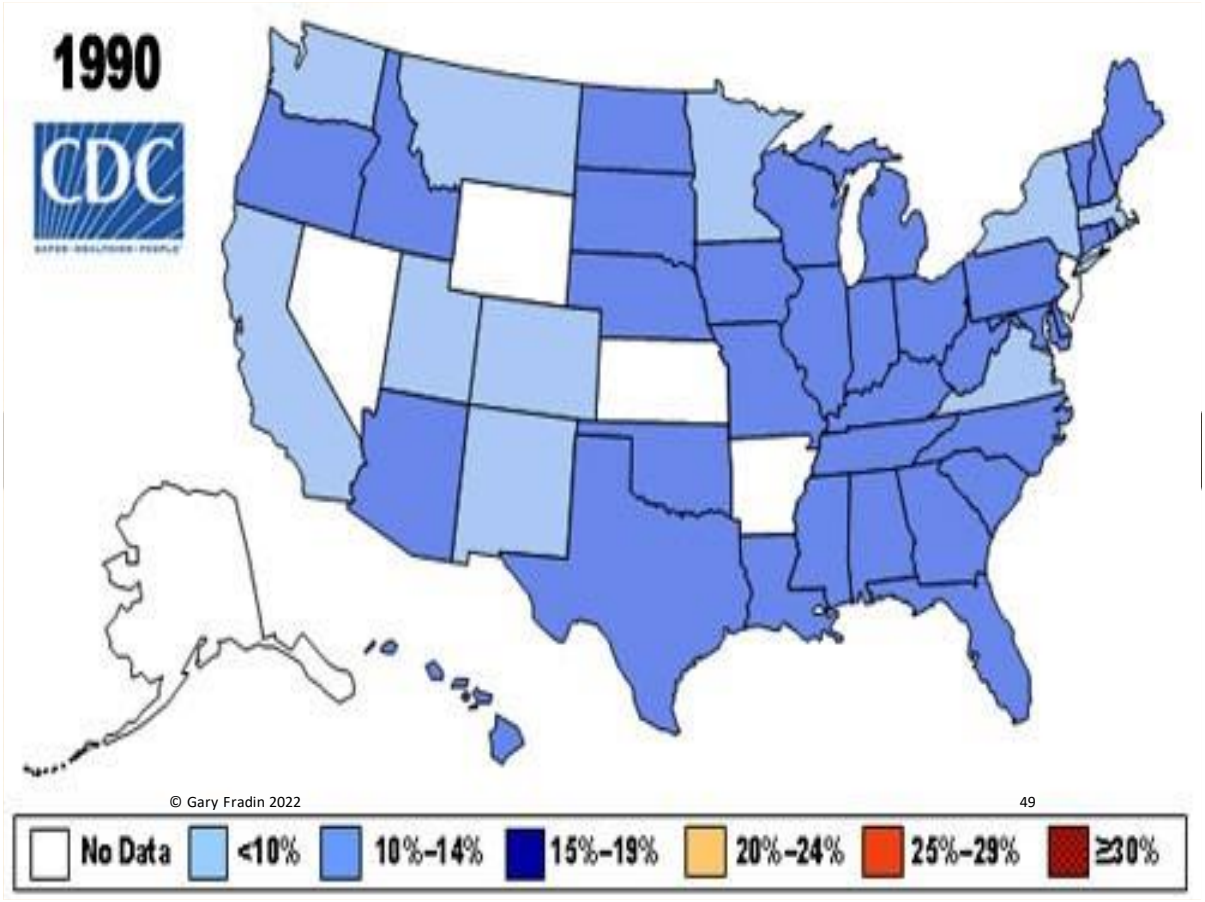
[211] Average charge for Covid 19 hospitalization by state, Alia Paavola, Becker's Hospital Review, October 20, 2021

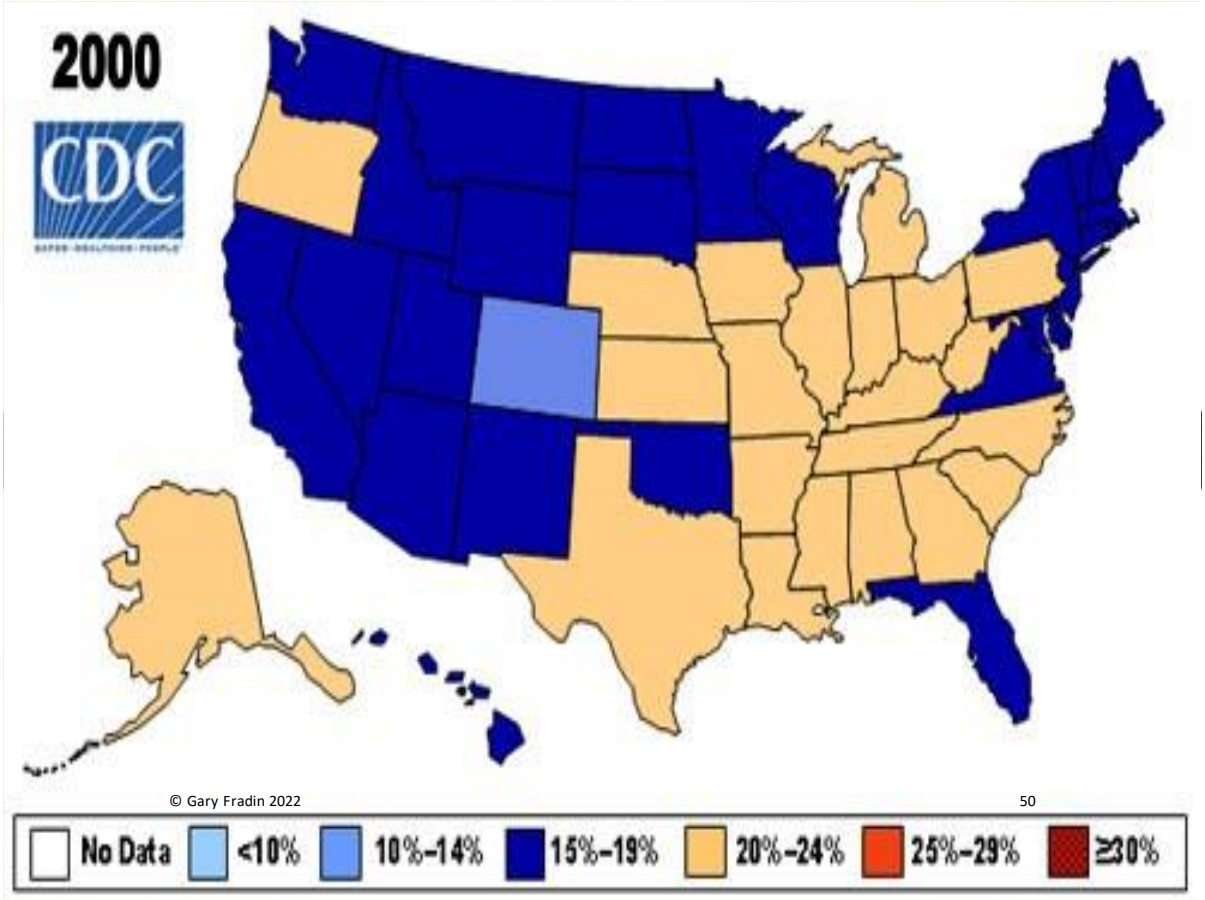
[212] Rising growth in expenses and rising inflation fuel financial challenges for America's hospitals and hospital systems, https://www.aha.org/guidesreports/2022-04-22-massive-growth-expenses-and-rising-inflation-fuel-continued-financial#:~:text=Medical%20supply%20expenses%20grew%2020.6,%2C%20from%20pre%2Dpandemic%20levels.

lower obesity would work toward our healthcare reform goals of better outcomes at lower costs for more people, which greater obesity would work in the opposite direction. In fact, I'll push this even further and suggest that healthcare reforms that fail to address or control obesity set themselves up for failure.

Let's see how we've done and use CDC charts as our guide. We'll start in 1990, before our healthcare reform packages, to set a baseline. The chart below shows obesity by state in 1990. The 4 white states mean 'no data', the 19 light colored states have less than 10% of their populations obese, and the remaining darker states have 10 – 14% of their populations obese. Note also that the CDC's grid at the bottom tops out at greater than 30% obese, a situation the CDC presumably figured unlikely to occur.

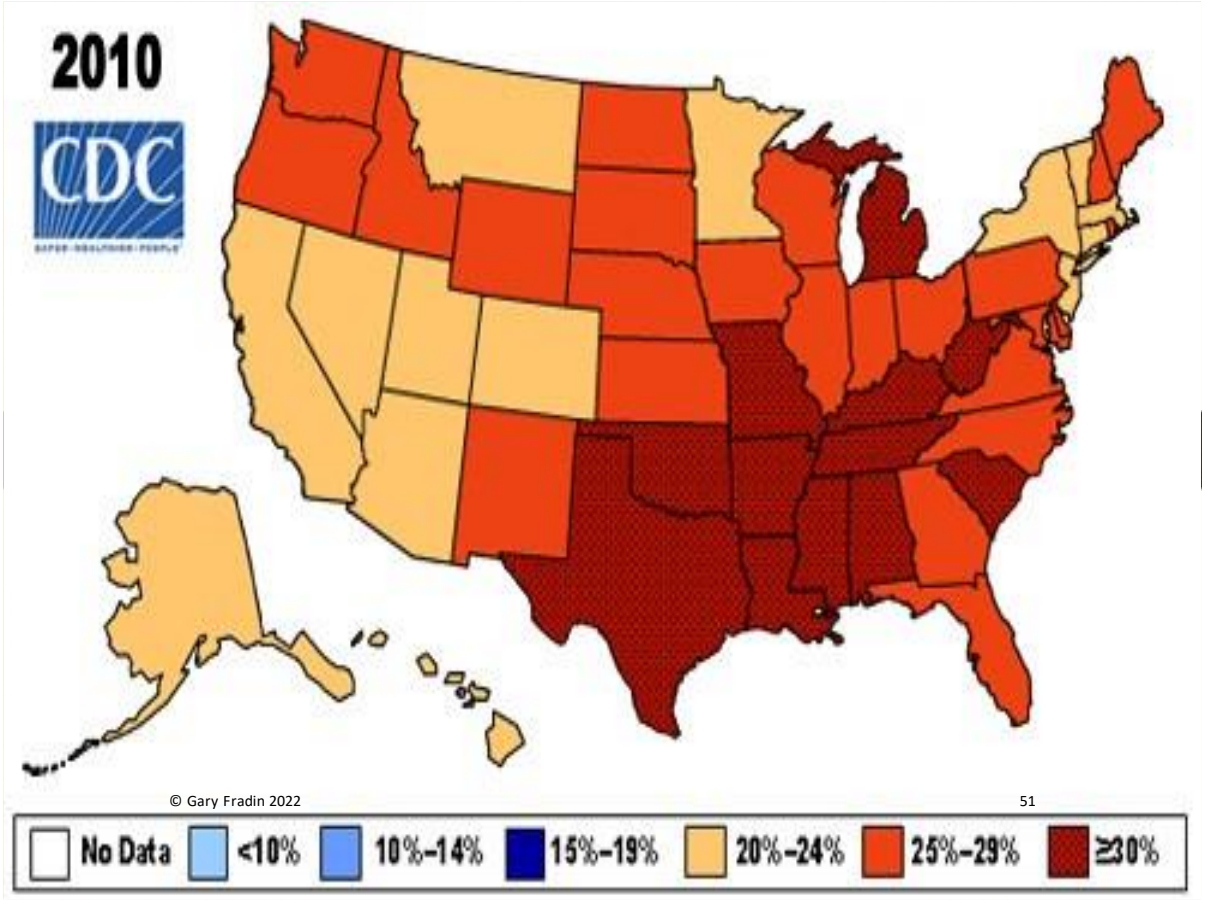


Then, 10 years later, our map changed. Same CDC methodology, same metrics, same format but a vastly different obesity map in only 10 years.



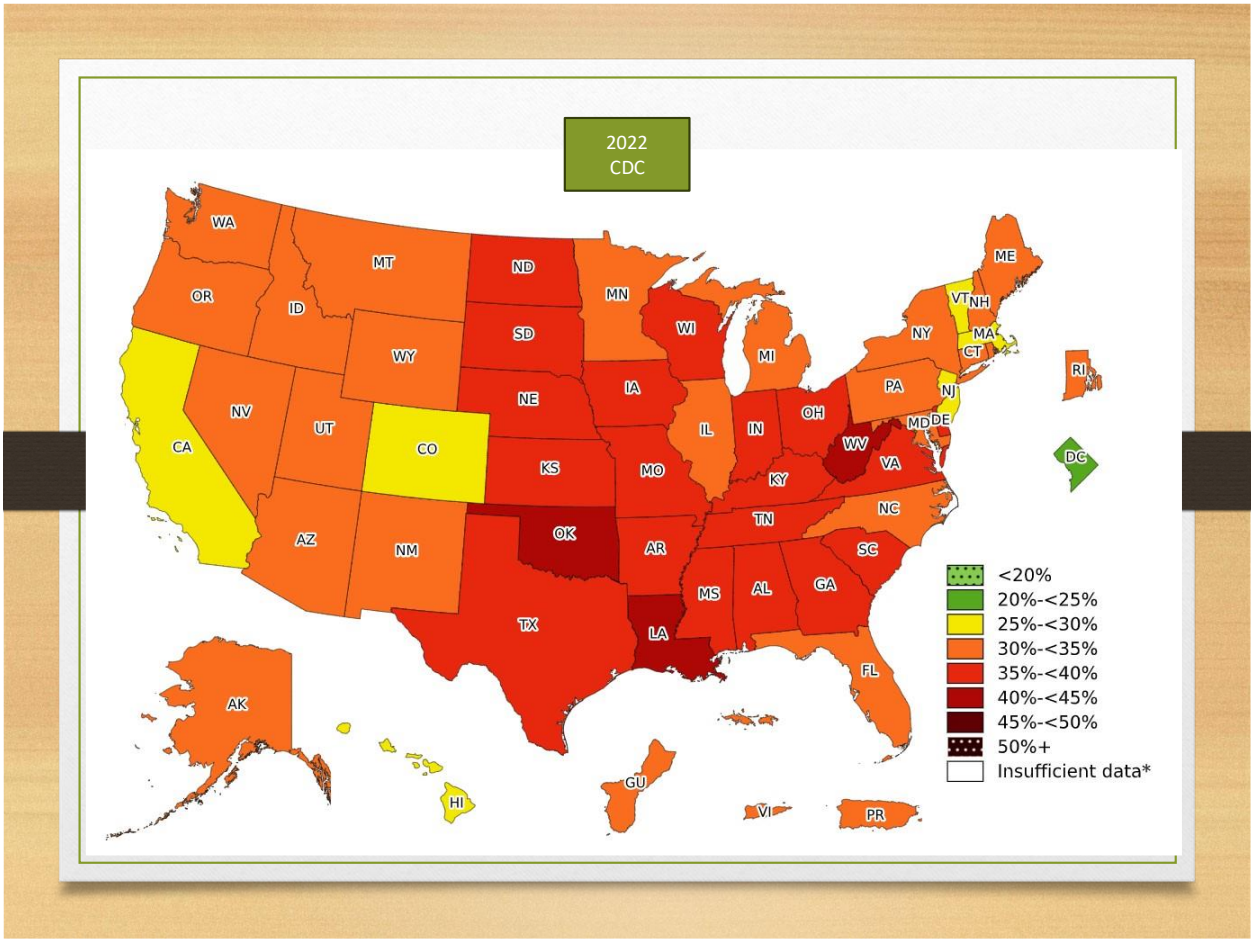
No state is less than 10% obese and only Colorado is less than 14% - the highest level of any state just 10 years before. Now, in 2000, over half the states are 20 – 24% obese, a level no one had reached in 1990.

We then passed the Medicare Modernization Act and the Affordable Care Act…and our map changed dramatically again.



Forget about being less than 20% obese, a level no state had approached just 20 years before. Now no state is less than 20% obese and 11 states had hit the CDC's top limit of 'greater than 30%' obese, a situation the CDC thought unlikely just 20 years previously.

This led the CDC to rethink their format and methodology. In 2022, the CDC had a completely different map.



Only 1 area – DC, not even a state - was less than 25% obese and only 5 less than 30% obese. All the others were greater than 30% obese and a handful exceeded 40%. That's exceptional growth since passage of the Medicare Modernization Act and Affordable Care Act, one that makes achievement of those reform goals overly difficult.

A different CDC study estimated that 42% of us were obese in 2018 and Dr. Mozaffarian, our old friend from the Tufts School of Nutrition, estimated at 1 in 4 teenagers were pre-diabetic.

How, I wonder, can we reduce healthcare spending, improve healthcare outcomes and insure more people with a national obesity rate of 42% and 25% of US teenagers suffering from pre-diabetes. My short answer: you can't.

Let's now move from obesity on the demand side of our 'supply and demand' analysis to the supply side and discuss industry consolidation in the healthcare arena. As a basic economic principle, if you have increasing demand for services – which we have from obesity – and fewer medical care suppliers, then you will see prices rise. Let's examine our post-reform history.

First, hospitals have merged to create large hospital systems. Though they had been merging fairly actively prior to passage of the Affordable Care Act – in Boston, for example, Brigham and Women's merged with Mass General in 1994 – mergermania continued in the hospital sector. Between 2011 and 2017, i.e. post passage of the Affordable Care Act, some 1587 hospitals or about 25% of the US total, merged. These merged hospital systems became the largest (or 2nd largest depending on Amazon) employer in most states. This middle class or wealthier employee population represented votes at the state level to promote the hospital system's interests. The hospital's coffers represented lobbying dollars to promote the hospital system's interests. The merged hospital system spoke with one voice in negotiations with health insurers. And the hospital's wealth funded high priced lawyers to defend the hospital system's interests against aggressive state attorneys general who wished to curb hospital dominance.

The net result was higher medical prices with, according to a 202 analysis in the New England Journal of Medicine, no significant change in 30 day readmission or mortality rates, i.e. no care quality improvement.[213] The Inspector General at the US Department of Health and Human Services phrased this differently in 2021 saying "hospitals increasingly billed for inpatient stays at the most expensive level from FY 2014 through FY 2019" because "these stays are vulnerable to … upcoding".[214] (Upcoding means labelling the patient as sicker to get a higher insurance or Medicare payments.)

The net result: fewer hospitals, caused by the huge number of hospital mergers, used their market power to raise prices.

Hospitals not only merged together but also purchase physician groups to act as 'patient feeders', directing patients to specific hospitals. Between 2016 – 2019, hospitals purchased some 9000 physician practices, again constraining the supply of medical care providers in a region.

Then private equity groups entered the picture, purchasing about 22 physician practices between 2018 and 2019. Private equity purchasers had specific goals: either make a good return on their purchase investment or build an asset for future sale, or both. This motivated physicians to perform more procedures at higher prices. According to a 2022 American Medical Association study 'prices rose 26% in private equity-backed practices, while prices at similar practices without private equity investment grew by 12.9%'.[215]

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[213] Beaulieu et al, Changes in Quality of Care After Hospital Mergers and Acquisitions, New England Journal of Medicine, 2020

[214] HHS Inspector General Data Brief, February 2021 OEI-01-18-00380

[215] Zhu, Private Equity Acquisitions of Physician Medical Groups, JAMA Network Research Letter, Feb 18, 2020

Merged hospitals, combined with acquired physician practices, reduced the number of independent, competitive, healthcare providers dramatically post-healthcare reform. (The actual number of physicians did not decrease, just the number of businesses competing.) Faced with less competition, these large, merged businesses did what any large business would do in similar circumstances: they raised prices. How, I wonder, do negotiations go between a hospital system that controls 75% of the beds in a region and most of the physicians, and an insurer who has a 15% market share?

So far, I've suggested that demand for healthcare services rose post-healthcare reform due to obesity (among other factors) and the supply of healthcare providers available to deal with that increased demand fell due to industry consolidation. Now let's switch focus and discuss the environment in which all this took place. We'll introduce a new term: 'diseases of despair' or alcoholism, drug abuse and suicide combined.

People who die from alcoholism, drug abuse or suicide are said to die 'deaths of despair'. Some numbers to set the scene:

- Alcohol is linked to 95,000 annual deaths according to the CDC. This is about double gunshot deaths.[216]
- 500,000 Americans have died from drug abuse since 1999 including 107,000 in 2021.[217]
- 48,000 annual suicides.[218]

Note that neither the Medicare Modernization Act of 2003 nor the Affordable Care Act of 2010 ameliorated this mortality trend.

AMA 2022 study, Robeznieks, 'Physicians warned of the pitfalls behind private equity promises, Aug 1, 2022 https://www.ama-assn.org/practice-management/private-practices/physicians-warned-pitfalls-behind-private-equity-promises

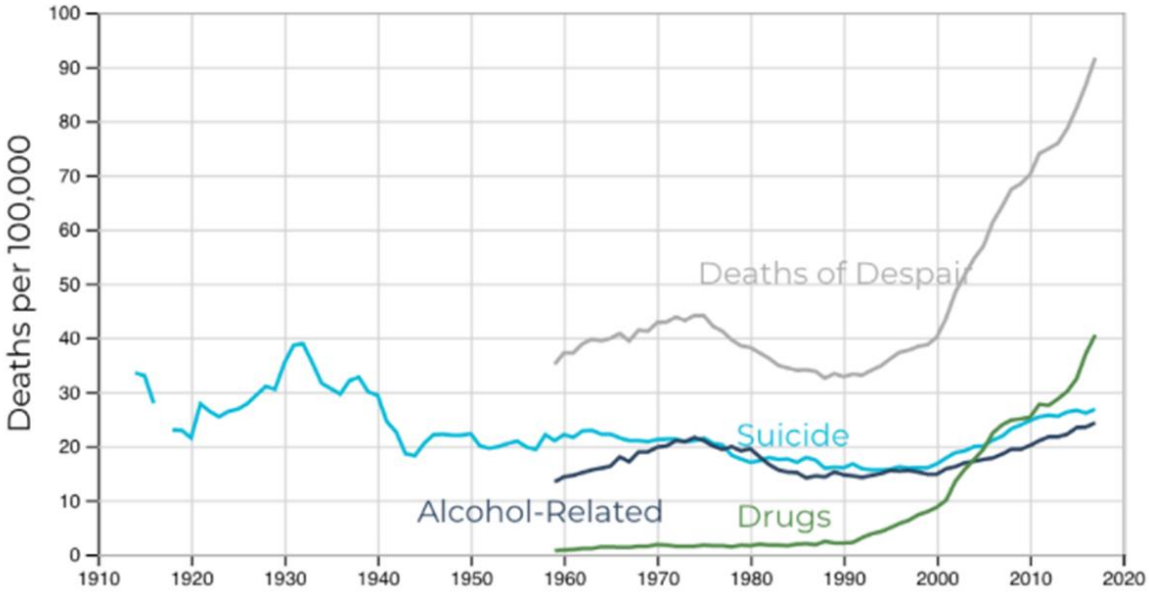
[216] Forbes https://www.forbes.com/sites/joshuacohen/2018/07/19/diseases-of-despair-contribute-to-declining-u-s-life-expectancy/#277e57f0656b, Gunshot deaths https://www.cdc.gov/nchs/fastats/injury.htm

[217] CDC estimate https://www.cdc.gov/media/releases/2020/p1218-overdose-deaths-covid-19.html

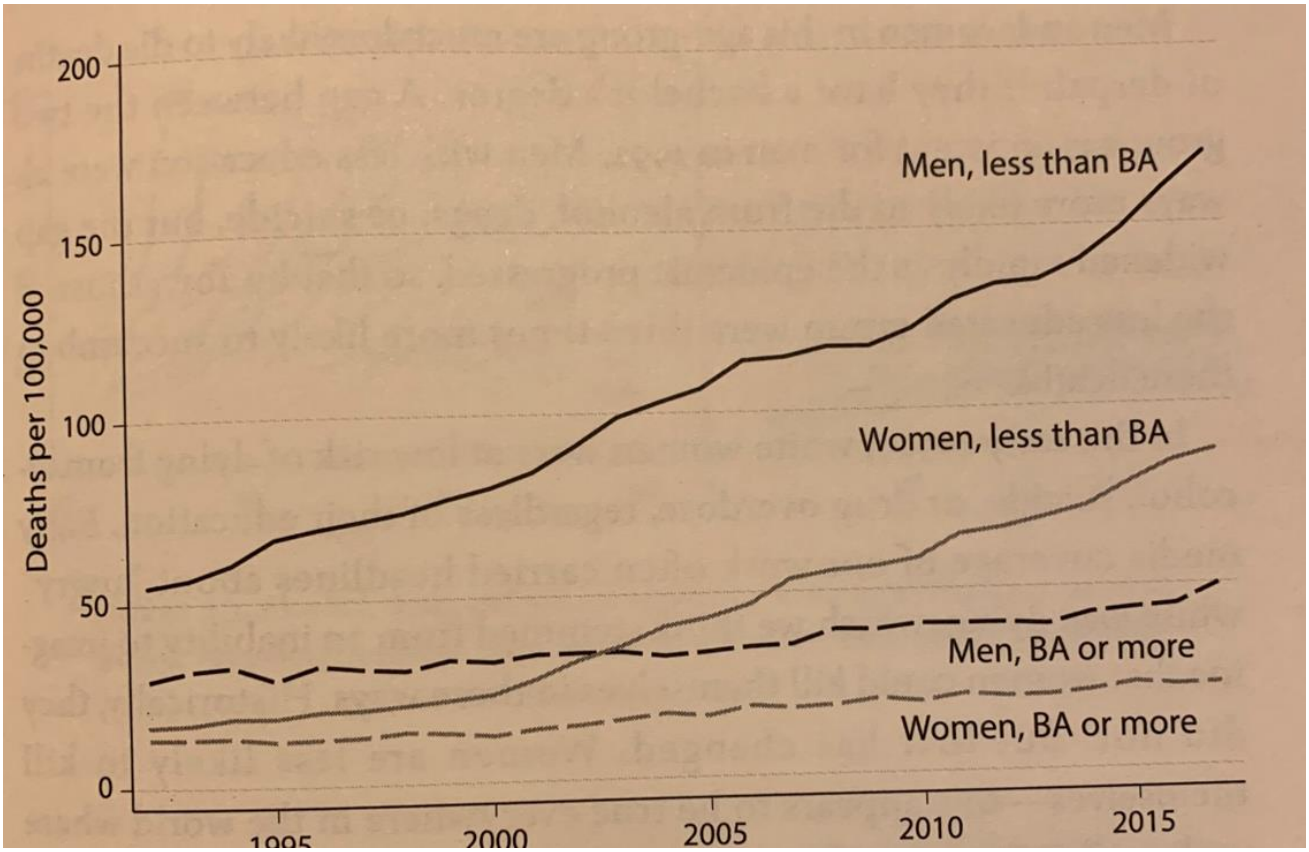
[218] Reference for Figure 3 chart **SEP 05** 2019 United States Congress Joint Economic Committee "Long term trends in deaths of despair"

https://www.jec.senate.gov/public/index.cfm/republicans/2019/9/long-term-trends-in-deaths-of-despair

Figure 3. Deaths of Despair and Its Components, 1914-2017, Crude Rates, Non-Hispanic Whites Ages 45-54



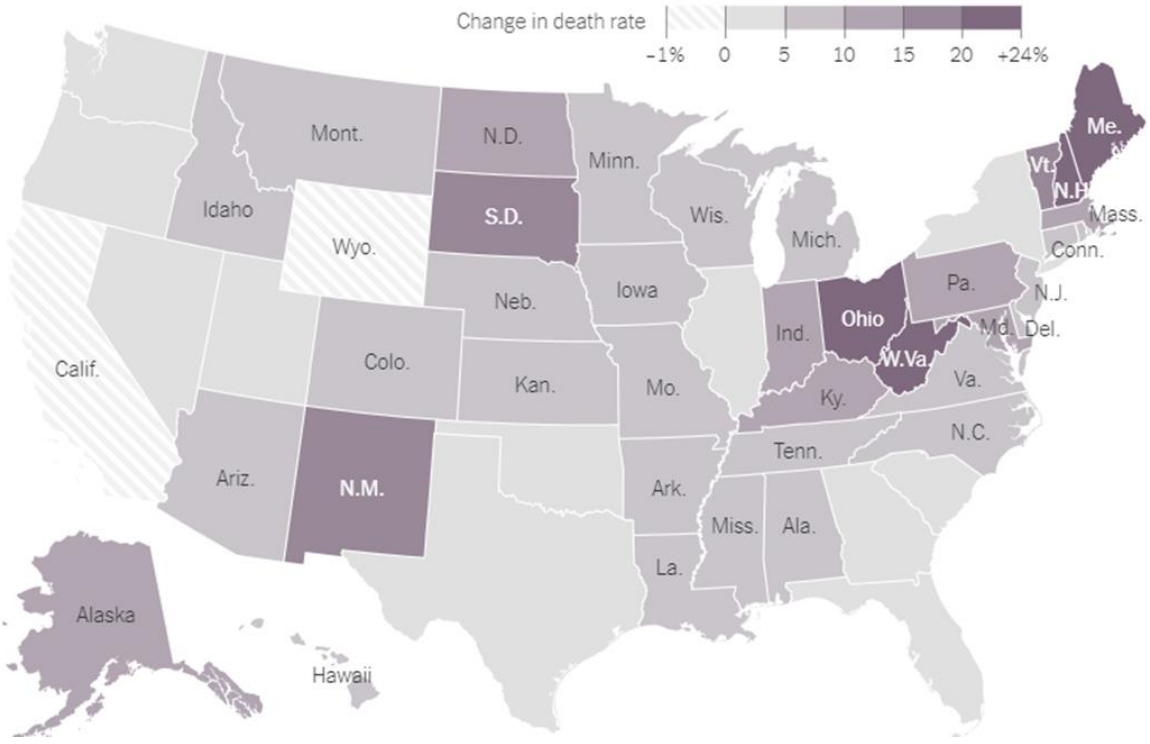
Deaths of despair fall disproportionately on middle aged, white, non-college educated men. The following chart, ‘drug, alcohol and suicide mortality among white, non-Hispanics aged 45 – 54’ shows this. It’s from the 2020 book Deaths of Despair by Angus Deaton and Anne Case.



The next chart shows the net impacts of both healthcare reforms, the Medicare Modernization Act and Affordable Care Act. It shows the increase in mortality between 2010 and 2017 among people aged 25 – 64. These are the folks who should finish their education, begin and develop their careers, get married, have kids, build community and pay taxes. In all states except California and Wyoming, the death rate of this group has increased since passage of the ACA. In the darkest colored state, the death rate increase has been 20% or more.[219]

Death rate **increases** per state 2010 - 2017, people aged 25 – 64

[219] NY Times, It's Not Just Poor White People Driving a Decline in Life Expectancy, Kolata and Tavernise, Feb 18, 2021 https://www.nytimes.com/2019/11/26/health/life-expectancy-rate-usa.html



I understand the components of healthcare reform and what they are supposed to do. Health insurance exchanges are designed to help people shop more easily for health insurance policies. Eliminating annual and lifetime caps allow patients to receive more medical care. Health Savings Accounts combined with annual deductibles and price lists can help people purchase lower cost commodities like MRIs, X rays and a few other relatively low cost products.

But I don't understand how expanding HSAs, increasing insurance options or publishing medical prices reduce obesity, because they don't.

I don't understand how any component of healthcare reform helps people navigate through our 'insane' (Harvard Business School's Regina Herzlinger's term) or 'uniquely dysfunctional' (Columbia School of Public Health's Jonathan Engle's term) healthcare system when 1 hospital system controls 70% of the physicians and beds in a region, because they don't.

And I don't understand how any component of healthcare reform addresses deaths of despair because they don't.

In other words, I don't see any financial, political, insurance or payment format solution to our healthcare system problems. We've seen in the combination of Medicare Modernization Act and Affordable Care Act that incremental reforms don't work. And we know that dramatic, radical healthcare system reforms are politically impossible. The situation looks hopeless.

What might save us?

To answer this question, I propose a quick review of America's history of change, an analysis of how we have solved unsolvable problems in the past. By studying how we solved these problems in the past, we can see how we will likely solve our healthcare system problems in the future.

I am guided in this analysis by two thoughtful comments. The first comes from Herbert Stein, a well-known economist in the last century – Chairman of the Council of Economic Advisors to Presidents Nixon and Ford, for example – who famously observed that 'trends that can't continue, won't'. Something, in other words, always intercedes to avoid utter catastrophe. I suspect Stein is right about this.

The second comes from Mark Twain who equally famously observed that 'history doesn't repeat itself but it rhymes.' Historical examples, in other words, don't tell us exactly what will happen in the future but they suggest a direction.

Let's explore a non-healthcare problem from the late 1800s that could have destroyed civilization as we know it. The problem is horse refuse in major cities. We'll focus on New York since I have some data about this courtesy of the New York Times.[220]

Building technologies changed in the 1870s or so, with Andrew Carnegie's commercialization of steel. Buildings were no longer limited to 4 or 5 stories but could now reach 40, 50 or more. This led to more people living and working per acre.

At the same time, immigrants flooded to New York, increasing the city's population from 950,000 in 1870 to 3.4 million in 1900. More people jammed into tighter spaces meant more need for goods and services on, for example, Manhattan Island.

All these goods and services were transported by horse and buggy. In fact, according to the New York Times, there were more than 150,000 horses in New York in 1880. Each horse, according to their estimate, generated 22 pounds of manure per day. That's 1,650 tons! Plus, again the Times' estimate, 10,000 gallons on urine each day. Plus, again the Times' estimate, about 15,000 horses died each year on the streets – not a bad estimate assuming that each of the 150,000 horses lived an average of 10 years.

All this – the manure, the urine and the horse carcasses – combined to pose a huge disease threat, potentially big enough to destroy cities as they then existed.

Let's now apply current healthcare reform thinking to the horse refuse problem. The market based approach to healthcare reform, a.k.a. the Medicare Modernization Act, would have proposed deregulating horse management, refuse collection and refuse dispersal. Market based thinkers like to deregulate. They probably also would have proposed tax breaks for companies that researched, implemented and demonstrated

[220] Lee, When Horses Posed a Public Health Hazard, NY Times, June 9, 2008

new and ‘better’ horse refuse control technologies and practices. Market based thinkers like tax breaks. They would have wanted to create an environment in which entrepreneurs and business builders would flourish, figuring that the market would solve the horse refuse problem more efficiently than any other approach.

By contrast, the government solution team, a.k.a. the Affordable Care Act thinkers, would have proposed a new government authority to oversee and manage horses. They likely would have wanted more regulations to control every aspect of horse management from feeding to housing to exercising and to refuse collection and dispersal. They would have wanted to license horse owners and users to ensure that the newest thinking and technologies applied to horse rearing. In short, the government solution team would have wanted to pass lots of rules to regulate as much about horses as possible.

I hope this brief historical example shows how both approaches – the market based and government solution – would have failed miserably to solve New York City’s horse problem…just as they have failed to solve our healthcare system problems.

We know what ultimately solved the horse problem in New York – someone invented a car. The horse problem disappeared shortly thereafter. A new technology, unrelated to horse refuse, completely changed the paradigm and eliminated the manure problem.

Our question has changed. It’s no longer ‘what form of healthcare reform can we best solve our healthcare system problems?’ Instead it has become ‘what is the healthcare equivalent of cars?’. I have 4 ideas.

First, the combination of plant based proteins and new medications to address obesity. Things like Impossible Meats, Beyond Meat burgers and the like. Burger King introduced the Impossible Whopper in 2019 to positive reviews. Indeed, as part of my research for this chapter, I visited my local Burger King and ate one; it was delicious. As good as premium burgers and, arguable, healthier. We regularly eat these at home though, truth be told, I prefer the Beyond Burger taste – an individual preference.

Plant based meats act and taste like premium beef and, with their increased scale and 2022 inflation, have become less expensive. This portends a positive trend.

Combine this movement from animal to plant based protein new obesity drugs like semaglutide, trade name Wegovy, manufactured by Nova Nordisk. A high quality study found that obese patients lost an average of 15% of their body weight over 68 weeks, making it twice as effective as older drugs. A similar new anti-obesity drug is Saxenda, also manufactured by Nova Nordisk.

This combination of plant based proteins and new anti-obesity medications could – emphasize ‘could’ – have a significant impact on our obesity rates. Stay tuned.

A second potential healthcare equivalent of cars is gene editing using CRISPR technologies. Full disclosure: as a non-scientist, I do not understand how DNA editing

works. But as an occasional medical news article reader, I have seen reports about sickle cell and leukemia patients being ***cured*** by DNA editing.[221] 'Cured' means there is no evidence that the disease exists in the patient, different from 'remission'. That's tremendously exciting. DNA editing research and trials are continuing in many directions. Again, stay tuned.

A third potential healthcare equivalent of cars is mRNA technology, or messenger RNA. Again as a non-scientist, I don't know how this works. But mRNA technologies are the basis of the Pfizer and Moderna anti-Covid vaccinations that apparently worked quite well. Messenger RNA instructs the body to make specific new proteins. Still early days but a promising and exciting technology.

And a fourth potential healthcare equivalent of cars is the movement to home based healthcare and away from hospital care. Wall Street is betting that this movement will success. Consider these purchase prices from home based healthcare companies in 2021:

- Kindred at Home purchased by Humana, 2021 with **$8.1 billion** market value
- LHC Group Inc, market cap **$5.5 billion** Sept 2021
- Encompass Health, market cap **$7.9 billion**, Sept 2021
- LHC Group, purchased by UHC, 3/22 for **$5.4 billion**

Compare those prices to publicly traded hospital company market values, also in 2021: Tenet Health, 65 hospitals, $8 billion market value; Universal Health, 211 hospitals, $12 billion.

Which, if any, of these potential healthcare equivalent of cars will succeed? I don't know. Maybe all, maybe none.

[221] Sickle Cell success – BBC report Feb 20, 2022 'Sickle Cell: 'The Revolutionary Gene Editing….' https://www.bbc.com/news/health-60348497, Leukemia cure, Boston Globe, 2/3/22 'Doctors: Cancer Patients Cured a Decade After Gene Therapy', Laura Ungar

The Medicare Modernization Act of 2003

Sometimes it's useful for brokers – and all professionals for that matter – to read a legislative summary of important laws. This chapter provides such a summary about the Medicare Modernization Act of 2003. Read this as one attempt to plug some of the obvious holes in our healthcare system; it created, among other things, Health Savings Accounts, Health Reimbursement Accounts, Medicare Part D (Prescription Drugs) and Medicare Part C a.k.a. Medicare Advantage.

The next chapter will present similar information about the Affordable Care Act.

Public Law No: 108-173 (12/08/2003)

Medicare Prescription Drug, Improvement, and Modernization Act of 2003 - **Title I: Medicare Prescription Drug Benefit** (Sec. 101) Amends title XVIII (Medicare) of the Social Security Act (SSA) to add a new part D (Voluntary Prescription Drug Benefit Program). Establishes a new optional Medicare prescription drug benefit program augmenting with a comprehensive, flexible, and permanent voluntary prescription drug benefit program the limited coverage of certain outpatient prescription drugs, biologicals, and vaccines currently covered under the Medicare program under its original fee-for-service component under both Medicare parts A (Hospital Insurance) and B (Supplementary Medical Insurance) and under its managed care, medical savings account (MSA), and private fee-for-service component under Medicare part C (Medicare+Choice).

Provides under this new prescription drug benefit program for offering eligible Medicare beneficiaries, regardless of income or health status, access to more coverage options, options which provide enhanced benefits, with cost-sharing, and additional beneficiary protections and assistance, such as access to negotiated prices, catastrophic coverage limits, and premium subsidies for certain low-income beneficiaries.

Provides for these options to be offered through both: (1) a new Medicare part C Medicare Advantage (MA) program that integrates basic medical coverage with added prescription drug coverage, including coverage through specialized MA plans for special needs individuals; and (2) a new separate, stand-alone Medicare Prescription Drug plan (PDP) program under Medicare part D that relies on private plans to provide coverage and to bear a portion of the financial risk for drug costs.

Makes this new program effective January 1, 2006.

Provides that until this new permanent prescription drug benefit program is effective, the Secretary of Health and Human Services (HHS) shall establish a program to endorse prescription drug discount card programs in order to provide access to prescription drug discounts through prescription drug card sponsors for discount card eligible individuals throughout the United States and to provide for transitional assistance for transitional

assistance eligible individuals enrolled in such endorsed programs. Provides that the program shall not apply to covered discount card drugs dispensed after December 31, 2005, and transitional assistance shall be available after such date to the extent the assistance relates to drugs dispensed on or before such date.

Allows beneficiaries entitled to benefits under Medicare part A or enrolled under Medicare part B (eligible beneficiaries) to elect to enroll under new Medicare part D, and: (1) provided that they are not enrolled in an MA plan, keep their current Medicare fee-for-service coverage and receive qualified prescription drug coverage (as described below) through enrollment in Medicare part D in a new PDP that is offered in the geographic area in which the beneficiary resides; or (2) enroll in the new Medicare part C MA program in an MA plan, give up their current Medicare fee-for-service coverage, and receive qualified prescription drug coverage under the plan along with basic and possibly enhanced medical coverage through health maintenance organization (HMO) or revised MSA coverage options under the new MA program established by this Act under Medicare part C (and as otherwise provided under Medicare+Choice under Medicare part C as discussed more fully below under title II (MedicareAdvantage) of this Act).

Provides an exception for MA enrollees: (1) enrolled in MSA plans to receive qualified coverage of prescription drugs through enrollment in a PDP; (2) enrolled in private-fee-for service plans that do not provide qualified prescription drug coverage to receive qualified coverage of prescription drugs through enrollment in PDP plans; and (3) enrolled in an MA prescription drug plan (MA-PD) to receive qualified prescription drug coverage under that plan.

Directs the Secretary to establish a process for the enrollment, disenrollment, termination, and change of enrollment of Medicare part D eligible individuals in prescription drug plans. Establishes an initial enrollment period beginning November 15, 2005 .

Directs the Secretary to conduct activities designed to broadly disseminate information to part D eligible individuals (and prospective part D eligible individuals) regarding the coverage under Medicare part D, including information comparing the plans offered by eligible entities under Medicare part D that are available to eligible beneficiaries in an area.

Divides qualified prescription drug coverage into either a standard coverage benefit package or an alternative prescription drug coverage with at least actuarially equivalent benefits, both with access to negotiated drug prices. Outlines the standard coverage package, which includes, for 2006, a $250 deductible, 25 percent cost-sharing for drug costs between $250 and the initial coverage limit of $2,250, then no coverage; except that the beneficiary shall have access to negotiated prices, regardless of the fact that no benefits may be payable under the coverage, until incurring out-of-pocket costs for covered drugs in a year equal $3,600, with the beneficiary thereafter to pay five percent

of the cost of a prescription, or a copayment of $2 for a generic drug and $5 for any other drug, whichever is greater. Includes as negotiated prices all discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations. Increases these amounts in future years by the annual percentage increase in average per capita aggregate expenditures for covered drugs for the year ending the previous July.

Includes among the out-of-pocket costs counting toward the annual $3,600 limit any costs paid by the part D eligible individual (or by another person such as a family member) under the Medicaid program or under a State pharmaceutical assistance program for which the individual (or other person) is not reimbursed.

Allows a PDP or an MA plan to provide a different prescription drug benefit design from the standard prescription drug coverage as long as the Administrator of the Medicare Benefits Administration approves of such benefit design.

Directs the Secretary to ensure that each part D eligible individual has available a choice of enrollment in at least two qualifying plans in the area in which the individual resides, at least one of which is a prescription drug plan. Provides that in such case in which such plans are not available the part D eligible individual shall be given the opportunity to enroll in a fallback prescription drug plan.

Establishes beneficiary protection requirements for qualified prescription drug plans, such as requiring each PDP sponsor offering a prescription drug plan to: (1) have a mechanism for providing specific information on a timely basis to enrollees upon request; (2) have in place with respect to covered part D drugs a cost-effective drug utilization management program and a medication therapy management program; and (3) provide that each pharmacy that dispenses a covered part D drug shall inform an enrollee of any differential between the price of the drug to the enrollee and the price of the lowest priced generic covered part D drug under the plan that is therapeutically equivalent and bioequivalent and available at such pharmacy.

Directs the Secretary to establish, and allows the Secretary to revise PDP regions in a manner that is consistent with the requirements below for the establishment and revision of MA regions, and to the extent practicable PDP regions shall be the same as MA regions. Requires a PDP sponsor to submit to the Secretary bid and other described information with respect to each prescription drug plan it offers for review by the Secretary for the purpose of conducting negotiations concerning the terms and conditions of the proposed bid submitted and other terms and conditions of a proposed plan in order for the Secretary to approve or disapprove the plan. Provides that in order to promote competition under new Medicare part D and in carrying out such part, the Secretary may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponosors and may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs.

Establishes organizational requirements for PDP sponsors, such as licenses, and requires that they enter into a contract with the Secretary to be eligible to receive payments.

Provides for premium and cost-sharing subsidies for low-income subsidy-eligible individuals.

Provides: (1) for the establishment of risk corridors for each PDP that determines the amount of risk that the PDP shall be exposed to for drug spending, and the resultant adjustment in payment attributable to this risk; and (2) that a PDP sponsor and MA organization that offers a plan that provides supplemental prescription drug benefits shall be at full financial risk for the provision of such supplemental benefits. Prohibits adjustment in payments made by reason of this paragraph from affecting the monthly beneficiary premium or the MA monthly prescription drug beneficiary premium.

Creates within the Federal Supplementary Medical Insurance Trust Fund the Medicare Prescription Drug Account for payments for low-income subsidy payments, subsidy payments, payments to qualified retiree prescription drug plans, and administrative expenses. Authorizes appropriations. Requires transfers to be made to the Medicaid account for increased administrative costs. Requires amounts withheld for late penalties to be deposited into the Fund. Requires States to make payments to the Account for dual eligibles as provided for under Medicaid.

Directs the Secretary to establish requirements for PDPs to ensure the effective coordination between a part D plan and a State Pharmaceutical Assistance Program with respect to payment of premiums and coverage and payment for supplemental prescription drug benefits for part D eligible individuals enrolled under both types of plans. Requires the Secretary to apply such coordination requirements to described Rx plans, which include Medicaid programs and group health plans and the Federal Employees Health Benefit Program (FEHBP), in the same manner as such requirements apply to a State Pharmaceutical Assistance Program.

Requires the prescription drug discount program and the transitional assistance program to be implemented by the Secretary so that interim prescription drug discount cards and transitional assistance are first available by not later than six months after the enactment of this Act in 2004 and 2005 until coverage under the new part D program becomes effective on January 1, 2006. Requires each prescription drug card sponsor that offers an endorsed discount card program to provide each discount card eligible individual entitled to benefits, or enrolled, under Medicare part A (Hospital Insurance) or part B (Supplementary Medical Insurance) with access to negotiated prices and savings on prescription drugs through enrollment in an endorsed discount card program.

Allows card sponsors to charge annual enrollment fees, not to exceed $30. Requires the fee to be uniform for all discount eligible individuals enrolled in the program. Requires a prescription drug card sponsor offering an endorsed discount card program

to provide that each pharmacy that dispenses a covered discount card drug shall inform a discount card eligible individual enrolled in the program of any differential between the price of the drug to the enrollee and the price of the lowest priced generic covered discount card drug under the program that is therapeutically equivalent and bioequivalent and available at such pharmacy.

Provides that a discount card eligible individual is an individual whose income is not more than 135 percent of the poverty line and who is entitled to have payment made of any annual enrollment fee and to have payment made, up to $600 in 2004, under such endorsed program of 90 percent of the costs incurred for covered discount card drugs.

Creates within the Federal Supplementary Medical Insurance Trust Fund the Transitional Assistance Account for payments for transitional assistance. Makes necessary appropriations.

(Sec. 103) Establishes certain requirements for States as a condition of receiving Federal Medicaid assistance, such as requiring States to provide the Secretary with Medicaid eligibility information necessary to carry out transitional prescription drug assistance verification.

Provides for: (1) Federal phase-in of the costs of premiums and cost-sharing and cost-sharing subsidies for dually eligible individuals; and (2) coordination of Medicaid with Medicare prescription drug benefits to provide that Medicare is the primary payer for covered drugs for dual eligibles.

Exempts prices negotiated from manufacturers for discount card drugs under an endorsement card program and prices negotiated by a PDP under part D, an MA-PD plan, or a qualified retiree prescription plan from the calculation of Medicaid "best price."

Extends the Qualifying-1 (Q-1) program through September 30, 2004, and expands outreach requirements for the Commissioner of Social Security to include outreach activities for transitional assistance and low-income subsidy individuals.

(Sec. 104) Prohibits, effective January 1, 2006, the selling, issuance, or renewal of Medigap Rx policies for part D enrollees, but permits the renewal of a Medigap Rx policy that was issued before January 1, 2006. Permits persons enrolling under part D during the initial enrollment period while covered under a Medigap Rx policy to enroll in a Medigap policy without prescription drug coverage or to continue the policy in effect as modified to exclude drugs. Provides that after the end of such period the individual may continue the policy in effect subject to such modification.

Guarantees issuance of a substitute Medigap policy for persons, enrolling in part D during the initial part D enrollment period, who at the time of such enrollment were enrolled in and terminated enrollment in a Medigap policy H, I, or J or a pre-standard policy that included drug coverage. Guarantees the enrollment for any policies A, B, C, and F within the same carrier of issue. Prevents the issuer from discriminating in the

pricing of such policy on the basis of such individual's health status, claims experience, receipt of health care or medical condition. Prohibits the issuer from imposing an exclusion of benefits based on a pre-existing condition under such policy. Provides that the guarantee applies for enrollments occurring in the new Medigap plan within 63 days of termination of enrollment in a Medigap plan H, I, or J.

Directs the Secretary to request the National Association of Insurance Commissioners to review and revise standards for benefit packages taking into account the changes in benefits resulting from the enactment of this Act and to otherwise update standards to reflect other changes in law included in such Act.

(Sec. 105) Includes additional provisions related to Medicare prescription drug discount cards and transitional assistance program, such as the exclusion of program costs from the calculation of the part B premium. Applies Medicare confidentiality provisions to drug pricing data.

(Sec. 106) Establishes a State Pharmaceutical Assistance Transition Commission to develop a proposal for addressing the unique transitional issues facing State pharmaceutical assistance programs as a result of the enactment of this Act.

(Sec. 107) Requires the Secretary to study and report to Congress on variations in per capita spending for covered part D drugs among PDP regions to determine the amount of such variation that is attributable to price variations and the differences in per capita utilization that is not taken into account in the health status risk adjustment made to PDP bids.

Requires the Secretary to conduct a review of the current standards of practice, clinical services, and other service requirements generally used for pharmacy services in long-term care settings and evaluate the impact of those standards with respect to patient safety, reduction of medication errors and quality of care.

Directs the Secretary to enter into a contract with the Institutes of Medicine of the National Academy of Science to carry out a comprehensive study for a report to Congress on drug safety and quality issues in order to provide a blueprint for a system-wide change. Authorizes appropriations.

Directs the Secretary to provide for a study and report to Congress on the feasibility and advisability of providing for contracting with PDP sponsors and MA organizations under parts C and D of title XVIII on a multi-year basis.

Requires the Comptroller General to conduct a study for a report to the Congress on the extent to which drug utilization and access to covered part D drugs by subsidy eligible individuals differs from such utilization and access for individuals who would qualify as such subsidy eligible individuals except for application of the assets test.

Directs the Secretary to undertake a study for a report to Congress of how to make prescription pharmaceutical information, including drug labels and usage instructions, accessible to blind and visually impaired individuals.

(Sec. 108) Authorizes the Secretary to make grants to physicians for the purpose of assisting them to implement electronic prescription drug programs that comply with appropriate standards. Authorizes appropriations.

(Sec. 109) Expands the work of quality improvement organizations to include part C and part D. Requires such organizations to offer providers, practitioners, MA organizations, and PDP sponsors quality improvement assistance pertaining to prescription drug therapy.

Directs the Secretary to request the Institute of Medicine of the National Academy of Sciences to conduct an evaluation of the peer review program under SSA title XI.

(Sec. 110) Directs the Federal Trade Commission to conduct a study for a report to Congress on differences in payment amounts for pharmacy services provided to enrollees in group health plans that utilize pharmacy benefit managers.

(Sec. 111) Directs the Comptroller General of the United States to conduct an initial and final study for a report to Congress on trends in employment-based retiree health coverage, including coverage under FEHBP, and the options and incentives available under this Act which may have an effect on the voluntary provision of such coverage.

Title II: Medicare Advantage - Subtitle A: Implementation of Medicare Advantage Program - (Sec. 201) Amends SSA title XVIII part C (Medicare+Choice) to replace the current Medicare+Choice program with the Medicare Advantage (MA) program.

Subtitle B: Immediate Improvements - (Sec. 211) Revises the payment system, requiring all plans to be paid at a rate at least as high as the rate for traditional Medicare fee-for-service plans. Makes change in budget neutrality for blend. Increases minimum percentage increase to national growth rate. Includes costs of Department of Defense and Department of Veterans Affairs military facility services to Medicare-eligible beneficiaries in calculation of payment rates.

Directs the Medicare Payment Advisory Commission (MEDPAC) to conduct a study that assesses the method used for determining the adjusted average per capita cost (AAPCC).

Requires the Secretary to submit to Congress a report that describes the impact of additional financing provided under this Act and other Acts on the availability on Medicare Advantage plans in different areas and its impact on lowering premiums and increasing benefits under such plans.

Requires a Medicare Payment Advisory Commission (MEDPAC) study and report to Congress with respect to authority regarding disapproval of unreasonable beneficiary cost-sharing.

Subtitle C: Offering of Medicare Advantage (MA) Regional Plans; Medicare Advantage Competition - (Sec. 221) Directs the Secretary to establish regional plans to encourage private plans to serve Medicare beneficiaries in from ten to 50 regions, including in rural areas, within the 50 States and the District of Columbia beginning not later than January 1, 2005.

Prohibits the Secretary from offering a local preferred provider organization plan under Medicare part C during 2006 or 2007 in a service area unless such plan was offered under such part (including under a demonstration project under such part) in such area as of December 31, 2005. Includes risk corridors for plans during the first two years of the program in 2006 and 2007; a stabilization fund to encourage plan entry and limit plan withdrawals; a blended benchmark that will allow plan bids to influence the benchmark amount; and network adequacy stabilization payments to assist plans in forming adequate networks, particularly in rural areas.

(Sec. 222) Provides that beginning in 2006, each MA organization shall submit to the Secretary for each MA plan for the service area in which it intends to be offered in the following year the monthly aggregate bid amount for the provision of all items and services under the plan for the type of plan and year involved.

Requires this monthly bid amount, with respect to which the Secretary has authority to negotiate, to be compared against respective benchmark amounts for MA local and MA regional plans, with plans that submit bids below the benchmark to be paid their bids, plus 75 percent of the difference between the benchmark and the bid which must be returned to beneficiaries in the form of additional benefits or reduced premiums. Provides that for plans that bid above the benchmark the government will pay the benchmark amount, and the beneficiary will pay the difference between the benchmark and the bid amount as a premium.

Requires the MA plan to provide an enrollee a monthly rebate equal to 75 percent of any average per capita savings as applicable to the plan and year involved. Allows the beneficiary rebate to be credited toward the provision of supplemental health care benefits, the prescription drug premium, or the Medicare part B premium. Requires the plan to disclose to the Secretary information on the form and amount of the rebate or the actuarial value in the case of supplemental health care benefits. Provides that for MA plans providing rebates the MA monthly basic beneficiary premium will be zero.

Provides that: (1) for MA plans with bids above the applicable benchmark, the MA monthly basic beneficiary premium will equal the amount by which the bid exceeds the benchmark; (2) the MA monthly prescription drug beneficiary premium is the base beneficiary premium less the amount of rebate credited toward such amount; and (3)

the MA monthly supplemental beneficiary premium means the portion of the aggregate monthly bid amount for the year that is attributable to the provision of supplemental health benefits, less the amount of rebate credited toward such portion.

Allows enrollees to have their MA premiums deducted directly from their social security benefits, through an electronic funds transfer, or such other means as specified by the Secretary. Requires all premium payments withheld to be credited to the appropriate Trust Fund (or Account therof), as specified by the Secretary, and paid to the MA organization involved.

Subtitle D: Additional Reforms - (Sec. 231) Allows specialized MA plans for special needs individuals to be any type of coordinated care plan. Designates two specific segments of the Medicare population as special needs beneficiaries, but also provides the Secretary the authority to designate other chronically ill or disabled beneficiaries as special needs beneficiaries. Permits certain restriction on enrollment for specialized MA plans for special needs individuals. Provides authority to designate other plans as specialized MA plans.

(Sec. 232) Establishes that the MA program is a Federal program operated under Federal rules. Provides that State laws do not apply except State licensing laws or State laws relating to plan solvency.

(Sec. 233) Makes the Medicare Medical Savings Account (MSA) demonstration program a permanent program option and eliminates the capacity limit and the deadline for enrollment. Provides that non-contract providers furnishing services to enrollees of MSAs will be subject to the same balanced billing limitations as non-contract providers furnishing services to enrolleees of coordinated care plans. Eliminates requirements for the Secretary to submit to Congress periodic reports on the numbers of individuals enrolled in such plans and on the evaluation being conducted.

(Sec. 234) Allows a reasonable cost reimbursement contract to operate indefinitely unless two other plans of the same type enter the cost contract's service area. Requires these two other plans to meet the following minimum enrollment requirements: (1) at least 5,000 enrollees for the portion of the area that is within a metropolitan statistical area having more than 250,000 people and counties contiguous to such an area; and (2) at least 1,500 enrollees for any other portion of such area.

(Sec. 235) Amends the Consolidated Omnibus Budget Reconciliation Act of 1985 to extend Municipal Health Services Demonstration projects through December 31, 2006, for beneficiaries who reside in the city in which the project is operated.

(Sec. 236) Amends SSA title XVIII to provide that protections against balance billing apply to PACE providers and beneficiaries enrolled with such PACE providers in the same manner as such protections apply to any individual enrolled with a Medicare +Choice organization under part C or with an eligible organization.

Provides that MA provisions relating to limitations on balance billing against MA organizations for noncontract physicians and other entities with respect to services covered under Medicare shall apply to PACE providers, PACE program eligible individuals enrolled with such PACE providers, and physicians and other entities that do not have a contract or other agreement establishing payment amounts for services furnished to such an individual in the same manner as provisions apply to MA organizations, individuals enrolled with such organizations, and physicians and other entities referred to under such provisions.

Amends SSA title XIX (Medicaid) to provide that, with respect to services covered under the State plan but not under Medicare that are furnished to a PACE program eligible individual enrolled with a PACE provider by a provider participating under the State plan that does not have a contract or other agreement with the PACE provider that establishes payment amounts for such services, such participating provider may not require the PACE provider to pay the participating provider an amount greater than the amount that would otherwise be payable for the service to the participating provider under the State plan.

(Sec. 237) Provides that Federally Qualified Heatlh Centers (FQHCs) will receive a wrap-around payment for the reasonable costs of care provided to Medicare managed care patients served at such centers. Raises reimbursements to FQHCs in order that when they are combined with MA payments and cost-sharing payments from beneficiaries they equal 100 percent of the reasonable costs of providing such services. Extends the safe harbor to include any remuneration between a FQHC (or entity controlled by an FQHC) and an MA organization.

(Sec. 238) Requires the Secretary to enter into an arrangement under which the Institute of Medicine of the National Academy of Sciences shall conduct an evaluation (for the Secretary and Congress) of leading health care performance measures in the public and private sectors and options to implement policies that align performance with payment under the Medicare program.

Subtitle E: Comparative Cost Adjustment (CCA) Program - (Sec. 241) Directs the Secretary to establish a program for the application of comparative cost adjustment in CCA areas, to begin January 1, 2010, and last six years, and to test whether direct competition between private plans and the original Medicare fee-for-service program will enhance competition in Medicare.

Title III: Combatting Waste, Fraud, and Abuse - (Sec. 301) Amends SSA title XVIII to allow the Secretary to make a conditional Medicare payment if a primary plan has not made or cannot reasonably be expected to make prompt payment. Requires the payment to be contingent on reimbursement by the primary plan to the appropriate Medicare trust fund. Requires a primary plan as well as an entity that receives payment from a primary plan to reimburse the Medicare Trust Funds for any payment made by the Secretary if the primary plan was obligated to make payment. Makes other changes

with regard to Medicare as a secondary payer to address the Secretary's authority to recover payment from any and all responsible entities and to bring action, including the collection of double damages, to recover payment under the Medicare secondary payer provisions.

(Sec. 302) Directs the Secretary to establish and implement quality standards for suppliers of items and services of durable medical equipment, prosthetics and orthotics, and certain other items and services. Requires the Secretary to establish standards for clinical conditions for payment for items of durable medical equipment.

Replaces the current demonstration projects for competitive acquisition of items and services with a permanent program requiring the Secretary to establish and implement programs under which competitive acquisition areas are established throughout the United States for contract award purposes for the furnishing of competitively priced described items and services (including durable medical equipment and medical supplies) for which payment is made under Medicare part B. Allows such areas to differ for different items and services.Allows the Secretary to exempt from such programs rural areas and areas with low population density within urban areas that are not competitive, unless there is a significant national market through mail order for a particular item or service and items and services for which the application of competitive acquisition is not likely to result in significant savings.Requires payment under Medicare part B for competitively priced items and services to be based on bids submitted and accepted for such items and services, and based on such bids the Secretary shall determine a single payment amount for each item or service in each competitive acquisition area. Requires Medicare payment to be equal to 80 percent of the payment amount determined, with beneficiaries paying the remaining 20 percent (after meeting the part B deductible).

Directs the Secretary to conduct a demonstration project on the application of competitive acquisition to clinical diagnostic laboratory tests.

Requires the Comptroller General to conduct a study for a report to Congress on the impact of competitive acquisition of durable medical equipment on suppliers and manufacturers of such equipment and on patients.

Provides that for durable medical equipment, prosthetic devices, prosthetics and orthotics, the update will be 0 points in 2004 through 2008, and that after 2008 for those items not included in competitive bidding the update will be the consumer price index.

Provides that for 2005 the payment amount for certain items, oxygen and oxygen equipment, standard wheelchairs, nebulizers, diabetic lancets and testing strips, hospital beds and air mattresses, will be reduced.

Provides that for prosthetic devices and orthotics and prosthetics in 2004, 2005, and 2006, the update will be 0 percentage points and for a subsequent year is equal to the

percentage increase in the consumer price index for all urban customers for the 12-month period ending in June of the previous year.

Directs the Inspector General of the Department of Health and Human Services to conduct a study for a report to Congress to determine the extent to which (if any) suppliers of covered items of durable medical equipment that are subject to the competitive acquisition program under Medicare are soliciting physicians to prescribe certain brands or modes of delivery of covered items based on profitability.

(Sec. 303) Amends SSA title XVIII to: (1) require the Secretary, beginning in 2004, to make adjustments in practice expense relative value units for certain drug administration services when establishing the physician fee schedule; (2) require the Secretary to use the survey data submitted to the Secretary as of January 1, 2003, by a certain physician speciality organization; and (3) require the Secretary, beginning in 2005, to use supplemental survey data to adjust practice expense relative value units for certain drug administration services in the physician fee schedule if that supplemental survey data includes information on the expenses associated with administering drugs and biologicals the administration of drugs and biologicals, the survey meets criteria for acceptance, and the survey is submitted by March 1, 2004, for 2005, or March 1, 2005, for 2006. (States that this latter provision shall apply only to a speciality that receives 40 percent or more of its Medicare payments in 2002 from drugs and biologicals and shall not apply with respect to the survey submitted by a certain physician speciality organization.) Exempts the adjustments in practical expense relative value units for certain drug administration services from the budget neutrality requirements in 2004.

Requires the Secretary to: (1) promptly evaluate existing drug administration codes for physicians' services to ensure accurate reporting and billing for such services, taking into account levels of complexity of the administration and resource consumption; (2) make adjustments to the nonphysician work pool methodology for the determination of practice expense relative value units under the physician fee schedule so that practice expense relative value units for services determined under such methodology are not affected relative to the practice expense relative value units of services not determined under such methodology; and (3) review and appropriately modify Medicare's payment policy in effect on October 1, 2003, for the administration of more than one drug or biological to an individual on a single day through the push technique. Makes the increase in expenditures resulting from this provision exempt from the budget-neutrality requirement in 2004.

Requires a transitional adjustment or additional payment for services furnished from January 1, 2004, through December 31, 2005, to be made for drug administration services. Requires the part B payment to be made to the physician and equal a percentage of the payment otherwise made.

Directs the MEDPAC to review the payment changes made under this section insofar as they affect payments under Medicare part B for items and services furnished by oncologists and for drug administration services furnished by other specialists. Requires MEDPAC to submit a report to the Secretary and Congress and for the Secretary to make appropriate payment adjustments on the basis of such report.

Provides that the following drugs and biologicals are to be paid at 95 percent of the average wholesale price (AWP): (1) a drug or biological furnished before January 1, 2004; (2) blood clotting factors furnished during 2004; (3) a drug or biological furnished during 2004 that was not available for part B payment as of April 1, 2003; (3) pneumoccal influenza and hepatitis B vaccines furnished on or after January 1, 2004; and (4) a drug or biological furnished during 2004 in connection with the furnishing of renal dialysis services if separately billed by renal dialysis facilities. Provides in general that payments for other drugs furnished in 2004 will equal 85 percent of the AWP (determined as of April 1, 2003). Provides that, beginning in 2005, drugs or biologicals, except for pneumococcal, influenza, and hepatitis B vaccines and those associated with certain renal dialysis services, will be paid using either the average sales price methodology or through the competitive acquisition program. Provides that infusion drugs furnished through covered durable medical equipment starting January 1, 2004, will be paid at 95 percent of the AWP in effect on October 1, 2003, and that those infusion drugs which may be furnished in a competitive area starting January 1, 2007, will be paid at the competitive price. Provides that intravenous immune globulin will be paid at 95 percent of the AWP in 2004 and paid according to the average sales price method in 2005.

Authorizes the Secretary to substitute a different percent of the April 1, 2003 AWP, but not less than 80 percent.

Establishes the use of the average sales price methodology for payment for drugs and biologicals (except for pneumococcal, influenza, and hepatitis B vaccines and those associated with certain renal dialysis services) that are furnished on or after January 1, 2005. Creates an exception to this methodology in the case of a physician who elects to participate in the newly established competition acquisition program.

Directs the Inspector General of the Department of Health and Human Services to conduct studies to determine the widely available market prices of drugs and biologicals.

Directs the Secretary to conduct a study for a report to Congress on sales of drugs and biologicals to large volume purchasers for purposes of determining whether the price at which such drugs and biologicals are sold to such purchasers does not represent the price such drugs and biologicals are made available for purchase to prudent investors.

Directs the Inspector General to conduct a study for a report to Congress on adequacy of reimbursement rate under average sales price methodology.

Directs the Secretary to establish and implement a competitive acquisition program to acquire and pay for competitively biddable drugs and biologicals through the establishment of competitive acquisition areas for the award of contracts. Gives each physician the opportunity annually to elect to obtain drugs and biologicals under the program, rather than the program above using average sales methodology. Directs the Secretary to begin to phase-in the program beginning in 2006.

(Sec. 304) Makes the amendments applicable above applicable to payments for drugs or biologicals and drug administration services furnished by physicians in specialties other than the specialties of hematology, hematology/oncology, and medical oncology.

(Sec. 305) Amends SSA title XVIII to provide that in the case of inhalation drugs or biologicals furnished through covered durable medical equipment that are furnished in 2004, the payment amount will be at 85 percent of AWP, and in 2005 and subsequent years, the payment amount will be the amount provided under the average sales price methodology.

Directs the Comptroller General to conduct a study to examine the adequacy of current reimbursements for inhalation therapy under the Medicare program for a report to Congress.

(Sec. 306) Requires the Secretary to conduct a demonstration project to demonstrate the use of recovery audit contractors under the Medicare Integrity Program in identifying underpayments and overpayments and recoupoing overpayments under the Medicare program for services for which payment is made under Medicare part A or part B. Requires a report to Congress on the demonstration program.

(Sec. 307) Directs the Secretary to establish a pilot program to identify efficient, effective, and economical procedures for long term care facilities or providers to conduct background checks on prospective direct patient access employees. Makes necessary appropriations.

Title IV: Rural Provisions - Subtitle A: Provisions Relating to Part A Only - (Sec. 401) Amends SSA title XVIII part A to require Medicare, for discharges during a fiscal year beginning with FY 2004, to direct the Secretary to compute a standardized amount for hospitals located in any area within the United States and within each region equal to the standardized amount computed for the previous fiscal year for hospitals located in a large urban area (or, beginning with FY 2005, for all hospitals in the previous year) increased by the applicable percentage increase. Directs the Secretary to compute, for discharges occuring in a fiscal year beginning with 2004, an average standardized amount for hospitals located in any area of Puerto Rico that is equal to the average standardized amount computed for FY 2003 for hospitals in a large urban area (or, beginning with FY 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase for the year involved.

(Sec. 402) Provides that for discharges after April 1, 2004, a hospital that is not a large urban hospital that qualifies for a disproportionate share (DSH) adjustment will receive its DSH payments using the current DSH adjustment formula for large urban hospitals, subject to a limit. Caps the DSH adjustment formula at 12 percent for any of these hospitals except rural referral centers.

(Sec. 403) Provides that for discharges on or after October 1, 2004, the Secretary is required to decrease the labor-related share to 62 percent of the standardized amount when such change results in higher total payments to the hospital. Provides that for discharges occurring on or after October 1, 2004, the Secretary is also required to decrease the labor-related share to 62 percent of the standardized amount for hospitals in Puerto Rico when such change results in higher total payments to the hospital.

(Sec. 404) Directs the Secretary, after revising the market basket weights to reflect the most current data, to establish a frequency for revising such weights, including the labor share, in such market basket to reflect the most current data available more frequently than once every five years. Requires the Secretary to include in the publication of the final rule for payment for inpatient hospital services for FY 2006, an explanation of the reasons for, and options considered, in determining such frequency.

(Sec. 405) Reimburses inpatient, outpatient, and covered skilled nursing facility services provided by a critical access hospital (CAH) at 101 percent of reasonable costs of services furnished to Medicare beneficiaries.

Expands reimbursement of on-call emergency room providers to include physician's assistants, nurse practitioners, and clinical nurse specialists for the costs associated with covered Medicare services provided on or after January 1, 2005.

Allows an eligible CAH to be able to receive payments made on a periodic interim payment (PIP) basis for its inpatient services. Requires the Secretary to develop alternative methods for the timing of PIP payments to the CAHs.

Prohibits the Secretary from requiring that all physicians or practitioners providing services in a CAH assign their billing rights to the entity in order for the CAH to be paid on the basis of 115 percent of the fee schedule for any individual physician or practitioner who did not assign billing rights to the CAH. Prohibits a CAH from receiving payment based on 115 percent of the fee schedule for any individual physician or practitioner who did not assign billing rights to the CAH.

Allows a CAH to operate up to 25 beds while deleting the requirement that only 15 of the 25 beds be used for acute care at any time.

Establishes an authorization to award rural hospital flexibility grants at $35 million each year from FY 2005 through FY 2008 and in subsequent years requires a State to consult with the hospital association and rural hospitals in the State on the most appropriate way to use such funds. Prohibits a State from spending more than the

lesser of 15 percent of the grant amount for administrative expenses or the State's federally negotiated indirect rate for administering the grant. Provides that in FY 2005 up to five percent of the total amount appropriated for grants will be available to the Health Resources and Services Administration for administering such grants.

Permits a CAH to establish a distinct part psychiatric or rehabilitation unit that meets the applicable requirements that would otherwise apply to the distinct part if the distinct part were established by a "subsection (d) hospital." Limits the total number of beds that may be established for a distinct part unit to no more than ten. Provides that if a distinct part unit does not meet the applicable requirements during a cost reporting period then no Medicare payment will be made to the CAH for services furnished in such unit during such period. Requires Medicare payments to resume only after the CAH demonstrates that the requirements have been met. Requires Medicare payments for services provided in the distinct part units to equal the amount of the payments that would otherwise be made on a prospective payment basis to distinct part units of a CAH.

Allows certain milage standards to be waived in the case of a facility that was designated as a CAH before January 1, 2006 and was certified by the State as being a necessary provider of health care services.

(Sec. 406) Requires the Secretary to provide for an additional payment amount to each low-volume hospital for discharges occurring during a fiscal year beginning with FY 2005.

(Sec. 407) Provides that in no case will a hospital be denied treatment as a sole community hospital or payment because data are unavailable for any cost reporting period due to changes in ownership, changes in fiscal intermediaries, or other extraordinary circumstances so long as data from at least one applicable base cost reporting period is available.

(Sec. 408) Expands the definition of attending physician in hospice to include a nurse practitioner.

(Sec. 409) Directs the Secretary to conduct a demonstration project for the delivery of hospice care to Medicare beneficiaries in rural areas. Provides that under the project Medicare beneficiaries who are unable to receive hospice care in the facility for lack of an appropriate caregiver are provided such care in a facility of 20 or fewer beds which offers, within its walls, the full range of services provided by hospice programs.

(Sec. 410) Excludes certain rural health clinic and Federally-qualified health center services from the prospective payment system for skilled nursing facilities.

(Sec. 410A) Directs the Secretary to establish a demonstration program to test the feasibility and advisability of the establishment of rural community hospitals to furnish covered inpatient hospital services to Medicare beneficiaries.

Subtitle B: Provisions Relating to Part B Only - (Sec. 411) Extends until January 1, 2006 the hold harmless provisions governing hospital outpatient department (OPD) reimbursement for small rural hospitals and sole community hospitals.

Requires the Secretary to conduct a study to determine if the costs incurred by hospitals located in rural areas by ambulatory payment classification groups exceed those costs incurred by hospitals located in urban areas. Provides that if appropriate the Secretary is required to provide for a payment adjustment to reflect the higher costs of rural providers by January 1, 2006.

(Sec. 412) Directs the Secretary to increase the work geographic index to 1.00 for any locality for which such work geographic index is less than 1.00 for services furnished on or after January 1, 2004, and before January 1, 2007.

(Sec. 413) Establishes a new five percent incentive payment program designed to reward both primary care and specialist care physicians for furnishing physicians' services on or after January 1, 2005, and before January 1, 2008 in physician scarity areas.

Directs the Secretary to pay the current law ten percent Health Professional Shortage Area (HPSA) incentive payment for services furnished in full county primary care geographic area HPSAs automatically rather than having the physician identify the health professional shortage area involved.

Directs the Comptroller General to conduct a study for a report to Congress on the differences in payment amounts under the Medicare physician fee schedule for physicians' services in different geographic areas.

(Sec. 414) Revises payment for ambulance services to provide for, when phasing in the application of the payment rates under the fee schedule, for each level of ground service furnished in a year, for the portion of the payment amount that is based on the fee schedule to be the greater of the amount determined under such national fee schedule or a blended rate of the national fee schedule and the regional fee schedule for the region involved, whichever resulted in a larger payment, with the blended rate to be based 100 percent on the national fee schedule.

Requires the Secretary to establish a regional fee schedule for each of the nine census divisions. Provides for adjustment in payment for certain long trips. Directs the Secretary to provide for a percentage increase in the base rate of the fee schedule for ground ambulance services furnished on or after July 1, 2004, and before January 1, 2010 that originate in a qualified rural area. Increases by two percent the payments for ground ambulance services orginating in a rural area or a rural census tract for services furnished on or after July 1, 2004, and before January 1, 2007. Provides that the fee schedule for ambulances in other areas will by increased by one percent. Provides that these increased payments will not affect Medicare payments for covered ambulance services after 2007.

Requires the Comptroller General to submit to Congress a report on how costs differ among the types of ambulance providers and on access, supply, and quality of ambulance services in those regions and States that have a reduction in payment under the Medicare ambulance fee schedule.

(Sec. 415) Provides that the regulations governing the use of ambulance services will provide that, to the extent that any ambulance service (whether ground or air) may be covered, that a rural air ambulance service will be reimbursed at the air ambulance rate if: (1) the air ambulance service is reasonable and necessary based on the health condition of the individual being transported at or immediately prior to the time of the transport; and (2) the air ambulance service complies with the equipment and crew requirements established by the Secretary.

(Sec. 416) Provides that hospitals with fewer than 50 beds in qualified rural areas will receive 100 percent reasonable cost reimbursement for clinical diagnostic laboratory tests covered under Medicare part B that are provided as outpatient hospital services during a cost reporting period beginning during the two year period beginning on July 1, 2004.

(Sec. 417) Amends the Balanced Budget Act of 1997 to extend the telemedicine demonstration project by 4 years and to increase total funding for the project.

(Sec. 418) Directs the Secretary to evaluate demonstration projects conducted by the Secretary under which skilled nursing facilities are treated as originating sites for telehealth services for a report to Congress.

Subtitle C: Provisions Relating to Parts A and B - (Sec. 421) Provides that with respect to episodes and visits on or after April 1, 2004, and before April 1, 2005, in the case of home health services furnished in a rural area, the Secretary is required to increase the payment amount otherwise made for such services by five percent. Prevents such temporary additional payment increase from being used in calculating future home health payment amounts.

(Sec. 422) Provides that a teaching hospital's total number of Medicare-reimbursed resident positions will be reduced for cost reporting periods starting July 1, 2005, if its reference resident level is less than its applicable resident limit. Exempts rural rural hospitals with fewer than 250 acute care inpatient beds from such reduction. Provides that for such other hospitals the reduction will equal 75 percent of the difference between the hospital's limit and its reference resident level. Authorizes the Secretary to increase the applicable resident limit for each qualifying applicant hospital by such numbers as the Secretary may approve for portions of cost reporting periods occurring on or after July 1, 2005.

Subtitle D: Other Provisions - (Sec. 431) Amends SSA title XI to provide that any remuneration in the form of a contract, lease, grant, loan, or other agreement between a public or non-profit private health center and an individual or entity providing goods or

services to health center would not be a violation of the anti-kickback statue if such agreement contributes to the ability of the health center to maintain or increase the availability or quality of services provided to a medically underserved population.

(Sec. 432) Amends SSA title VII to expand the functions of the Office of Rural Health Policy to include administering grants, cooperative agreements, and contracts to provide technical assistance and other necessary activities to support activities related to improving health care in rural areas.

(Sec. 433) Directs MEDPAC to conduct a study of specified rural provisions of this title for various reports to Congress.

(Sec. 434) Directs the Secretary to waive such provisions of the Medicare program as are necessary to conduct a demonstration project under which frontier extended stay clinics in isolated rural areas are treated as providers of items and services under the Medicare program. Authorizes appropriations.

Title V: Provisions Relating to Part A - Subtitle A: Inpatient Hospital Services - (Sec. 501) Amends SSA title XVIII with respect to hospital payment updates to provide that: (1) an acute hospital will receive an update of the market basket from FY 2005 through FY 2007 if it submits data on the ten quality indicators established by the Secretary as of November 1, 2003; and (2) an acute hospital that does not submit data to the Secretary will receive an update of the market basket percentage minus 0.4 percentage points for the fiscal year in question and that the Secretary will not take this reduction into account when computing the applicable percentage increase in subsequent years.

Directs the Comptroller General to conduct a study to determine: (1) the appropriate level and distribution of Medicare payments in relation to costs for short-term general hospitals under the inpatient prospective payment system; and (2) the need for geographic adjustments to reflect legitmate differences in hospital costs across different geographic areas, kinds of hospitals, and types of cases.

(Sec. 502) Expands the formula for determining the indirect medical education adjustment percentage to cover the period from April 1, 2004 to on and after October 1, 2007.

(Sec. 503) Requires the Secretary to add new diagnosis and procedure codes in April 1 of each year without requiring the Secretary to adjust the payment (or diagnosis-related group classification) until the fiscal year that begins after such date.

Requires the Secretary when establishing whether diagnosis related group (DRG) payment is adequate to apply a threshold that is the lesser of 75 percent of the standardized amount (increased to reflect the difference between costs and charges) or 75 percent of one standard deviation for the diagnosis-related group involved. Requires the mechanism established to recognize the costs of new medical services and

technologies under the appropriate Medicare payment system to be adjusted to provide, before publication of a proposed rule, for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of individuals entitled to benefits under Medicare part A (Hospital Insurance).

Directs the Secretary, before establishing any add-on payment with respect to a new technology, to seek to identify one or more diagnosis-related groups associated with such technology and, within such groups, the Secretary is required to assign an eligible new technology into a diagnosis-related group where the average costs of care most closely approximate the costs of care of using the new technology. Prohibits the making of an add-on payment in such case. Provides that funding for new technology will no longer be budget neutral.

(Sec. 504) Provides that hospitals in Puerto Rico will receive Medicare payments based on a 50-50 split between Federal and local amounts before April 1, 2004. Provides that starting April 1, 2004 through September 30, 2004, payment will be based on a 62.5 percent Federal amount and a 37.5 percent local amount, and that starting October 1, 2004, payment will be based on a 75 percent Federal amount and a 25 percent local amount.

(Sec. 505) Directs the Secretary to establish a process and payment adjustment to recognize commuting patterns of hospital employees who reside in a county and work in a different area with a higher wage index.

(Sec. 506) Requires that hospitals that participate in Medicare and that provide Medicare covered inpatient hospital services under the contract health services program funded by the Indian Health Service and operated by the Indian Health Service, an Indian tribe, an Indian tribal organization, or an urban Indian organization be paid in accordance with regulations promulgated by the Secretary regarding admission practices, payment methodologies, and rates of payment. Requires that these rates of payment must be accepted as payment in full for the items and services provided.

(Sec. 507) Modifies the "whole hospital" exception to the prohibition against physicians referring Medicare patients to entities in which they or their immediate family members have financial interests to provide for a period of 18 months from the date of enactment of this Act during which there is excluded from such exception (and thereby subjected to the prohibition) those circumstances in which a physician's ownership interest is in a "subsection d hospital"devoted primarily or exclusively to cardiac, orthopedic, surgical, or other specialties designated by the Secretary. Exempts from such provision speciality hospitals in operation or under development as of November 18, 2003.

Requires that, in order to maintain the exception, the speciality hospital may not increase the number of physician investors as of November 18, 2003; change or expand the field of specialization it treats; expand beyond the main campus; or increase

the total number of beds in its facilities by more than the greater of five beds or 50 percent of the number of beds in the hospital as of November 18, 2003.

Makes a similar modification with respect to the rural provider exception.

Directs the Secretary in determining whether a hospital is under development as of November 18, 2003 to consider whether architectural plans have been completed, funding has been received, zoning requirements have been met, and necessary approvals from appropriate State agencies have been received, and other evidence the Secretary determines would indicate whether a hospital is under development as of such date.

Directs MEDPAC to conduct a study to determine: (1) any differences in the costs of health care services furnished to patients by physician-owned specialty hospitals and the costs of such services furnished by local full-service community hospitals within specific diagnosis-related groups; (2) the extent to which speciality hospitals, relative to local full-service community hospitals, treat patients in certain diagnosis-related groups within a category, such as cardiology, and an analysis of the selection; (3) the financial impact of physician-owned specialty hospitals on local full-service community hospitals; (4) how the current diagnosis-related group system should be updated to better reflect the cost of delivering care in a hospital setting; and (5) the proportions of payments received, by type of payer, between the specialty hospitals and local full-service community hospitals.

Directs the Secretary to conduct a study of a representative sample of specialty hospitals to: (1) determine the percentage of patients admitted to physician-owned specialty hospitals who are referred by physicians with an ownership interest; (2) determine the referral patterns of physician owners; (3) compare the qualty of care furnished in physician-owned speciality hospitals and in local full-service community hospitals for similar conditions and patient satisfaction with such care; and (5) assess the differences in uncompensated care between the specialty hospital and local full-service community hospitals, and the value of any tax exemption availabble to such hospitals.

(Sec. 508) Directs the Secretary to establish not later than January 1, 2004, by instruction or otherwise a process under which a hospital may appeal the wage index classification otherwise applicable to the hospital and select another area within the State to which to be reclassified. Provides that a qualifying hospital (which must be a "subsection (d) hospital" is not eligible for a change in wage index classification on the basis of distance or commuting. Requires the qualifying hospital to meet such other criteria, such as quality, as the Secretary may specify by instruction or otherwise. Provides that if the Medicare Geographic Reclassification Review Board determines that the hospital is a qualifying hospital, the hospital shall be reclassified to the area selected. Requires such reclassification to apply with respect to discharges occurring during the three year period beginning with April 2, 2004. Limits the total aggregate

amount of additional expenditures resulting from application of this paragraph to $900 million.

Subtitle B: Other Provisions - (Sec. 511) Increases the per diem RUG payment for a skilled nursing facility (SNF) resident with acquired immune deficiency syndrome (AIDS). Provides that such payment increase will not apply on and after such date when the Secretary certifies that the SNF case mix adjustment adequately compensates for the facility's increased costs associated with caring for a resident with AIDS.

(Sec. 512) Provides coverage of certain physician's services for certain terminally ill individuals who have not elected the hospice benefit and have not previously received these physician's services.

(Sec. 513) Directs the Comptroller General to conduct a study of portable diagnostic ultrasound services furnished to Medicare beneficiaries in SNFs for a report to Congress.

Title VI: Provisions Relating to Part B - Subtitle A: Provisions Relating to Physicians' Services - Amends SSA title XVIII with respect to payment for physicians' services to: (1) provide that the update to the conversion factor for 2004 and 2005 will not be less than 1.5 percent; (2) modify the formula for calculating the sustainable growth rate to provide that the gross domestic product factor will be based on the annual average change over the preceding 10 years (a 10-year rolling average); (3) provide that in calendar years 2004 and 2005, for physicians's services provided in Alaska, the Secretary is required to increase geographic practice cost indices to a level of 1.67 for each of the work, practice expense, and malpractice cost indices that would otherwise be less than 1.67; and (4) allow podiatrists, dentists, and optometrists to enter into private contracts with Medicare beneficiaries.

(Sec. 604) Directs the Comptroller General to conduct a study for a report to Congress on access of Medicare beneficiaries to physicians's services under the Medicare program.

(Sec. 605) Requires the Secretary to review and consider alternative data sources than those currently used to establsih the geographic index for the practice expense component under the Medicare physician fee schedule no later than January 1, 2005. Requires the Secretary to select two physician payment localties for such purposes, one to be a rural area and the other one will be a statewide locality that includes both urban and rural areas.

(Sec. 606) Directs MEDPAC to submit to Congress: (1) a report on the effect of refinements to the practice expense component of payments for physicians' services after the transition to a full resource-based payment system in 2002; and (2) a report on the extent to which increases in the volume of physicians' services under Medicare part B are a result of care that improves the health and well-being of Medicare beneficiaries.

Subtitle B: Preventive Services - (Sec. 611) Authorizes Medicare coverage of: (1) an initial preventive physical examination; (2) cardiovascular screening blood tests; and (3) diabetes screening tests.

(Sec. 614) Excludes screening mammography and diagnostic mammography from the outpatient prospective payment system (OPPS).

Subtitle C: Other Provisions - (Sec. 621) Provides that for specified covered OPD drugs and biologicals starting in 2004 payment would be made based on a percentage of the reference AWP for the drug or biological.

Directs the Comptroller General to conduct a survey in each of 2004 and 2005 to determine the hospital acquisition costs for each specified covered outpatient drug. Requires the amount of payment for an orphan drug designated by the Secretary that is furnished as part of a covered OPD service (or group of services) during 2004 and 2005 to equal such amount as the Secretary may specify. Requires the Comptroller General not later than April 1, 2005 to furnish data from such surveys to the Secretary for use in setting payment rates for 2006.

Requires the Comptroller General, no later than 30 days after the date the Secretary promulgates the proposed rules setting forth the payment rates for 2006, to evaluate such rates and submit a report to Congress on their appropriateness.

Directs MEDPAC to submit to the Secretary a report on adjustment of payment for ambulatory payment classifications for specified covered outpatient drugs to take into account overhead and related expenses, such as pharmacy services and handling costs. Authorizes the Secretary to adjust the weights for ambulatory payment classifications for specified covered outpatient drugs to take into account appropriate recommendations to such effect in the report.

Provides that the additional expenditures that result from the previous changes will not be taken into account in establishing the conversion, weighting and other adjustment factors for 2004 and 2005, but will be taken into account for subsequent years.

Provides that with respect to payment under Medicare part B for an outpatient drug or biological covered under such part that is furnished as part of covered OPD services for which an HCPCS code has not been assigned, the amount provided for payment for such drug or biological under such part shall be equal to 95 percent of the AWP for the drug or biological.

Provides that for drugs and biologicals furnished in 2005 and 2006, the Secretary is required to reduce the threshold for establishing a separate ambulatory payment classification (APC) group for drugs or biologicals from $150 to $50 per admission. Makes these separate drug and biological APC groups ineligible for outlier payments. Provides that starting in 2004, Medicare transitional pass-through payments for drugs and biologicals covered under a competitive acquisition contract will equal the average

price for the drug or biological for all competitive acquisition areas calculated and adjusted by the Secretary for that year.

Requires the Secretary to make payment for each brachytherapy device furnished under the hospital outpatient prospective payment system equal to the hospital's charges for each device furnished, adjusted to costs for all brachytherapy devices furnished on or after January 1, 2004, and before January 1, 2007. Provides that charges for such devices will not be included in determining any outlier payment.

Directs the Secretary to create additional groups of covered OPD services that classify such devices separately from the other services (or group of services) paid for under the hospital outpatient prospective payment system in a manner reflecting the number, the radioactive isotope, and the radioactive intensity of the brachytherapy devices furnished to each patient, including the use of separate APCs for brachytherapy devices made from palladium-103 and iodine-125 devices.

Requires the Comptroller General to conduct a study for a report to Congress and the Secretary on the appropriate payment amounts needed for devices of brachytherapy. Requires the report to include specific recommendations for appropriate payments for such devices.

(Sec. 622) Prohibits the Secretary from publishing regulations that apply a functional equivalence standard to a drug or biological. Applies this prohibition to the application of a functional equivalence standard on or after the date of enactment of this Act, unless such application was made prior to enactment and the Secretary applies such standard to such drug or biological only for the purpose of determining eligibility of such drug or biological for transitional pass-through payments.

(Sec. 623) Increases the composite rate for renal dialysis by 1.6 percent for 2005.

Provides that provisions prohibiting the Secretary from providing for an exception under provisions for Medicare coverage for end stage renal disease patients that require the Secretary to provide by regulation for a method (or methods) for determining prospectively the amounts of payments to be made for dialysis services furnished by providers of services and renal dialysis facilities to individuals in a facility and to such individuals at home, and that provisions setting a deadline of July 1, 2001, for new applications for an exception rate in the case of a facility that during 2000 did not file for an exception rate under such former provisions, shall not apply as of October 1, 2002, to pediatric facilities that do not have an exception rate in effect on such date. Requires that for purposes of this paragraph the term pediatric facility means a renal facility at least 50 percent of whose patients are individuals under 18 years of age.

Directs the Inspector General of HHS to conduct two studies for reports to the Secretary with respect to drugs and biologicals (including erythropoietin) furnished to end-stage renal disease patients under the Medicare program which are separately billed by end stage reneal disease facilities.

Requires the Secretary to establish a basic case-mix adjusted prospective payment system for dialysis services. Requires the basic case-mix adjusted system to begin for services furnished on January 1, 2005. Requires the system to adjust for a limited number of patient characteristics.

Provides that payments for separately billed drugs and biologicals (other than erythropoietin) will be 95 percent of the AWP for 2004, the acquisition costs in 2005 (including for 2005), and, beginning in 2006, for such drugs and biologicals (including erythropoietin), such acquisition cost or the average sales price payment methodology for the drug or biological as the Secretary may specify.

Requires drugs and biologicals (including erythropoietin) which were separately billed on the day before the enactment of this Act to continue to be separately billed on and after such date.

Directs the Secretary to establish a demonstration project for the use of a fully case-mix adjusted, bundled payment system for end stage renal disease services, beginning January 1, 2006. Authorizes appropriations.

Requires the Secretary to submit a report to Congress detailing the elements and features for the design and implementation of a bundled prospective payment system for services furnished by end stage renal disease facilities including, to the maximum extent feasible, bundling of drugs, clinical laboratory tests, and other items that are separately billed by such facilities.

(Sec. 624) Provides for an additional two-year moratorium on therapy caps for 2004 and 2005.

Requires the Secretary to submit by March 31, 2004 overdue reports on payment and utilization of outpatient therapy services that are required by the Balanced Budget Act of 1997 and the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BIPA).

Requires the Comptroller General to identify for a report to Congress conditions or diseases that may justify waiving the application of the therapy caps with respect to such conditions or diseases.

(Sec. 625) Waives the late enrollment penalty for military retirees who did not enroll in Medicare part B upon becoming eligible for Medicare. Provides that the waiver applies to the late enrollment penalty for military retirees, 65 and over, who enrolled in the TRICARE for Life program from 2001 to 2004. Requires this waiver to apply to premiums for months beginning with January 2004. Directs the Secretary to establish a method for providing rebates of premium penalties paid for months on or after January 2004 for which a penalty does not apply under such waiver provision but for which a penalty was previously collected.

Directs the Secretary to provide for a special Medicare part B enrollment period for these military retirees beginning as soon as possible after enactment of this Act and ending December 31, 2004.

(Sec. 626) Provides that in FY 2004, starting April 1, 2004, the ambulatory surgery center (ASC) update will be the Consumer Price Index for all urban consumers (U.S. city average) as estimated as of March 31, 2003, minus 3.0 percentage points. Provides that in FY 2005, the last quarter of calendar year 2005, and each of calendar years 2006 through 2009, the ASC update will be zero percent.

Provides that upon implementation of the new ASC payment system, the Secretary will no longer be required to update ASC rates based on a survey of the actual audited costs incurred by a representative sample of ASCs every five years.

Provides that subject to recommendations by the General Accounting Office, the Secretary will implement a revised payment system for payment of surgical services furnished in ASCs. Requires the new system to be implemented so that it is first effective on or after January 1, 2006, and not later than January 1, 2008.

Requires the Comptroller General to conduct a study for a report to Congress that compares the relative costs of procedures furnished in ambulatory surgical centers to the relative costs of procedures furnished in hospital outpatient departments.

(Sec. 627) Limits payment for custom molded shoes with inserts or extra-depth shoes with inserts for an individual with severe diabetic foot disease by the amount that would be paid if they were considered to be a prosthetic or orthotic device. Allows the Secretary to establish lower payment limits than these amounts if shoes and inserts of an appropriate quality are readily available at lower amounts. Requires the Secretary to establish a payment amount for an individual substituting modifications to the covered shoe that would assure that there is no net increase in Medicare expenditures.

(Sec. 628) Provides that there will be no updates to the clinical diagnostic laboratory test fee schedule for 2004 through 2008.

(Sec. 629) Keeps the Medicare part B deductible at $100 through 2004, increasing it to $110 for 2005, and providing that in subsequent years the deductible will be increased by the same percentage as the Medicare part B premium increase.

(Sec. 630) Requires the Secretary to make payment under Medicare part B to a hospital or an ambulatory care clinic (whether provider-based or free standing) that is operated by the Indian Health Service or by an Indian tribe or tribal organization for all Medicare part B covered items and services furnished during the five year period beginning on January 1, 2005.

Subtitle D: Additional Demonstrations, Studies, and Other Provisions - (Sec. 641) Requires the Secretary to conduct a demonstration project under Medicare part B under which payment is made for drugs or biologicals that are prescribed as replacements for

existing covered drugs and biologicals that are furnished incident to a physician's professional service which are not usually self-administered. Requires the project to provide for cost-sharing applicable with respect to such drugs or biologicals in the same manner as the cost-sharing applicable under part D for standard prescription drug coverage.

(Sec. 642) Includes intravenous immune globulin for the treatment in the home of primary immune deficiency diseases as a covered medical service under Medicare.

(Sec. 643) Directs MEDPAC to conduct a study for a report to Congress on the feasibility and advisability of providing for payment under Medicare part B for surgical first assisting services furnished by a certified registered nurse first assistant to Medicare beneficiaries.

(Sec. 644) Requires MEDPAC to conduct a study for a report to Congress on the practice expense relative values established by the Secretary under the Medicare physician fee schedule for physicians in the specialties of thoracic and cardiac surgery to determine whether such values adequately take into account the attendant costs that such physicians incur in providing clinical staff for patient care in hospitals.

(Sec. 645) Directs the Secretary to conduct a study for a report to Congress on the feasibility and advisability of providing for payment for vision rehabiliation services furnished by vision rehabilitation professionals.

Requires the Secretary to submit to Congress a report on the feasibility of establishing a two-year demonstration project under which the Secretary enters into arrangements with vision care preferred provider organization networks to furnish and pay for conventional eyeglasses subsequent to each cataract surgery with insertion of an intraocular lens on behalf of Medicare beneficiaries.

(Sec. 646) Amends SSA title XVIII to direct the Secretary to establish a 5-year demonstration program under which the Secretary is required to approve demonstration projects that examine health delivery factors that encourage the delivery of improved quality in patient care.

(Sec. 647) Directs MEDPAC to conduct a study for a report to Congress on the feasibility and advisability of allowing Medicare fee-for-service beneficiaries direct access to outpatient physical therapy services and physical therapy services furnished as a comprehensive rehabilitation facility service.

(Sec. 648) Directs the Secretary to establish demonstration projects under which the Secretary is required to evaluate methods that improve the quality of care provided to individuals with chronic conditions and that reduce expenditures that would otherwise be made under the Medicare program on behalf of such individuals for such chronic conditions. Requires the Secretary to conduct a demonstration project in at least one area that the Secretary determines has a population of individuals entitled to benefits

under Medicare part A, and enrolled under Medicare part B, with a rate of incidence of diabetes that significantly exceeds the national average rate of all areas.

(Sec. 649) Directs the Secretary to establish a pay-for-performance demonstration program with physicians to meet the needs of eligible beneficiaries through the adoption and use of health information technology and evidence-based outcomes measures

(Sec. 650) Requires the Comptroller General to conduct a study for a report to the Congress on concierge care to determine the extent to which such care is used by Medicare beneficiaries and has impacted upon the access of Medicare beneficiaries to items and services for which reimbursement is provided under the Medicare program.

(Sec. 651) Directs the Secretary to establish demonstration projects for the purpose of evaluating the feasibility and advisability of covering chiropractic services under the Medicare program. Requires the Secretary to conduct an evaluation of the demonstration projects for a report to Congress along with such recommendations for legislation or administrative action as the Secretary determines appropriate.

Title VII: Provisions Relating to Parts A and B - Subtitle A: Home Health Services - (Sec. 701) Amends SSA title XVIII to change the time frame for the home health update from the Federal fiscal year to a calendar year basis beginning with 2004.

Increases home health agency payments by the full market basket percentage for the last quarter of 2003 (October, November, and September) and for the first quarter of 2004 (January, February, and March). Provides that the update for the remainder of 2004 and for 2005 and 2006 is the home health market basket percentage increase minus 0.8 percentage points.

(Sec. 702) Directs the Secretary to conduct a two-year demonstration project under Medicare part B under which Medicare beneficiaries with chronic conditions are deemed to be homebound for purposes of receiving home health services under the Medicare program. Authorizes appropriations.

(Sec. 703) Requires the Secretary to establish a demonstration project under which the Secretary is required, as part of a plan of an episode of care for home health services established for a Medicare beneficiary, to permit a home health agency, directly or under arrangements with a medical adult day-care facility, to provide medical adult day-care services as a substitute for a portion of home health services that would otherwise be provided in the beneficiary's home.

(Sec. 704) Prohibits the Secretary during a described period of suspension from requiring a home health agency to gather or submit OASIS (Outcomes and Assessment Information Set) information that relates to an individual who is not eligible for benefits under either Medicare or Medicaid (non-Medicare/Medicaid OASIS information).

Requires the Secretary to conduct a study for a report to Congress on how non-Medicare/Medicaid OASIS information is and can be used by large home health agencies.

(Sec. 705) Directs MEDPAC to conduct a study for a report to Congress on payment margins of home health agencies under the home health prospective payment system.

(Sec. 706) Allows a religious nonmedical health care institution to provide home health services to individuals meeting conditions for coverage of religious nonmedical health care institutional services.

Subtitle B: Graduate Medical Education - (Sec. 711) Provides that hospitals with per resident amounts above 140 percent of the geographically adjusted national average amount would not get an update from FY 2004 through FY 2013.

(Sec. 712) Provides that Congress intended to provide an exception to the initial residency period for geriatric residency or fellowship programs to accomodate programs that require two years of training to initially become board eligible in the geriatric speciality.

(Sec. 713) Provides that for one year from January 1, 2004, for purposes of applying provisions for the payment of indirect medical education and direct medical education costs, the Secretary is required to allow all hospitals to count residents in osteopathic and allopathic family practice programs in existence as of January 1, 2002, who are training at non-hospital sites, without regard to the financial arrangement between the hospital and the teaching physician practicing in the non-hospital site to which the resident has been assigned.

Requires the Inspector General of the Department of Health and Human Services to conduct a study for a report to Congress on the appropriateness of alternative payment methodologies for the costs of training residents in non-hospital settings.

Subtitle C: Chronic Care Improvement - (Sec. 721) Amends SSA title XVIII to require the Secretary to provide for the phased-in development, testing, evaluation, and implementation of chronic care improvement programs. Requires the programs to be designed to improve clinical quality and beneficiary satisfaction and achieve spending targets with respect to expenditures under Medicare for targeted beneficiaries with one or more threshold conditions. Makes necessary appropriations.

(Sec. 722) Requires each MA organization to have an ongoing quality improvement program for improving the quality of care provided to enrollees in each MA plan offered by such organization (other than an MA private fee-for-service plan or an MSA plan) effective for contract years beginning January 1, 2006. Requires as part of the quality improvement program for each MA organization to have a chronic care improvement program.

(Sec. 723) Directs the Secretary to develop a plan to improve quality of care and to reduce the cost of care for chronically ill Medicare beneficiaries. Authorizes appropriations.

Subtitle D: Other Provisions - (Sec. 731) Requires the Secretary to make available to the public the factors considered in making national coverage determinations of whether an item or service is reasonable and necessary. Allows for public comment in national coverage determinations. Directs the Secretary to develop a plan to evaluate new local coverage determinations to determine which determinations should be adopted nationally and to what extent greater consistency can be acheived among local coverage determinations. Prohibits the Secretary in the case of an individual entitled to benefits under Medicare part A, or enrolled under part B, or both who participates in a category A clinical trial, from excluding payment for coverage of routine costs of care furnished to such individual in the trial.

Directs the Secretary to implement revised procedures for the issuance of temporary national HCPCS codes under Medicare part B.

(Sec. 732) Amends BIPA to provide that direct payment for the technical component of pathology services provided to Medicare beneficiaries who are inpatients or outpatients of acute care hospitals will be made for services furnished during 2005 and 2006.

(Sec. 733) Directs the Secretary, acting through the National Institute of Diabetes and Digestive and Kidney Disorders, to conduct a clinical investigation of pancreatic islet cell transplantation which includes Medicare beneficiaries. Authorizes appropriations. Requires the Secretary to pay for the routine costs as well as transplantation and appropriate related items and services in the case of Medicare beneficiaries who are participating in such a clinical trial as if such transplantation were covered under Medicare.

(Sec. 734) Directs the Secretary to transfer to the Hospital Insurance Trust Fund an amount that would have been held by that fund if the clerical error had not occurred. Appropriates to the Trust Fund an amount determined by the Secretary of the Treasury to be equal to the interest income lost by the Trust Fund through the date on which the appropriation is being made as a result of the clerical error involved.

(Sec. 735) Requires MEDPAC to examine the budgetary consequences of a recommendation before making the recommendation and to review the factors affecting the efficient provision of expenditures for services in different health care sectors under Medicare fee-for-service.

Requires the Commission to conduct a study for a report to Congress on the need for current data and sources of current data available to determine the solvency and financial circumstances of hospitals and other Medicare providers of services. Requires the Commission to submit to Congress a report on investments and capital financing of

hospitals participating under Medicare and access to capital financing for private and not-for-profit hospitals.

Requires the Comptroller General to appoint experts in the area of pharmaco-economics or prescription drug benefit programs to the Commission.

(Sec. 736) Makes technical corrections.

Title VIII: Cost Containment - Subtitle A: Cost Containment - Requires the Medicare Board of Trustees annual report to include information on: (1) projections of growth of general revenue Medicare spending as a percentage of the total Medicare outlays for the fiscal year and each of the succeeding six fiscal years, previous fiscal years, and 10, 50, and 75 years after such fiscal year; (2) comparisons with the growth trends for the gross domestic product, private health costs, national health expenditures, and other appropriate measures; (3) expenditures and trends in expenditures under Medicare part D; and (4) a financial analysis of the combined Medicare trust funds if general revenue funding for Medicare is limited to 45 percent of total Medicare outlays. Requires the trust fund reports to include a determination as to whether there is projected to be excess general revenue Medicare funding for any of the succeeding six fiscal years. Provides that an affirmative determination of excess general revenue funding of Medicare for two consecutive annual reports will be treated as a funding warning for Medicare in the second year for the purposes of requiring presidential submission of legislation to Congress.

(Sec. 802) Amends Federal money and finance law to provide in the event that a Medicare funding warning is made, the President is required to submit to Congress, within the 15-day period beginning on the date of the budget submission to Congress for the succeeding year, proposed legislation to respond to such warning. Provides that if during the year in which the warning is made, legislation is enacted which eliminates excess general revenue Medicare funding for the 7-fiscal-year period, then the President is not required to make a legislative proposal.

Expresses the sense of Congress that legislation submitted in this regard should be designed to eliminate excess general revenue Medicare funding for the seven-fiscal year period that begins in such year.

(Sec. 803) Sets out the procedures for House and Senate consideration of the President's legislative proposal.

Subtitle B: Income-Related Reduction in Part B Premium Subsidy - (Sec. 811) Provides that beginning in 2007, beneficiaries with incomes over $80,000 for an individual or $160,000 for a married couple will be asked to contribute more to the cost of their Medicare benefits through payment of a higher premium since the monthly amount of the premium subsidy applicable to the premium shall be reduced by a monthly adjustment amount that is based on the product of the sliding scale percentage

and the unsubsidized part B premium amount and is phased-in beginning in 2007 through 2010.

Amends the Internal Revenue Code to direct the Secretary of the Treasury, upon written request from the Commissioner of Social Security, to make appropriate disclosure of tax return information to carry out the Medicare part B premium subsidy adjustment.

Title IX: Administrative Improvements, Regulatory Reduction, and Contracting Reform - (Sec. 900) Amends SSA title XVIII (Medicare) to establish within the Centers for Medicare & Medicaid Services (CMS) a center to administer Medicare parts C and D, provide notice of Medicare benefits and related information to beneficiaries, and perform such other duties as the Secretary may specify.

Amends SSA title XI to require that an actuary within the office of Chief Actuary of CMS have duties exclusively related to parts C and D of Medicare and related provisions.

Amends Federal civil service law to increase the pay grade for the Administrator of CMS to Executive Level III, beginning January 1, 2004.

Changes references from the Health Care Financing Administration to the Centers for Medicare and Medicaid Services.

Subtitle A: Regulatory Reform - (Sec. 901) Provides that the term "supplier" means, unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under this title.

(Sec. 902) Requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed regulation or an interim final regulation. Prohibits the timeframe established from being no longer than three years except under exceptional circumstances. Provides that if the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation.

(Sec. 903) Bars retroactive application of any substantive changes in regulations, manual instructions, interpretative rules, statements of policy, or guidelines unless the Secretary determines such retroactive application is needed to comply with statutory requirements or is in the public interest. Provides that no substantive change may go into effect until 30 days after the change is issued or published unless it is needed to comply with statutory requirements or is in the public interest. Prohibits compliance action from being taken against a provider of services or supplier with respect to

noncompliance with such a substantive change for items and services furnished before the effective date of such a change.

Provides that if a provider or supplier follows written guidance provided by the Secretary or by a Medicare contractor when furnishing items or services or submitting a claim and the guidance is inaccurate, the provider or supplier is not subject to any penalty or interest (including interest on a repayment plan).

(Sec. 904) Requires the Comptroller General to conduct a study for a report to Congress to determine the feasibility and appropriateness of establishing in the Secretary authority to provide legally binding advisory opinions on appropriate interpretation and application of regulations to carry out the Medicare program.

Requires the Secretary to periodically submit to Congress a report on the administration of Medicare and areas of inconsistency or conflict among various provisions under law and regulation.

Subtitle B: Contracting Reform - (Sec. 911) Amends SSA title XVIII to permit the Secretary to contract competitively with any eligible entity to serve as a Medicare contractor. Eliminates the distinction between Medicare part A contractors (fiscal intermediaries) and Medicare part B contractors (carriers), and merges separate authorities for fiscal intermediaries and carriers into a single authority for the new contractor. Authorizes these new contractors, called Medicare Administrative Contractors, to assume all the functions of the current fiscal intermediaries and carriers: determining payments; making payments; providing education and outreach to beneficiaries; communicating with providers and suppliers; and additional functions as are necessary.

(Sec. 912) Requires Medicare administrative contractors to implement a contractor-wide information security program to provide information security for the operation and assets of the contractor with respect to such functions under Medicare. Requires Medicare administrative contractors to undergo an annual independent evaluation of their information security programs.

Subtitle C: Education and Outreach - (Sec. 921) Amends SSA title XVIII to require the Secretary to: (1) coordinate the educational activities provided through Medicare administrative contractors to maximize the effectiveness of Federal education efforts for providers and suppliers; and (2) use specific claims payment error rates or similar methodology of Medicare administrative contractors in the processing or reviewing of Medicare develop and implement a methodology to measure the specific payment error rates in the processing or reviewing of Medicare claims to give such contractors an incentive to implement effective education and outreach programs for providers and suppliers.

Directs the Secretary to develop a strategy for communications with individuals entitled to benefits under Medicare part A or enrolled under Medicare part B, or both, and with

providers of services and suppliers under Medicare. Requires Medicare administrative contractors, for those providers of services and suppliers which submit claims to the contractor for claims processing and for those individuals entitled to benefits under part A or enrolled under part B, or both, with respect to whom claims are submitted for claims processing, provide general written responses (which may be through electronic transmission) in a clear, concise, and accurate manner to inquiries of providers of services, suppliers, and individuals entitled to benefits under part A or enrolled under part B, or both, concerning the programs under Medicare within 45 business days.

Directs the Secretary to ensure that Medicare administrative contractors provide, for those providers of services and suppliers which submit claims to the contractor for claims processing and for those individuals entitled to benefits under part A or enrolled under part B, or both, with respect to whom claims are submitted for claims processing, a toll-free telephone number at which such individuals, providers of services, and suppliers may obtain information regarding billing, coding, claims, coverage, and other appropriate information under Medicare. Requires monitoring of contractor responses. Authorizes appropriations.

Authorizes appropriations to the Secretary for enhanced provider and supplier training which are to be tailored for small providers or suppliers.

Requires the Secretary, and each Medicare contractor insofar as it provides services (including claims processing) for providers of services or supppliers, to maintain an Internet website which provides answers in an easily accessible format to frequently asked questions, and includes other published materials of the contractractor, that relate to providers of services and suppliers under Medicare.

Prohibits a Medicare contractor from using a record of attendance at (or failutre to attend) educational activities or other information gathered during an educational program to select or track providers of services or suppliers for the purpose of conducting any type of audit or prepayment review.

(Sec. 922) Directs the Secretary to establish a demonstration program under which described technical assistance is made available, upon request and on a voluntary basis, to small providers of services or suppliers in order to improve compliance with the applicable requirements of the programs under Medicare. Authorizes appropriations.

(Sec. 923) Requires the Secretary to appoint within HHS a Medicare Beneficiary Ombudsman to receive complaints and provide assistance with respect to such complaints and who shall have expertise and experience in the fields of health care and education of (and assistance to) individuals entitled to benefits under Medicare. Authorizes appropriations.

Directs the Secretary to provide through the toll free telephone number 1-800-MEDICARE for a means by which individuals seeking information about, or assistance

with, such programs who phone such toll-free numbers are transferred (without charge) to appropriate entities for the provision of such information or assistance.

Requires the Comptoller General to conduct a study for a report to Congress to monitor the accuracy and consistency of information provided to individuals entitled to benefits under part A or enrolled under part B, or both, through the toll-free telephone number.

(Sec. 924) Requires the Secretary to establish a demonstration program under which the Medicare specialists employed by HHS provide advice and assistance to individuals entitled to benefits under Medicare part A, or enrolled under part B, or both, regarding the Medicare program at the location of existing local offices of the Social Security Administration.

(Sec. 925) Directs the Secretary to provide information about the number of days of coverage remaining under the skilled nursing facility (SNF) benefit and the spell of illness involved in the explanation of Medicare benefits.

(Sec. 926) Requires the Secretary to publicly provide information that enables hospital discharge planners, Medicare beneficiaries, and the public to identify skilled nursing facilities (SNFs) that are participating in the Medicare program. Requires hospital discharge planning to evaluate a patient's need for SNF care.

Subtitle D: Appeals and Recovery - (Sec. 931) Directs the Commissioner of Social Security and the Secretary to develop and transmit to Congress and the Comptroller General a transition plan under which the functions of administrative law judges responsbile for hearing cases under the Medicare program are transferred from the responsibility of the Commissioner and Social Security Administration to the Secretary and HHS.

Directs the Commissioner and the Secretary to implement the transition plan and transfer the administrative law judge functions from the Social Security Administration to the Secretary. Requires the Secretary to: (1) assure the independence of administrative law judges performing the administrative law judge functions transferred from the Centers for Medicare & Medicaid Services and its contractors; and (2) provide for an appropriate geographic distribution of administrative law judges performing the administrative law judge functions transferred throughout the United States to ensure timely access to such judges.

Authorizes additional appropriations to increase the number of administrative law judges, improve education and training opportunities for administrative law judges, and increase the staff of the Departmental Appeals Board.

(Sec. 932) Directs the Secretary to establish a process where a provider, supplier, or a beneficiary who has filed an appeal may obtain access to judicial review when a review entity determines, within 60 days of a complete written request, that the Departmental Appeals Board does not have the authority to decide the question of law or regulation

relevant to the matters in controversy and there is no material issue of fact in dispute. Provides that the determination by such review entity shall be considered a final decision and not be subject to review by the Secretary.

Permits expedited access to judicial review for cases where the Secretary does not enter into or renew provider agreements.

Requires the Secretary to develop and implement a process to expedite appeals of provider terminations and certain other remedies imposed on SNFs, including denial of payment for new admissions and temporary management, if imposed on an immediate basis. Allows an expedited appeal where a finding of substandard quality of care has resulted in the disapproval of a skilled nursing facility's nurse aide training program. Requires the Secretary to give priority to cases where termination has been imposed on a provider.

Allows the Secretary to waive disapproval of a nurse aide training program, upon application by a nursing facility if the imposition of the civil monetary penalty was not related to the quality of care provided to residents of the facility.

Provides that in addition to any amounts otherwise appropriated, such additional sums are authorized to be appropriated for FY 2004 and each subsequent fiscal year as may be necessary to reduce by 50 percent the average time for administrative determinations on appeals.

(Sec. 933) Revises the Medicare appeals process to: (1) require providers and suppliers to present all evidence for an appeal at the reconsideration level that is conducted by a qualified independent contractor (QTC) unless good cause precluded the introduction of the evidence; (2) provide for the use of beneficiaries' medical records in QIC reconsiderations; (3) require that notice of decisions or determinations, redeterminations, reconsiderations, and appeals be written in a manner calculated to be understood by a beneficiary and include reasons for the decision or determination or redetermination and the process for further appeal; (4) specify the eligibility requirements for QICs and their reviewer employees that relate to medical and legal expertise, independence, and prohibitions linked to decisions being rendered; and (5) reduce the required number of QICs from 12 to four.

(Sec. 934) Permits Medicare contractors to conduct random prepayment reviews only to develop a contractor-wide or program-wide claims payment error rate or under such additional circumstances as may be provided under regulations, developed in consultation with providers of services and suppliers. Establishes limitations on initiation of non-random prepayment review.

(Sec. 935) Provides that in situations where repaying a Medicare overpayment within 30 days creates a hardship for a provider or supplier, the Secretary is required, upon the request of the provider or supplier, to enter into an extended repayment plan of at least six months duration, but not longer than three years (or five years in the case of

extreme hardship, as determined by the Secretary). Provides that if the Secretary has reason to suspect that the provider or supplier may file for bankruptcy or otherwise cease to do business or discontinue participation in Medicare or there is an indication of fraud or abuse, the Secretary is not obligated to enter into an extended repayment plan with the provider or supplier.

Provides that if a provider or supplier fails to make a payment in accordance with a repayment plan, the Secretary may immediately seek to offset or otherwise recover the total balance outstanding under the repayment plan.

Provides that if post-payment audits are conducted, the Medicare contractor is required to provide the provider or supplier with written notice of the itent to conduct the audit. Provides that if a Medicare contractor audits a provider or supplier, the contractor shall: (1) give the provider or supplier a full review and explanation of the findings of the audit in a manner that is understandable to the provider or supplier and permits the development of an appropriate corrective action plan; (2) inform the provider or supplier of the appeal rights under Medicare as well as consent settlement options; (3) give the provider of services or supplier an opportunity to provide additional information to the contractor; and (4) take into account such information provided, on a timely basis, by the provider of services or supplier. Provides that such provisions shall not apply if the provision of notice or findings would compromise pending law enforcement activities, whether civil or criminal, or reveal findings of law enforcement-related audits. Requires the Secretary to establish a standard methodology for Medicare contractors to use in selecting a sample of claims for review in the case of an abnormal billing pattern.

(Sec. 936) Requires the Secretary to establish by regulation a provider enrollment process with hearing rights in the case of a denial or non-renewal.

(Sec. 937) Requires the Secretary to develop a process so providers and suppliers can correct minor errors in claims that were submitted for payment without having to initiate an appeal.

(Sec. 938) Amends SSA title XVIII to direct the Secretary to establish a prior determination process where physicians and beneficiaries can request through the Medicare administrative contractor whether Medicare covers certain physicians' services before such services are provided only if the physician requestor is a participating physician, but only with respect to physicians' services to be furnished to an individual who is entitled to benefits under Medicare and who has consented to the physician making the request for those physician services and the beneficiary is an individual entitled to benefits under Medicare, but only with respect to a physicians' service for which the individual receives an advance beneficiary notice from a physician who receives direct payment for that service.

Requires the Secretary to establish a process for the collection of information on the instances in which an advance beneficiary notice has been provided and on instances

in which a beneficiary indicates on such a notice that the beneficiary does not intend to seek to have the item or service that is the subject of the notice furnished. Directs the Secretary to establish a program of outreach and education for beneficiaries and providers of services and other persons on the appropriate use of advanced beneficiary notices and coverage policies under the Medicare program.

Requires the Comptroller General to submit to Congress a report on the use of advanced beneficiary notices under Medicare. Directs the Comptroller General to submit to Congress a report on the use of the prior determination process under such section.

(Sec. 939) Directs the Secretary to permit a provider of services or supplier to appeal any determination of the Secretary relating to services rendered under Medicare to an individual who subsequently dies if there is no other party available to appeal such determination.

(Sec. 940) Adds 30 days to the timeframe for deciding an appeal at the redetermination and reconsideration levels of appeal.

Indexes the amount in controversary for appeals to the consumer price index for all urban consumers, rounded to the nearest multiple of $10 beginning in 2005.

(Sec. 940A) Directs the Secretary to establish a mediation process for local coverage determinations using a physician trained in mediation and employed by the Centers for Medicare & Medicaid Services.

Requires the Secretary to include in the contract with Medicare administrative contractors the performance duties expected of a medical director of a Medicare administrative contractor.

Subtitle E: Miscellaneous Provisions - (Sec. 941) Prohibits the Secretary from implementing any new or modified documentation guidelines for evaluation and management physician services under Medicare on or after the enactment of this Act unless the Secretary: (1) has developed the guidelines in collaboration with practicing physicians (including both generalists and specialists) and provided for an assessment of the proposed guidelines by the physician community; (2) has established a plan that contains specific goals, including a schedule, for improving the use of such guidelines; (3) has conducted appropriate and representative pilot projects to test such guidelines; (4) finds, based on reports submitted with respect to pilot projects conducted for such or related guidelines, that described objectives for evaluation and management guidelines will be met in the implementation of such guidelines; and (5) has established, and is implementing, a program to educate physicians on the use of such guidelines and that includes appropriate outreach.

Directs the Secretary to carry out a study of the following for a report to Congress: (1) the development of a simpler, alternative system of requirements for documentation

accompanying claims for evaluation and management physician services for which payment is made under Medicare; and (2) consideration of systems other than current coding and documentation requirements for payment for such physician services. Directs the MEDPAC to conduct an analysis of the results of the study included in the report for a report to Congress.

Requires the Secretary to conduct a study of the appropriateness of coding in cases of extended office visits in which there is no diagnosis made for a report to Congress.

(Sec. 942) Requires the Secretary to establish a Council for Technology and Innovation within the Centers for Medicare & Medicaid Services to coordinate the activities of coverage, coding, and payment processes under Medicare with respect to new technologies and procedures and to coordinate the exchange of information on new technologies between CMS and other entities that make similar decisions.

Directs the Secretary to establish by regulation procedures for determining the basis for, and amount of, payment for any clinical diagnostic laboratory test with respect to which a new or substantially revised HCPCS code is assigned on or after January 1, 2005.

Requires the Comptroller General to conduct a study for a report to Congress that analyzes which external data can be collected in a shorter timeframe by the Centers for Medicare & Medicaid Services for use in computing payments for inpatient hospital services.

(Sec. 943) Prohibits the Secretary from requiring a hospital (including a critical access hospital) to ask questions (or obtain information) relating to Medicare secondary payor provisions in the case of reference laboratory services if the Secretary does not impose such requirement in the case of such services furnished by an independent laboratory.

(Sec. 944) Requires emergency room services provided to screen and stabilize a Medicare beneficiary after January 1, 2004 to be evaluated for Medicare's "reasonable and necessary" requirement on the basis of the information available to the treating physician or practitioner at the time the services were ordered. Provides that except in the case where a delay would jeopardize the health or safety of individuals, the Secretary is required to request a peer review organization review before making a compliance determination that would terminate a hospital's Medicare participation because of Emergency Medical Treatment and Labor Act (EMTALA) violations.

(Sec. 945) Directs the Secretary to establish a Technical Advisory Group to review issues related to EMTALA and its implementation.

(Sec. 946) Permits a hospice to: (1) enter into arrangements with another hospice program to provide care in extraordinary, exigent or other non-routine circumstances, such as unanticipated high patient loads, staffing shortages due to illness or other events, or temporary travel by a patient outside the hospice's service area; and (2) bill and be paid for the hospice care provided under these arrangements.

(Sec. 947) Requires that public hospitals, not otherwise subject to the Occupational Safety and Health Act of 1970, comply with the Bloodborne Pathogens standard. Provides that a hospital that fails to comply with such requirement will be subject to a civil monetary penalty, but cannot be terminated from participating in Medicare.

(Sec. 948) Makes BIPA-related technical amendments and corrections.

(Sec. 949) Amends SSA title XI to permit the administrator of a Federal health care program to waive certain 5-year exclusions if the exclusion of a sole community physician or sole source of essential specialized services in a community will impose a hardship. Provides that the mandatory exclusions that can be waived are those related to convictions associated with program-related crimes; health care fraud; and controlled substances.

(Sec. 950) Amends SSA title XVIII to prohibit a group health plan providing supplemental or secondary coverage to Medicare beneficiaries from requiring dentists to obtain a claim denial from Medicare for dental benefits that are not covered by Medicare before paying the claim.

(Sec. 951) Requires the Secretary to arrange to furnish to "subsection (d)" hospitals the data necessary for such hospitals to compute the number of patient days used in computing the disproportionate patient percentage for that hospital for the current cost reporting year.

(Sec. 952) Allows physicians and non-physician practitioners to reassign payment for Medicare-covered services, regardless of where the service was provided so long as there is a contractual arrangement between the physician and the entity under which the entity submits the bill for such services. Allows the Secretary to provide for other enrollment qualifications to assure program integrity.

(Sec. 953) Requires the Comptroller General to report to Congress on: (1) the appropriateness of the updates in the conversion factor including the appropriateness of the sustainable growth rate formula for 2002 and subsequently; and (2) all aspects of physician compensation for services furnished under Medicare and how those aspects interact and the effect on appropriate compensation for physician services.

Directs the Secretary to provide, in an appropriate annual publication available to the public, a list of national coverage determinations made under Medicare in the previous year and information on how to get more information with respect to such determinations.

Requires the Comptroller General to submit to Congress a report on the implications if there were flexibility in the application of the Medicare conditions of participation for home health agencies with respect to groups or types of patients who are not Medicare beneficiaries.

Directs the Inspector General of HHS to submit a report to Congress on: (1) the extent to which hospitals provide notice to Medicare beneficiaries in accordance with applicable requirements before they use the 60 lifetime reserve days under the hospital benefit; and (2) the appropriateness and feasibility of hospitals providing a notice to such beneficiaries before the completely exhaust such lifetime reserve days.

Title X: Medicaid and Miscellaneous Provisions - Subtitle A: Medicaid Provisions - (Sec. 1001) Amends SSA title XIX to establish a temporary increase in DSH allotments for FY 2004 and for certain subsequent fiscal years.

Raises the temporary floor for extremely low DSH states for FY 2004 and subsequent fiscal years.

Provides for an appropriate DSH allotment adjustment for FY 2004 and 2005 for States with statewide "Section 1115" waivers which have been revoked or terminated before the end of either such fiscal year and for which there is no DSH allotment for the State. Requires the State whose waiver was revoked or terminated to submit an amendment to its State plan that would describe the methodology to be used by the State to identify and make payments to DSH hospitals, including children's hospitals and institutions for mental diseases or other mental health facilities (other than State-owned institutions or facilities), on the basis of the proportion of patients served by such hospitals that are low-income patients with special needs.

Directs the Secretary to require, with respect to FY 2004 and each fiscal year thereafter, a State as a condition of receiving Medicaid payments to submit to the Secretary an annual report identifying each DSH hospital that received a payment, the amount such hospital received, and such other information as the Secretary determines necessary to ensure the appropriateness of the DSH payments for the previous fiscal year.

Requires the State to annually submit to the Secretary an independent certified audit that verifies: (1) the extent to which hospitals have reduced their uncompensated care costs to reflect the total amount of claimed expenditures; (2) payment compliance; (3) only the uncompensated care costs of providing inpatient hospital and outpatient hospital services to described individuals are included in the calculation of the hospital-specific limits; (3) the State included all payments under Medicaid, including supplemental payments, in the calculation of such hospital-specific limits; and (4) the State has separately documented and retained a record of all of its costs and claimed expenditures under Medicare, uninsured costs in determining payment adjustments, and any payments made on behalf of the uninsured from payment adjustments.

(Sec. 1002) Permits certain high-volume DSH safety net providers to negotiate with pharmaceutical companies and to receive discounts on the prices of inpatient drugs for the lowest price they can get. (Currently such entities are only able to receive discounts on the prices of outpatient drugs because of a Center for Medicare and Medicaid Services interpretation of the best price exemption under the Medicaid drug rebate

program). Provides for the application of specified auditing and recordkeeping requirements with respect to such high-volume DSH hospital safety net providers.

(Sec. 1003) Amends the Omnibus Budget Reconciliation Act of 1989, as amended by the Omnibus Budget Reconciliation Act of 1993 and the Balanced Budget Act of 1997, to permanently extend the moratorium on the determination of Saginaw Community Hospital as an institution for mental disease.

Subtitle B: Miscellaneous Provisions - (Sec. 1011) Appropriates for FY 2005 through 2008 specified funding out of any funds in the Treasury not otherwise appropriated to the Secretary for the purpose of making allotments to States for payments to eligible providers for unreimbursable costs incurred by providing emergency health care services to: (1) undocumented aliens; (2) aliens who have been parolded into the United States at a United States port of entry for the purpose of receiving eligible services; and (3) Mexican citizens permitted to enter the United States for not more than 72 hours under the authority of a biometric machine readable border crossing identification card.

(Sec. 1012) Directs the Secretary to establish the Commission on Systemic Interoperability to develop a comprehensive strategy for the adoption and implementation of health care information technology standards, that includes a timeline and prioritization for such adoption and implementation. Authorizes appropriations.

(Sec. 1013) Provides that in order to improve the quality, effectiveness, and efficiency of health care delivered pursuant to Medicare, Medicaid, and the State Children's Health Insurance Program, the Secretary is required to conduct and support research to meet the priorities and requests for scientific evidence and information identified by such programs with respect to: (1) the outcomes, comparative clinical effectiveness, and appropriateness of health care items and services; and (2) strategies for improving the efficiency and effectiveness of such programs, including the ways in which such items and services are organized, managed, and delivered under such programs. Requires the Secretary to establish a process to develop priorities that will guide the research, demonstrations, and evaluation activities undertaken pursuant to this section. Directs the Secretary to evaluate and synthesize available scientific evidence related to health care items and services identified as priorities and to disseminate such evaluations and syntheses to various prescription drug plans to enhance patient safety and quality of health care. Authorizes appropriations.

(Sec. 1014) Directs the Secretary to establish the Citizen's Health Care Working Group to hold hearings to examine: (1) the capacity of the public and private health care systems to expand coverage options; (2) the cost of health care and the effectiveness of care provided at all stages of the disease; (3) innovative State strategies used to expand health care coverage and lower health care costs; (4) local community solutions to accessing health care coverage; (5) efforts to enroll individuals currently eligible for public or private health care coverage; (6) the role of evidence-based medical practices that can be documented as restoring, maintaining, or improving a patient's health, and

the use of technology in supporting providers in improving quality of care and lowering costs; and (7) strategies to assist purchasers of health care to become more aware of the impact of costs and to lower the costs of health care. Requires the Working Group to prepare and make available to health care consumers through the Internet and other appropriate public channels a report entitled "The Health Report to the American People." Directs the Working Group to initiate health care community meetings throughout the United States to address certain topics and to prepare and make available to the public initial recommendations on health care coverage and ways to improve and strengthen the health care system. Requires the Working Group to submit to Congress for appropriate action the final set of recommendations put together after the period of public comment. Authorizes appropriations.

(Sec. 1015) Makes appropriations to carry out this Act to be transferred from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund: (1) not to exceed $1,000,000,000 for the Centers for Medicare and Medicaid Services; and (2) not to exceed $500,000,000 for the Social Security Administration. Provides from these latter funds for the Social Security Administration to reimburse the Internal Revenue Service for expenses in carrying out this Act. Allows the President to transfer such amounts between the Centers for Medicare and Medicaid Services and the Social Security Administration.

(Sec. 1016) Amends SSA title XVIII to direct the Secretary to establish a loan program that provides loans to qualifying hospitals for payment of the capital costs of projects designed to improve the cancer-related health care infrastructure of the hospital, including construction, renovation, or other capital improvements. Makes appropriations.

Title XI: Access to Affordable Pharmaceuticals - Subtitle A: Access to Affordable Pharmaceuticals - (Sec. 1101) - Amends the Federal Food, Drug, and Cosmetic Act to revise provisions (Hatch-Waxman Act) with respect to abbreviated new drug applications (ANDAs) to require the ANDA applicant to submit a more detailed statement when filing a paragraph IV certification than currently mandated.

Requires the ANDA applicant to notify the patent holder and the brand name company (if different) of a paragraph IV certification within 20 days.

Prohibits the ANDA applicant from amending the application to include a drug different from that approved by the Food and Drug Administration (FDA), but allows the applicant to amend the application if seeking approval for a different strength of the same drug.

Authorizes the FDA to approve the ANDA on the date of an appeals court decision, the date of a settlement order or consent decree, or when a district court decision is not appealed.

Allows the paragraph IV ANDA applicant to request a declaratory judgment regarding the validity of the patent if an infringement suit is not filed within 45 days of the notification but provides however if sued that the patent holder and the brand name

company (if different) may file a counter claim to require that changes be made to correct the patient information submitted.

Disallows damages from being awarded in either case.

Provides that: (1) if a declaratory judgment is pursued, the action is to be brought in the judicial district where the defendant has its principle place of business; and; (2) in a declaratory judgment the holder of an approved new drug application may obtain access to confidential information contained in the application; and (3) the 180-day exclusivity period is to begin on the date of the first commercial marketing of the generic drug by any first ANDA applicants.

Requires a first ANDA applicant to forfeit the 180-day exclusivity period under certain circumstances including failure to market within a specified time frame, withdrawal of the application, amendment of the certification and failure to obtain tentative marketing approval.

Prohibits other subsequent ANDA applicants from being permitted the 180-day exclusivity period if all first ANDA applicants forfeit.

(Sec. 1103) Defines "bioavailability" as the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

Subtitle B: Federal Trade Commission Review - (Sec. 1112) Requires that agreements between brand name companies and generic firms regarding the manufacture or sale of a generic drug that is equivalent to the pharmaceutical marketed by the patent owner must be filed with the Assistant Attorney General and the Federal Trade Commission (FTC) for review within ten days after the agreements are executed.

(Sec. 1114) Exempts from disclosure under the Freedom of Information Act any information or documentary material filed with the Assisstant Attorney General or FTC pursuant to this subtitle, and prohibits such information or documentary material from being made public, except as may be relevant to any administrative or judicial action or proceeding.

(Sec. 1115) Subjects parties which fail to file such agreements to civil penalties.

(Sec. 1116) Allows the FTC to engage in rulemaking to carry out this subtitle.

Subtitle C: Importation of Prescription Drugs - (Sec. 1121) Directs the Secretary to promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States. Sets forth specified provisions respecting: (1) importer and foreign seller recordkeeping and information requirements; (2) qualified laboratory drug testing; (3) registration with the Secretary of Canadian sellers; and (4) approved labeling.

Declares that the Secretary should: (1) focus enforcement on cases in which individual importation poses a significant public health threat; and (2) exercise discretion to permit individuals to make such importation for non-risk personal use.

Authorizes the Secretary to grant individuals a waiver of the prohibition of importation of a prescription drug or device. Directs the Secretary to grant individuals a waiver of such prohibition for an approved prescription drug imported from Canada that is: (1) imported from a licensed pharmacy for not more than 90-day personal use; (2) accompanied by a valid prescription; (3) in a final finished dosage that was manufactured in a registered establishment; and (4) imported under such other conditions as the Secretary determines necessary to ensure public safety.

(Sec. 1122) Directs the Secretary to conduct a study on the importation of drugs into the United States for submission in a report to the Congress.

Title XII: Tax Incentives For Health And Retirement Security - (Sec. 1201) Amends the IRC to permit eligible individuals who are covered by a high deductible health plan with a deductible of at least $1,000 up to $2,250 (subject to an annual cost of living adjustment) for self-only coverage with annual out of pocket expenses (deductibles, co-payments, not premiums) not exceeding $5,000, and a deductible of at least $2,000 up to $4,500 (subject to an annual cost of living adjustment) for family coverage with annual out of pocket expenses (deductibles, co-payments, not premiums) not exceeding $10,000, and not covered by any other other health plan that is not a high deductible health plan (except plans for any benefit provided by permitted insurance and plans for coverage for accidents, disability, dental care, vision care, or long-term care) to establish Health Savings Accounts (HSAs) for taxable years beginning with 2004 to pay for qualified medical expenses. Provides that: (1) contribution levels are to be determined monthly based on how many months of the year the individual is covered by a HDHP; and (2) a plan shall not fail to be treated as a high deductible health plan by reason of failing to have a deductible for preventive care. Prohibits Medicare-eligible individuals from participating in HSAs.

Includes as qualified medical expenses any expense for coverage under: (1) a COBRA continuation plan; (2) a qualified long-term care insurance contract; (3) a health plan during a period in which the individual is receiving unemployment compensation; and (4) health insurance premiums for individuals eligible for Medicare, other than premiums for Medigap policies program

Allows an eligible individual establishing an HSA to take a tax deduction for the taxable year of an amount equal to the aggregate contributions paid during the taxable year by or on behalf of such individual to an HSA of such individual, up to the limits specified above for self-only and family coverage. Allows the deduction whether or not the individual itemizes other deductions.

Allows contributions to remain in the HSA at the end of the year and to earn tax-exempt interest until they are withdrawn for uses other than for qualified medical expenses in which case they are to be included in the gross income of the account beneficiary and subjected to a ten percent penalty, except in cases of disability or death or where the contributions are distributed after the account beneficiary attains Medicare eligibility. Requires contributions to be in cash, except in the case of certain rollover contributions. Allows additional "catch up" contributions for eligible individuals age 55 or older.

Allows an HSA trustee to be a bank, an insurance company, or another person.

Permits rollovers from Archer MSAs.

Prohibits any payment or distribution out of an HSA for qualified medical expenses from being treated as an expense paid for medical care.

Allows employers to contribute to the HSAs of their employees and excludes amounts contributed from the employee's income and from employment taxes.

Imposes an excise tax on: (1) the failure of employer to make comparable HSA contributions; and (2) excess contributions.

Allows HSAs to be offered under cafeteria plans.

(Sec. 1202) Excludes from gross income any special subsidy payment received under employer-sponsored qualified retiree prescription drug plan programs.

(Sec. 1203) Creates an exception to information reporting requirements relating to information at the source for flexible spending arrangements and a health reimbursement arrangement that is treated as employer-provided coverage.

The Affordable Care Act

The Obama administration passed the Affordable Care Act (ACA), a.k.a. the Patient Protection and Affordable Care Act (PPACA), a.k.a. ObamaCare. All these terms – Affordable Care Act, PPACA and ObamaCare – mean exactly the same thing as all refer to exactly the same legislation.

Public Law No: 111-148 (03/23/2010)

(This measure has not been amended since it was passed by the Senate on December 24, 2009. The summary of that version is repeated here.)

Patient Protection and Affordable Care Act - **Title I: Quality, Affordable Health Care for All Americans - Subtitle A: Immediate Improvements in Health Care Coverage for All Americans -** (Sec. 1001, as modified by Sec. 10101) Amends the Public Health Service Act to prohibit a health plan ("health plan" under this subtitle excludes any "grandfathered health plan" as defined in section 1251) from establishing lifetime limits or annual limits on the dollar value of benefits for any participant or beneficiary after January 1, 2014. Permits a restricted annual limit for plan years beginning prior to January 1, 2014. Declares that a health plan shall not be prevented from placing annual or lifetime per-beneficiary limits on covered benefits that are not essential health benefits to the extent that such limits are otherwise permitted.

Prohibits a health plan from rescinding coverage of an enrollee except in the case of fraud or intentional misrepresentation of material fact.

Requires health plans to provide coverage for, and to not impose any cost sharing requirements for: (1) specified preventive items or services; (2) recommended immunizations; and (3) recommended preventive care and screenings for women and children.

Requires a health plan that provides dependent coverage of children to make such coverage available for an unmarried, adult child until the child turns 26 years of age.

Requires the Secretary of Health and Human Services (HHS) to develop standards for health plans (including grandfathered health plans) to provide an accurate summary of benefits and coverage explanation. Directs each such health plan, prior to any enrollment restriction, to provide such a summary of benefits and coverage explanation to: (1) the applicant at the time of application; (2) an enrollee prior to the time of enrollment or re-enrollment; and (3) a policy or certificate holder at the time of issuance of the policy or delivery of the certificate.

Requires group health plans to comply with requirements relating to the prohibition against discrimination in favor of highly compensated individuals.

Requires the Secretary to develop reporting requirements for health plans on benefits or reimbursement structures that: (1) improve health outcomes; (2) prevent hospital

readmissions; (3) improve patient safety and reduce medical errors; and (4) promote wellness and health.

Prohibits: (1) a wellness and health promotion activity implemented by a health plan or any data collection activity authorized under this Act from requiring the disclosure or collection of any information relating to the lawful use, possession, or storage of a firearm or ammunition by an individual; (2) any authority provided to the Secretary under this Act from being construed to authorize the collection of such information or the maintenance of records of individual ownership or possession of a firearm or ammunition; or (3) any health insurance premium increase, denial of coverage, or reduction of any reward for participation in a wellness program on the basis of the lawful use, possession, or storage of a firearm or ammunition.

Requires a health plan (including a grandfathered health plan) to: (1) submit to the Secretary a report concerning the ratio of the incurred loss (or incurred claims) plus the loss adjustment expense (or change in contract reserves) to earned premiums; and (2) provide an annual rebate to each enrollee if the ratio of the amount of premium revenue expended by the issuer on reimbursement for clinical services provided to enrollees and activities that improve health care quality to the total amount of premium revenue for the plan year is less than a 85% for large group markets or 80% for small group or individual markets.

Requires each U.S. hospital to establish and make public a list of its standard charges for items and services.

Requires a health plan to implement an effective process for appeals of coverage determinations and claims.

Sets forth requirements for health plans related to: (1) designation of a primary care provider; (2) coverage of emergency services; and (3) elimination of referral requirements for obstetrical or gynecological care.

(Sec. 1002) Requires the Secretary to award grants to states for offices of health insurance consumer assistance or health insurance ombudsman programs.

(Sec. 1003, as modified by Sec. 10101) Requires the Secretary to establish a process for the annual review of unreasonable increases in premiums for health insurance coverage.

(Sec. 1004) Makes this subtitle effective for plan years beginning six months after enactment of this Act, with certain exceptions.

Subtitle B: Immediate Actions to Preserve and Expand Coverage - (Sec. 1101) Requires the Secretary to establish a temporary high risk health insurance pool program to provide health insurance coverage to eligible individuals with a preexisting condition. Terminates such coverage on January 1, 2014, and provides for a transition to an American Health Benefit Exchange (Exchange).

(Sec. 1102, as modified by Sec. 10102) Requires the Secretary to establish a temporary reinsurance program to provide reimbursement to participating employment-based plans for a portion of the cost of providing health insurance coverage to early retirees before January 1, 2014.

(Sec. 1103, as modified by Sec. 10102) Requires the Secretary to establish a mechanism, including an Internet website, through which a resident of, or small business in, any state may identify affordable health insurance coverage options in that state.

(Sec. 1104) Sets forth provisions governing electronic health care transactions. Establishes penalties for health plans failing to comply with requirements.

(Sec. 1105) Makes this subtitle effective on the date of enactment of this Act.

Subtitle C: Quality Health Insurance Coverage for All Americans - Part I: Health Insurance Market Reforms - (Sec. 1201, as modified by Sec. 10103) Prohibits a health plan ("health plan" under this subtitle excludes any "grandfathered health plan" as defined in section 1251) from: (1) imposing any preexisting condition exclusion; or (2) discriminating on the basis of any health status-related factor. Allows premium rates to vary only by individual or family coverage, rating area, age, or tobacco use.

Requires health plans in a state to: (1) accept every employer and individual in the state that applies for coverage; and (2) renew or continue coverage at the option of the plan sponsor or the individual, as applicable.

Prohibits a health plan from establishing individual eligibility rules based on health status-related factors, including medical condition, claims experience, receipt of health care, medical history, genetic information, and evidence of insurability.

Sets forth provisions governing wellness programs under the health plan, including allowing cost variances for coverage for participation in such a program.

Prohibits a health plan from discriminating with respect to participation under the plan or coverage against any health care provider who is acting within the scope of that provider's license or certification under applicable state law.

Requires health plans that offer health insurance coverage in the individual or small group market to ensure that such coverage includes the essential health benefits package. Requires a group health plan to ensure that any annual cost-sharing imposed under the plan does not exceed specified limitations.

Prohibits a health plan from: (1) applying any waiting period for coverage that exceeds 90 days; or (2) discriminating against individual participation in clinical trials with respect to treatment of cancer or any other life-threatening disease or condition.

Part II: Other Provisions - (Sec. 1251, as modified by Sec. 10103) Provides that nothing in this Act shall be construed to require that an individual terminate coverage

under a group health plan or health insurance coverage in which such individual was enrolled on the date of enactment of this Act. Allows family members of individuals currently enrolled in a plan to enroll in such plan or coverage if such enrollment was permitted under the terms of the plan. Allows new employees and their families to enroll in a group health plan that provides coverage on the date of enactment of this Act.

Defines a "grandfathered health plan" as a group health plan or health insurance coverage in which an individual was enrolled on the date of enactment of this Act.

States that this subtitle and subtitle A shall not apply to: (1) a group health plan or health insurance coverage in which an individual was enrolled on the date of enactment of this Act, regardless of whether the individual renews such coverage after such date of enactment; (2) an existing group health plan that enrolls new employees under this section; and (3) health insurance coverage maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers that was ratified before the date of enactment of this Act until the date on which the last of the collective bargaining agreements relating to the coverage terminates.

Applies provisions related to uniform coverage documents and medical loss ratios to grandfathered health plans for plan years beginning after enactment of this Act.

(Sec. 1252) Requires uniform application of standards or requirements adopted by states to all health plans in each applicable insurance market.

(Sec. 1253, as added by Sec. 10103) Directs the Secretary of Labor to prepare an annual report on self-insured group health plans and self-insured employers.

(Sec. 1254, as added by Sec. 10103) Requires the HHS Secretary to conduct a study of the fully-insured and self-insured group health plan markets related to financial solvency and the effect of insurance market reforms.

(Sec. 1255, as modified by Sec. 10103) Sets forth effective dates for specified provisions of this subtitle.

Subtitle D: Available Coverage Choices for All Americans - Part I: Establishment of Qualified Health Plans - (Sec. 1301, as modified by Sec. 10104) Defines "qualified health plan" to require that such a plan provides essential health benefits and offers at least one plan in the silver level at one plan in the gold level in each Exchange through which such plan is offered.

(Sec. 1302, as modified by Sec. 10104) Requires the essential health benefits package to provide essential health benefits and limit cost-sharing. Directs the Secretary to: (1) define essential health benefits and include emergency services, hospitalization, maternity and newborn care, mental health and substance use disorder services, prescription drugs, preventive and wellness services and chronic disease management, and pediatric services, including oral and vision care; (2) ensure that the scope of the

essential health benefits is equal to the scope of benefits provided under a typical employer plan; and (3) provide notice and an opportunity for public comment in defining the essential health benefits. Establishes: (1) an annual limit on cost-sharing beginning in 2014; and (2) a limitation on the deductible under a small group market health plan.

Sets forth levels of coverage for health plans defined by a certain percentage of the costs paid by the plan. Allows health plans in the individual market to offer catastrophic coverage for individuals under age 30, with certain limitations.

(Sec. 1303, as modified by Sec. 10104) Sets forth special rules for abortion coverage, including: (1) permitting states to elect to prohibit abortion coverage in qualified health plans offered through an Exchange in the state; (2) prohibiting federal funds from being used for abortion services; and (3) requiring separate accounts for payments for such services. Prohibits any qualified health plan offered through an Exchange from discriminating against any individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions.

(Sec. 1304, as modified by Sec. 10104) Sets forth definitions for terms used in this title.

Part II: Consumer Choices and Insurance Competition Through Health Benefit Exchanges - (Sec. 1311, as modified by Sec. 10104) Requires states to establish an American Health Benefit Exchange that: (1) facilitates the purchase of qualified health plans; and (2) provides for the establishment of a Small Business Health Options Program (SHOP Exchange) that is designed to assist qualified small employers in facilitating the enrollment of their employees in qualified health plans offered in the small group market in the state.

Requires the Secretary to establish criteria for the certification of health plans as qualified health plans, including requirements for: (1) meeting market requirements; and (2) ensuring a sufficient choice of providers.

Sets forth the requirements for an Exchange, including that an Exchange: (1) must be a governmental agency or nonprofit entity that is established by a state; (2) may not make available any health plan that is not a qualified health plan; (3) must implement procedures for certification of health plans as qualified health plans; and (4) must require health plans seeking certification to submit a justification of any premium increase prior to implementation of such increase.

Permits states to require qualified health plans to offer additional benefits. Requires states to pay for the cost of such additional benefits.

Allows a state to establish one or more subsidiary Exchanges for geographically distinct areas of a certain size.

Applies mental health parity provisions to qualified health plans.

(Sec. 1312, as modified by Sec. 10104) Allows an employer to select a level of coverage to be made available to employees through an Exchange. Allows employees to choose to enroll in any qualified health plan that offers that level of coverage.

Restricts the health plans that the federal government may make available to Members of Congress and congressional staff after the effective date of this subtitle to only those health plans that are created under this Act or offered through an Exchange.

Permits states to allow large employers to join an Exchange after 2017.

(Sec. 1313, as modified by Sec. 10104) Requires an Exchange to keep an accurate accounting of all activities, receipts, and expenditures and to submit to the Secretary, annually, a report concerning such accountings. Requires the Secretary to take certain action to reduce fraud and abuse in the administration of this title. Requires the Comptroller General to conduct an ongoing study of Exchange activities and the enrollees in qualified health plans offered through Exchanges.

Part III: State Flexibility Relating to Exchanges - (Sec. 1321) Requires the Secretary to issue regulations setting standards related to: (1) the establishment and operation of Exchanges; (2) the offering of qualified health plans through Exchanges; and (3) the establishment of the reinsurance and risk adjustment programs under part V.

Requires the Secretary to: (1) establish and operate an Exchange within a state if the state does not have one operational by January 1, 2014; and (2) presume that an Exchange operating in a state before January 1, 2010, that insures a specified percentage of its population meets the standards under this section.

(Sec. 1322, as modified by Sec. 10104) Requires the Secretary to establish the Consumer Operated and Oriented Plan (CO-OP) program to foster the creation of qualified nonprofit health insurance issuers to offer qualified health plans in the individual and small group markets. Requires the Secretary to provide for loans and grants to persons applying to become qualified nonprofit health insurance issuers. Sets forth provisions governing the establishment and operation of CO-OP program plans.

(Sec. 1323, deleted by Sec. 10104)

(Sec. 1324, as modified by Sec. 10104) Declares that health insurance coverage offered by a private health insurance issuer shall not be subject to federal or state laws if a qualified health plan offered under the CO-OP program is not subject to such law.

Part IV: State Flexibility to Establish Alternative Programs - (Sec. 1331, as modified by Sec. 10104) Requires the Secretary to establish a basic health program under which a state may enter into contracts to offer one or more standard health plans providing at least the essential health benefits to eligible individuals in lieu of offering such individuals coverage through an Exchange. Sets forth requirements for such a plan. Transfers funds that would have gone to the Exchange for such individuals to the state.

(Sec. 1332) Authorizes a state to apply to the Secretary for the waiver of specified requirements under this Act with respect to health insurance coverage within that state for plan years beginning on or after January 1, 2017. Directs the Secretary to provide for an alternative means by which the aggregate amounts of credits or reductions that would have been paid on behalf of participants in the Exchange will be paid to the state for purposes of implementing the state plan.

(Sec. 1333, as modified by Sec. 10104) Requires the Secretary to issue regulations for the creation of health care choice compacts under which two or more states may enter into an agreement that: (1) qualified health plans could be offered in the individual markets in all such states only subject to the laws and regulations of the state in which the plan was written or issued; and (2) the issuer of any qualified health plan to which the compact applies would continue to be subject to certain laws of the state in which the purchaser resides, would be required to be licensed in each state, and must clearly notify consumers that the policy may not be subject to all the laws and regulations of the state in which the purchaser resides. Sets forth provisions regarding the Secretary's approval of such compacts.

(Sec. 1334, as added by Sec. 10104) Requires the Director of the Office of Personnel Management (OPM) to: (1) enter into contracts with health insurance issuers to offer at least two multistate qualified health plans through each Exchange in each state to provide individual or group coverage; and (2) implement this subsection in a manner similar to the manner in which the Director implements the Federal Employees Health Benefits Program. Sets forth requirements for a multistate qualified health plan.

Part V: Reinsurance and Risk Adjustment - (Sec. 1341, as modified by Sec. 10104) Directs each state, not later than January 1, 2014, to establish one or more reinsurance entities to carry out the reinsurance program under this section. Requires the Secretary to establish standards to enable states to establish and maintain a reinsurance program under which: (1) health insurance issuers and third party administrators on behalf of group health plans are required to make payments to an applicable reinsurance entity for specified plan years; and (2) the applicable reinsurance entity uses amounts collected to make reinsurance payments to health insurance issuers that cover high risk individuals in the individual market. Directs the state to eliminate or modify any state high-risk pool to the extent necessary to carry out the reinsurance program established under this section.

(Sec. 1342) Requires the Secretary to establish and administer a program of risk corridors for calendar years 2014 through 2016 under which a qualified health plan offered in the individual or small group market shall participate in a payment adjusted system based on the ratio of the allowable costs of the plan to the plan's aggregate premiums. Directs the Secretary to make payments when a plan's allowable costs exceed the target amount by a certain percentage and directs a plan to make payments

to the Secretary when its allowable costs are less than target amount by a certain percentage.

(Sec. 1343) Requires each state to assess a charge on health plans and health insurance issuers if the actuarial risk of the enrollees of such plans or coverage for a year is less than the average actuarial risk of all enrollees in all plans or coverage in the state for the year. Requires each state to provide a payment to health plans and health insurance issuers if the actuarial risk of the enrollees of such plan or coverage for a year is greater than the average actuarial risk of all enrollees in all plans and coverage in the state for the year. Excludes self-insured group health plans from this section.

Subtitle E: Affordable Coverage Choices for All Americans - Part I: Premium Tax Credits and Cost-sharing Reductions - Subpart A: Premium Tax Credits and Cost-sharing Reductions - (Sec. 1401, as modified by section 10105) Amends the Internal Revenue Code to allow individual taxpayers whose household income equals or exceeds 100%, but does not exceed 400%, of the federal poverty line (as determined in the Social Security Act [SSA]) a refundable tax credit for a percentage of the cost of premiums for coverage under a qualified health plan. Sets forth formulae and rules for the calculation of credit amounts based upon taxpayer household income as a percentage of the poverty line.

Directs the Comptroller General, not later than five years after enactment of this Act, to conduct a study and report to specified congressional committees on the affordability of health insurance coverage.

(Sec. 1402) Requires reductions in the maximum limits for out-of-pocket expenses for individuals enrolled in qualified health plans whose incomes are between 100% and 400% of the poverty line.

Subpart B: Eligibility Determinations - (Sec. 1411) - Requires the Secretary to establish a program for verifying the eligibility of applicants for participation in a qualified health plan offered through an Exchange or for a tax credit for premium assistance based upon their income or their citizenship or immigration status. Requires an Exchange to submit information received from an applicant to the Secretary for verification of applicant eligibility. Provides for confidentiality of applicant information and for an appeals and redetermination process for denials of eligibility. Imposes civil penalties on applicants for providing false or fraudulent information relating to eligibility.

Requires the Secretary to study and report to Congress by January 1, 2013, on procedures necessary to ensure the protection of privacy and due process rights in making eligibility and other determinations under this Act.

(Sec. 1412) Requires the Secretary to establish a program for advance payments of the tax credit for premium assistance and for reductions of cost-sharing. Prohibits any federal payments, tax credit, or cost-sharing reductions for individuals who are not lawfully present in the United States.

(Sec. 1413) Requires the Secretary to establish a system to enroll state residents who apply to an Exchange in state health subsidy programs, including Medicaid or the Children's Health Insurance Program (CHIP, formerly known as SCHIP), if such residents are found to be eligible for such programs after screening.

(Sec. 1414) Requires the Secretary of the Treasury to disclose to HHS personnel certain taxpayer information to determine eligibility for programs under this Act or certain other social security programs.

(Sec. 1415) Disregards the premium assistance tax credit and cost-sharing reductions in determining eligibility for federal and federally-assisted programs.

(Sec. 1416, as added by section 10105) Directs the HHS Secretary to study and report to Congress by January 1, 2013, on the feasibility and implication of adjusting the application of the federal poverty level under this subtitle for different geographic areas in the United States, including its territories.

Part II: Small Business Tax Credit - (Sec. 1421, as modified by section 10105) Allows qualified small employers to elect, beginning in 2010, a tax credit for 50% of their employee health care coverage expenses. Defines "qualified small employer" as an employer who has no more than 25 employees with average annual compensation levels not exceeding $50,000. Requires a phase-out of such credit based on employer size and employee compensation.

Subtitle F: Shared Responsibility for Health Care - Part I: Individual Responsibility - (Sec. 1501, as modified by section 10106) Requires individuals to maintain minimal essential health care coverage beginning in 2014. Imposes a penalty for failure to maintain such coverage beginning in 2014, except for certain low-income individuals who cannot afford coverage, members of Indian tribes, and individuals who suffer hardship. Exempts from the coverage requirement individuals who object to health care coverage on religious grounds, individuals not lawfully present in the United States, and individuals who are incarcerated.

(Sec. 1502) Requires providers of minimum essential coverage to file informational returns providing identifying information of covered individuals and the dates of coverage. Requires the IRS to send a notice to taxpayers who are not enrolled in minimum essential coverage about services available through the Exchange operating in their state.

Part II: Employer Responsibilities - (Sec. 1511) Amends the Fair Labor Standards Act of 1938 to: (1) require employers with more than 200 full-time employees to automatically enroll new employees in a health care plan and provide notice of the opportunity to opt-out of such coverage; and (2) provide notice to employees about an Exchange, the availability of a tax credit for premium assistance, and the loss of an employer's contribution to an employer-provided health benefit plan if the employee purchases a plan through an Exchange.

(Sec. 1513, as modified by section 10106) Imposes fines on large employers (employers with more than 50 full-time employees) who fail to offer their full-time employees the opportunity to enroll in minimum essential coverage or who have a waiting period for enrollment of more than 60 days.

Requires the Secretary of Labor to study and report to Congress on whether employees' wages are reduced due to fines imposed on employers.

(Sec. 1514, as modified by section 10106) Requires large employers to file a report with the Secretary of the Treasury on health insurance coverage provided to their full-time employees. Requires such reports to contain: (1) a certification as to whether such employers provide their full-time employees (and their dependents) the opportunity to enroll in minimum essential coverage under an eligible employer-sponsored plan; (2) the length of any waiting period for such coverage; (3) the months during which such coverage was available; (4) the monthly premium for the lowest cost option in each of the enrollment categories under the plan; (5) the employer's share of the total allowed costs of benefits provided under the plan; and (6) identifying information about the employer and full-time employees. Imposes a penalty on employers who fail to provide such report. Authorizes the Secretary of the Treasury to review the accuracy of information provided by large employers.

(Sec. 1515) Allows certain small employers to include as a benefit in a tax-exempt cafeteria plan a qualified health plan offered through an Exchange.

Subtitle G: Miscellaneous Provisions - (Sec. 1551) Applies the definitions under the Public Health Service Act related to health insurance coverage to this title.

(Sec. 1552) Requires the HHS Secretary to publish on the HHS website a list of all of the authorities provided to the Secretary under this Act.

(Sec. 1553) Prohibits the federal government, any state or local government or health care provider that receives federal financial assistance under this Act, or any health plan created under this Act from discriminating against an individual or institutional health care entity on the basis that such individual or entity does not provide a health care item or service furnished for the purpose of causing, or assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy killing.

(Sec. 1554) Prohibits the Secretary from promulgating any regulation that: (1) creates an unreasonable barrier to the ability of individuals to obtain appropriate medical care; (2) impedes timely access to health care services; (3) interferes with communications regarding a full range of treatment options between the patient and the health care provider; (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions; (5) violates the principle of informed consent and the ethical standards of health care professionals; or (6) limits the availability of health care treatment for the full duration of a patient's medical needs.

(Sec. 1555) Declares that no individual, company, business, nonprofit entity, or health insurance issuer offering group or individual health insurance coverage shall be required to participate in any federal health insurance program created by or expanded under this Act. Prohibits any penalty from being imposed upon any such issuer for choosing not to participate in any such program.

(Sec. 1556) Amends the Black Lung Benefits Act, with respect to claims filed on or after the effective date of the Black Lung Benefits Amendments of 1981, to eliminate exceptions to: (1) the applicability of certain provisions regarding rebuttable presumptions; and (2) the prohibition against requiring eligible survivors of a miner determined to be eligible for black lung benefits to file a new claim or to refile or otherwise revalidate the miner's claim.

(Sec. 1557) Prohibits discrimination by any federal health program or activity on the grounds of race, color, national origin, sex, age, or disability.

(Sec. 1558) Amends the Fair Labor Standards Act of 1938 to prohibit an employer from discharging or discriminating against any employee because the employee: (1) has received a health insurance credit or subsidy; (2) provides information relating to any violation of any provision of such Act; or (3) objects to, or refuses to participate in, any activity, policy, practice, or assigned task that the employee reasonably believed to be in violation of such Act.

(Sec. 1559) Gives the HHS Inspector General oversight authority with respect to the administration and implementation of this title.

(Sec. 1560) Declares that nothing in this title shall be construed to modify, impair, or supersede the operation of any antitrust laws.

(Sec. 1561) Amends the Public Health Service Act to require the Secretary to: (1) develop interoperable and secure standards and protocols that facilitate enrollment of individuals in federal and state health and human services programs; and (2) award grants to develop and adapt technology systems to implement such standards and protocols.

(Sec. 1562, as added by Sec. 10107) Directs the Comptroller General to study denials by health plans of coverage for medical services and of applications to enroll in health insurance.

(Sec. 1563, as added by Sec. 10107) Disallows the waiver of laws or regulations establishing procurement requirements relating to small business concerns with respect to any contract awarded under any program or other authority under this Act.

(Sec. 1563 [*sic*], as modified by Sec. 10107) Makes technical and conforming amendments.

(Sec. 1563 [*sic*]) Expresses the sense of the Senate that: (1) the additional surplus in the Social Security trust fund generated by this Act should be reserved for Social Security; and (2) the net savings generated by the CLASS program (established under Title VIII of this Act) should be reserved for such program.

Title II: Role of Public Programs - Subtitle A: Improved Access to Medicaid - (Sec. 2001, as modified by Sec. 10201) Amends title XIX (Medicaid) of the SSA to extend Medicaid coverage, beginning in calendar 2014, to individuals under age 65 who are not entitled to or enrolled in Medicare and have incomes at or below 133% of the federal poverty line. Grants a state the option to expand Medicaid eligibility to such individuals as early as April 1, 2010. Provides that, for between 2014 and 2016, the federal government will pay 100% of the cost of covering newly-eligible individuals.

Increases the federal medical assistance percentage (FMAP): (1) with respect to newly eligible individuals; and (2) between January 1, 2014, and December 31, 2016, for states meeting certain eligibility requirements.

Requires Medicaid benchmark benefits to include coverage of prescription drugs and mental health services.

Grants states the option to extend Medicaid coverage to individuals who have incomes that exceed 133% of the federal poverty line beginning January 1, 2014.

(Sec. 2002) Requires a state to use an individual's or household's modified gross income to determine income eligibility for Medicaid for non-elderly individuals, without applying any income or expense disregards or assets or resources test.

Exempts from this requirement: (1) individuals eligible for Medicaid through another program; (2) the elderly or Social Security Disability Insurance (SSDI) program beneficiaries; (3) the medically needy; (4) enrollees in a Medicare Savings Program; and (5) the disabled.

(Sec. 2003) Revises state authority to offer a premium assistance subsidy for qualified employer-sponsored coverage to children under age 19 to extend such a subsidy to all individuals, regardless of age.

Prohibits a state from requiring, as a condition of Medicaid eligibility, that an individual (or the individual's parent) apply for enrollment in qualified employer-sponsored coverage.

(Sec. 2004, as modified by Sec. 10201) Extends Medicaid coverage to former foster care children who are under 26 years of age.

(Sec. 2005, as modified by Sec. 10201) Revises requirements for Medicaid payments to territories, including an increase in the limits on payments for FY2011 and thereafter.

(Sec. 2006, as modified by Sec. 10201) Prescribes an adjustment to the FMAP determination for certain states recovering from a major disaster.

(Sec. 2007) Rescinds any unobligated amounts available to the Medicaid Improvement Fund for FY2014-FY2018.

Subtitle B: Enhanced Support for the Children's Health Insurance Program - (Sec. 2101, as modified by Sec. 10201) Amends SSA title XXI (State Children's Health Insurance Program) (CHIP, formerly known as SCHIP) to increase the FY2016-FY2019 enhanced FMAP for states, subject to a 100% cap.

Prohibits states from applying, before the end of FY2019, CHIP eligibility standards that are more restrictive than those under this Act.

Deems ineligible for CHIP any targeted low-income children who cannot enroll in CHIP because allotments are capped, but who are therefore eligible for tax credits in the Exchanges.

Requires the Secretary to: (1) review benefits offered for children, and related cost-sharing imposed, by qualified health plans offered through an Exchange; and (2) certify those plans whose benefits and cost-sharing are at least comparable to those provided under the particular state's CHIP plan.

Prohibits enrollment bonus payments for children enrolled in CHIP after FY2013.

Requires a state CHIP plan, beginning January 1, 2014, to use modified gross income and household income to determine CHIP eligibility.

Requires a state to treat as a targeted low-income child eligible for CHIP any child determined ineligible for Medicaid as a result of the elimination of an income disregard based on expense or type of income.

(Sec. 2102) Makes technical corrections to the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA).

Subtitle C: Medicaid and CHIP Enrollment Simplification - (Sec. 2201) Amends SSA title XIX (Medicaid) to require enrollment application simplification and coordination with state health insurance Exchanges and CHIP via state-run websites.

(Sec. 2202) Permits hospitals to provide Medicaid services during a period of presumptive eligibility to members of all Medicaid eligibility categories.

Subtitle D: Improvements to Medicaid Services - (Sec. 2301) Requires Medicaid coverage of: (1) freestanding birth center services; and (2) concurrent care for children receiving hospice care.

(Sec. 2303) Gives states the option of extending Medicaid coverage to family planning services and supplies under a presumptive eligibility period for a categorically needy group of individuals.

Subtitle E: New Options for States to Provide Long-Term Services and Supports - (Sec. 2401) Authorizes states to offer home and community-based attendant services

and supports to Medicaid beneficiaries with disabilities who would otherwise require care in a hospital, nursing facility, intermediate care facility for the mentally retarded, or an institution for mental diseases.

(Sec. 2402) Gives states the option of: (1) providing home and community-based services to individuals eligible for services under a waiver; and (2) offering home and community-based services to specific, targeted populations

Creates an optional eligibility category to provide full Medicaid benefits to individuals receiving home and community-based services under a state plan amendment.

(Sec. 2403) Amends the Deficit Reduction Act of 2005 to: (1) extend through FY2016 the Money Follows the Person Rebalancing Demonstration; and (2) reduce to 90 days the institutional residency period.

(Sec. 2404) Applies Medicaid eligibility criteria to recipients of home and community-based services, during calendar 2014 through 2019, in such a way as to protect against spousal impoverishment.

(Sec. 2405) Makes appropriations for FY2010-FY2014 to the Secretary, acting through the Assistant Secretary for Aging, to expand state aging and disability resource centers.

(Sec. 2406) Expresses the sense of the Senate that: (1) during the 111th session of Congress, Congress should address long-term services and supports in a comprehensive way that guarantees elderly and disabled individuals the care they need; and (2) long-term services and supports should be made available in the community in addition to institutions.

Subtitle F: Medicaid Prescription Drug Coverage - (Sec. 2501) Amends SSA title XIX (Medicaid) to: (1) increase the minimum rebate percentage for single source drugs and innovator multiple source drugs; (2) increase the rebate for other drugs; (3) require contracts with Medicaid managed care organizations to extend prescription drug rebates (discounts) to their enrollees; (4) provide an additional rebate for new formulations of existing drugs; and (5) set a maximum rebate amount.

(Sec. 2502) Eliminates the exclusion from Medicaid coverage of, thereby extending coverage to, certain drugs used to promote smoking cessation, as well as barbiturates and benzodiazepines.

(Sec. 2503) Revises requirements with respect to pharmacy reimbursements.

Subtitle G: Medicaid Disproportionate Share Hospital (DSH) Payments - (Sec. 2551, as modified by Sec. 10201) Reduces state disproportionate share hospital (DSH) allotments, except for Hawaii, by 50% or 35% once a state's uninsured rate decreases by 45%, depending on whether they have spent at least or more than 99.9% of their allotments on average during FY2004-FY2008. Requires a reduction of only 25% or 17.5% for low DSH states, depending on whether they have spent at least or more than

99.9% of their allotments on average during FY2004-FY2008. Prescribes allotment reduction requirements for subsequent fiscal years.

Revises DSH allotments for Hawaii for the last three quarters of FY2012 and for FY2013 and succeeding fiscal years.

Subtitle H: Improved Coordination for Dual Eligible Beneficiaries - (Sec. 2601) Declares that any Medicaid waiver for individuals dually eligible for both Medicaid and Medicare may be conducted for a period of five years, with a five-year extension, upon state request, unless the Secretary determines otherwise for specified reasons.

(Sec. 2602) Directs the Secretary to establish a Federal Coordinated Health Care Office to bring together officers and employees of the Medicare and Medicaid programs at the Centers for Medicare and Medicaid Services (CMS) to: (1) integrate Medicaid and Medicare benefits more effectively; and (2) improve the coordination between the federal government and states for dual eligible individuals to ensure that they get full access to the items and services to which they are entitled.

Subtitle I: Improving the Quality of Medicaid for Patients and Providers - (Sec. 2701) Amends SSA title XI, as modified by CHIPRA, to direct the Secretary to: (1) identify and publish a recommended core set of adult health quality measures for Medicaid eligible adults; and (2) establish a Medicaid Quality Measurement Program.

(Sec. 2702) Requires the Secretary to identify current state practices that prohibit payment for health care-acquired conditions and to incorporate them, or elements of them, which are appropriate for application in regulations to the Medicaid program. Requires such regulations to prohibit payments to states for any amounts expended for providing medical assistance for specified health care-acquired conditions.

(Sec. 2703) Gives states the option to provide coordinated care through a health home for individuals with chronic conditions. Authorizes the Secretary to award planning grants to states to develop a state plan amendment to that effect.

(Sec. 2704) Directs the Secretary to establish a demonstration project to evaluate the use of bundled payments for the provision of integrated care for a Medicaid beneficiary: (1) with respect to an episode of care that includes a hospitalization; and (2) for concurrent physicians services provided during a hospitalization.

(Sec. 2705) Requires the Secretary to establish a Medicaid Global Payment System Demonstration Project under which a participating state shall adjust payments made to an eligible safety net hospital or network from a fee-for-service payment structure to a global capitated payment model. Authorizes appropriations.

(Sec. 2706) Directs the Secretary to establish the Pediatric Accountable Care Organization Demonstration Project to authorize a participating state to allow pediatric medical providers meeting specified requirements to be recognized as an accountable

care organization for the purpose of receiving specified incentive payments. Authorizes appropriations.

(Sec. 2707) Requires the Secretary to establish a three-year Medicaid emergency psychiatric demonstration project. Makes appropriations for FY2011.

Subtitle J: Improvements to the Medicaid and CHIP Payment and Access Commission (MACPAC) - (Sec. 2801) Revises requirements with respect to the Medicaid and CHIP Payment and Access Commission (MACPAC) and the Medicare Payment Advisory Commission (MEDPAC), including those for MACPAC membership, topics to be reviewed, and MEDPAC review of Medicaid trends in spending, utilization, and financial performance.

Requires MACPAC and MEDPAC to consult with one another on related issues.

Makes appropriations to MACPAC for FY2010.

Subtitle K: Protections for American Indians and Alaska Natives - (Sec. 2901) Sets forth special rules relating to Indians.

Declares that health programs operated by the Indian Health Service (IHS), Indian tribes, tribal organizations, and Urban Indian organizations shall be the payer of last resort for services they provide to eligible individuals.

Makes such organizations Express Lane agencies for determining Medicaid and CHIP eligibility.

(Sec. 2902) Makes permanent the requirement that the Secretary reimburse certain Indian hospitals and clinics for all Medicare part B services.

Subtitle L: Maternal and Child Health Services - (Sec. 2951) Amends SSA title V (Maternal and Child Health Services) to direct the Secretary to make grants to eligible entities for early childhood home visitation programs. Makes appropriations for FY2010-FY2014.

(Sec. 2952) Encourages the Secretary to continue activities on postpartum depression or postpartum psychosis, including research to expand the understanding of their causes and treatment.

Authorizes the Secretary to make grants to eligible entities for projects to establish, operate, and coordinate effective and cost-efficient systems for the delivery of essential services to individuals with or at risk for postpartum conditions and their families. Authorizes appropriations for FY2010-FY2012.

(Sec. 2953, as modified by Sec. 10201) Directs the Secretary to allot funds to states to award grants to local organizations and other specified entities to carry out personal responsibility education programs to educate adolescents on both abstinence and contraception for the prevention of pregnancy and sexually transmitted infections, as

well as on certain adulthood preparation subjects. Makes appropriations for FY2010-FY2014.

(Sec. 2954) Makes appropriations for FY2010-FY2014 for abstinence education.

(Sec. 2955) Requires the case review system for children aging out of foster care and independent living programs to include information about the importance of having a health care power of attorney in transition planning.

Title III: Improving the Quality and Efficiency of Health Care - Subtitle A: Transforming the Health Care Delivery System - Part I: Linking Payment to Quality Outcomes under the Medicare Program - (Sec. 3001) Amends SSA title XVIII (Medicare) to direct the Secretary to establish a hospital value-based purchasing program under which value-based incentive payments are made in a fiscal year to hospitals that meet specified performance standards for a certain performance period.

Directs the Secretary to establish value-based purchasing demonstration programs for: (1) inpatient critical access hospital services; and (2) hospitals excluded from the program because of insufficient numbers of measures and cases.

(Sec. 3002) Extends through 2013 the authority for incentive payments under the physician quality reporting system. Prescribes an incentive (penalty) for providers who do not report quality measures satisfactorily, beginning in 2015.

Requires the Secretary to integrate reporting on quality measures with reporting requirements for the meaningful use of electronic health records.

(Sec. 3003) Requires specified new types of reports and data analysis under the physician feedback program.

(Sec. 3004) Requires long-term care hospitals, inpatient rehabilitation hospitals, and hospices, starting in rate year 2014, to submit data on specified quality measures. Requires reduction of the annual update of entities which do not comply.

(Sec. 3005) Directs the Secretary, starting FY2014, to establish quality reporting programs for inpatient cancer hospitals exempt from the prospective payment system.

(Sec. 3006, as modified by Sec. 10301) Directs the Secretary to develop a plan to implement value-based purchasing programs for Medicare payments for skilled nursing facilities (SNFs), home health agencies, and ambulatory surgical centers.

(Sec. 3007) Directs the Secretary to establish a value-based payment modifier, under the physician fee schedule, based upon the quality of care furnished compared to cost.

(Sec. 3008) Subjects hospitals to a penalty adjustment to hospital payments for high rates of hospital acquired conditions.

Part II: National Strategy to Improve Health Care Quality - (Sec. 3011, as modified by Sec. 10302) Amends the Public Health Service Act to direct the Secretary, through a

transparent collaborative process, to establish a National Strategy for Quality Improvement in health care services, patient health outcomes, and population health, taking into consideration certain limitations on the use of comparative effectiveness data.

(Sec. 3012) Directs the President to convene an Interagency Working Group on Health Care Quality.

(Sec. 3013, as modified by Sec. 10303) Directs the Secretary, at least triennially, to identify gaps where no quality measures exist as well as existing quality measures that need improvement, updating, or expansion, consistent with the national strategy for use in federal health programs.

Directs the Secretary to award grants, contracts, or intergovernmental agreements to eligible entities for purposes of developing, improving, updating, or expanding such quality measures.

Requires the Secretary to develop and update periodically provider-level outcome measures for hospitals and physicians, as well as other appropriate providers.

(Sec. 3014, as modified by Sec. 10304) Requires the convening of multi-stakeholder groups to provide input into the selection of quality and efficiency measures.

(Sec. 3015, as modified by Sec. 10305) Directs the Secretary to: (1) establish an overall strategic framework to carry out the public reporting of performance information; and (2) collect and aggregate consistent data on quality and resource use measures from information systems used to support health care delivery. Authorizes the Secretary to award grants for such purpose.

Directs the Secretary to make available to the public, through standardized Internet websites, performance information summarizing data on quality measures.

Part III: Encouraging Development of New Patient Care Models - (Sec. 3021, as modified by Sec. 10306) Creates within CMS a Center for Medicare and Medicaid Innovation to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to individuals. Makes appropriations for FY2010-FY2019.

(Sec. 3022, as modified by Sec. 10307) Directs the Secretary to establish a shared savings program that: (1) promotes accountability for a patient population; (2) coordinates items and services under Medicare parts A and B; and (3) encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery.

(Sec. 3023, as modified by Sec. 10308) Directs the Secretary to establish a pilot program for integrated care (involving payment bundling) during an episode of care

provided to an applicable beneficiary around a hospitalization in order to improve the coordination, quality, and efficiency of health care services.

(Sec. 3024) Directs the Secretary to conduct a demonstration program to test a payment incentive and service delivery model that utilizes physician and nurse practitioner directed home-based primary care teams designed to reduce expenditures and improve health outcomes in the provision of items and services to applicable beneficiaries.

(Sec. 3025, as modified by Sec. 10309) Requires the Secretary to establish a hospital readmissions reduction program involving certain payment adjustments, effective for discharges on or after October 1, 2012, for certain potentially preventable Medicare inpatient hospital readmissions.

Directs the Secretary to make available a program for hospitals with a high severity adjusted readmission rate to improve their readmission rates through the use of patient safety organizations.

(Sec. 3026) Directs the Secretary to establish a Community-Based Care Transitions Program which provides funding to eligible entities that furnish improved care transitions services to high-risk Medicare beneficiaries.

(Sec. 3027) Amends the Deficit Reduction Act of 2005 to extend certain Gainsharing Demonstration Projects through FY2011.

Subtitle B: Improving Medicare for Patients and Providers - Part 1: Ensuring Beneficiary Access to Physician Care and Other Services - (Sec. 3101, deleted by section 10310) (Sec. 3102) Extends through calendar 2010 the floor on geographic indexing adjustments to the work portion of the physician fee schedule. Revises requirements for calculation of the practice expense portion of the geographic adjustment factor applied in a fee schedule area for services furnished in 2010 or 2011. Directs the Secretary to analyze current methods of establishing practice expense geographic adjustments and make appropriate further adjustments (a new methodology) to such adjustments for 2010 and subsequent years.

(Sec. 3103) Extends the process allowing exceptions to limitations on medically necessary therapy caps through December 31, 2010.

(Sec. 3104) Amends the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 to extend until January 1, 2010, an exception to a payment rule that permits laboratories to receive direct Medicare reimbursement when providing the technical component of certain physician pathology services that had been outsourced by certain (rural) hospitals.

(Sec. 3105, as modified by Sec. 10311) Amends SSA title XVIII (Medicare) to extend the bonus and increased payments for ground ambulance services until January 1, 2011.

Amends the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) to extend the payment of certain urban air ambulance services until January 1, 2011.

(Sec. 3106, as modified by Sec. 10312) Amends the Medicare, Medicaid, and SCHIP Extension Act of 2007, as modified by the American Recovery and Reinvestment Act, to extend for two years: (1) certain payment rules for long-term care hospital services; and (2) a certain moratorium on the establishment of certain hospitals and facilities.

(Sec. 3107) Amends MIPPA to extend the physician fee schedule mental health add-on payment provision through December 31, 2010.

(Sec. 3108) Allows a physician assistant who does not have an employment relationship with a SNF, but who is working in collaboration with a physician, to certify the need for post-hospital extended care services for Medicare payment purposes.

(Sec. 3109) Amends title XVIII, as modified by MIPPA, to exempt certain pharmacies from accreditation requirements until the Secretary develops pharmacy-specific standards.

(Sec. 3110) Creates a special part B enrollment period for military retirees, their spouses (including widows/ widowers), and dependent children, who are otherwise eligible for TRICARE (the health care plan under the Department of Defense [DOD]) and entitled to Medicare part A (Hospital Insurance) based on disability or end stage renal disease, but who have declined Medicare part B (Supplementary Medical Insurance).

(Sec. 3111) Sets payments for dual-energy x-ray absorptiometry services in 2010 and 2011 at 70% of the 2006 reimbursement rates. Directs the Secretary to arrange with the Institute of Medicine of the National Academies to study and report to the Secretary and Congress on the ramifications of Medicare reimbursement reductions for such services on beneficiary access to bone mass measurement benefits.

(Sec. 3112) Eliminates funding in the Medicare Improvement Fund FY2014.

(Sec. 3113) Directs the Secretary to conduct a demonstration project under Medicare part B of separate payments for complex diagnostic laboratory tests provided to individuals.

(Sec. 3114) Increases from 65% to 100% of the fee schedule amount provided for the same service performed by a physician the fee schedule for certified-midwife services provided on or after January 1, 2011.

Part II: Rural Protections - (Sec. 3121) Extends through 2010 hold harmless provisions under the prospective payment system for hospital outpatient department services.

Removes the 100-bed limitation for sole community hospitals so all such hospitals receive an 85% increase in the payment difference in 2010.

(Sec. 3122) Amends the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, as modified by other federal law, to extend from July 1, 2010, until July 1, 2011, the reasonable cost reimbursement for clinical diagnostic laboratory service for qualifying rural hospitals with under 50 beds.

(Sec. 3123, as modified by Sec. 10313) Extends the Rural Community Hospital Demonstration Program for five additional years. Expands the maximum number of participating hospitals to 30, and to 20 the number of demonstration states with low population densities.

(Sec. 3124) Extends the Medicare-dependent Hospital Program through FY2012.

(Sec. 3125, as modified by Sec. 10314) Modifies the Medicare inpatient hospital payment adjustment for low-volume hospitals for FY2011-FY2012.

(Sec. 3126) Revises requirements for the Demonstration Project on Community Health Integration Models in Certain Rural Counties to allow additional counties as well as physicians to participate.

(Sec. 3127) Directs MEDPAC to study and report to Congress on the adequacy of payments for items and services furnished by service providers and suppliers in rural areas under the Medicare program.

(Sec. 3128) Allows a critical access hospital to continue to be eligible to receive 101% of reasonable costs for providing: (1) outpatient care regardless of the eligible billing method such hospital uses; and (2) qualifying ambulance services.

(Sec. 3129) Extends through FY2012 FLEX grants under the Medicare Rural Hospital Flexibility Program. Allows the use of grant funding to assist small rural hospitals to participate in delivery system reforms.

Part III: Improving Payment Accuracy - (Sec. 3131, as modified by Sec. 10315) Requires the Secretary, starting in 2014, to rebase home health payments by an appropriate percentage, among other things, to reflect the number, mix, and level of intensity of home health services in an episode, and the average cost of providing care.

Directs the Secretary to study and report to Congress on home health agency costs involved with providing ongoing access to care to low-income Medicare beneficiaries or beneficiaries in medically underserved areas, and in treating beneficiaries with varying levels of severity of illness. Authorizes a Medicare demonstration project based on the study results.

(Sec. 3132) Requires the Secretary, by January 1, 2011, to begin collecting additional data and information needed to revise payments for hospice care.

Directs the Secretary, not earlier than October 1, 2013, to implement, by regulation, budget neutral revisions to the methodology for determining hospice payments for routine home care and other services, which may include per diem payments reflecting

changes in resource intensity in providing such care and services during the course of an entire episode of hospice care.

Requires the Secretary to impose new requirements on hospice providers participating in Medicare, including requirements for: (1) a hospice physician or nurse practitioner to have a face-to-face encounter with the individual regarding eligibility and recertification; and (2) a medical review of any stays exceeding 180 days, where the number of such cases exceeds a specified percentage of them for all hospice programs.

(Sec. 3133, as modified by Sec. 10316) Specifies reductions to Medicare DSH payments for FY2015 and ensuing fiscal years, especially to subsection (d) hospitals, to reflect lower uncompensated care costs relative to increases in the number of insured. (Generally, a subsection [d] hospital is an acute care hospital, particularly one that receives payments under Medicare's inpatient prospective payment system when providing covered inpatient services to eligible beneficiaries.)

(Sec. 3134) Directs the Secretary periodically to identify physician services as being potentially misvalued and make appropriate adjustments to the relative values of such services under the Medicare physician fee schedule.

(Sec. 3135) Increases the presumed utilization rate for calculating the payment for advanced imaging equipment other than low-tech imaging such as ultrasound, x-rays and EKGs.

Increases the technical component payment "discount" for sequential imaging services on contiguous body parts during the same visit.

(Sec. 3136) Restricts the lump-sum payment option for new or replacement chairs to the complex, rehabilitative power-driven wheelchairs only. Eliminates the lump-sum payment option for all other power-driven wheelchairs. Makes the rental payment for power-driven wheelchairs 15% of the purchase price for each of the first three months (instead of 10%), and 6% of the purchase price for each of the remaining 10 months of the rental period (instead of 7.5%).

(Sec. 3137, as modified by Sec. 10317) Amends the Tax Relief and Health Care Act of 2006, as modified by other federal law, to extend "Section 508" hospital reclassifications until September 30, 2010, with a special rule for FY2010. ("Section 508" refers to Section 508 of the Medicare Modernization Act of 2003, which allows the temporary reclassification of a hospital with a low Medicare area wage index, for reimbursement purposes, to a nearby location with a higher Medicare area wage index, so that the "Section 508 hospital" will receive the higher Medicare reimbursement rate.)

Directs the Secretary to report to Congress a plan to reform the hospital wage index system.

(Sec. 3138) Requires the Secretary to determine if the outpatient costs incurred by inpatient prospective payment system-exempt cancer hospitals, including those for

drugs and biologicals, with respect to Medicare ambulatory payment classification groups, exceed those costs incurred by other hospitals reimbursed under the outpatient prospective payment system (OPPS). Requires the Secretary, if this is so, to provide for an appropriate OPPS adjustment to reflect such higher costs for services furnished on or after January 1, 2011.

(Sec. 3139) Allows a biosimilar biological product to be reimbursed at 6% of the average sales price of the brand biological product.

(Sec. 3140) Directs the Secretary to establish a Medicare Hospice Concurrent Care demonstration program under which Medicare beneficiaries are furnished, during the same period, hospice care and any other Medicare items or services from Medicare funds otherwise paid to such hospice programs.

(Sec. 3141) Requires application of the budget neutrality requirement associated with the effect of the imputed rural floor on the area wage index under the Balanced Budget Act of 1997 through a uniform national, instead of state-by-state, adjustment to the area hospital wage index floor.

(Sec. 3142) Directs the Secretary to study and report to Congress on the need for an additional payment for urban Medicare-dependent hospitals for inpatient hospital services under Medicare.

(Sec. 3143) Declares that nothing in this Act shall result in the reduction of guaranteed home health benefits under the Medicare program.

Subtitle C: Provisions Relating to Part C - (Sec. 3201, as modified by Sec. 10318) Bases the MedicareAdvantage (MA) benchmark on the average of the bids from MA plans in each market.

Revises the formula for calculating the annual Medicare+Choice capitation rate to reduce the national MA per capita Medicare+Choice growth percentage used to increase benchmarks in 2011.

Increases the monthly MA plan rebates from 75% to 100% of the average per capita savings.

Requires that bid information which MA plans are required to submit to the Secretary be certified by a member of the American Academy of Actuaries and meet actuarial guidelines and rules established by the Secretary.

Directs the Secretary, acting through the CMS Chief Actuary, to establish actuarial guidelines for the submission of bid information and bidding rules that are appropriate to ensure accurate bids and fair competition among MA plans.

Directs the Secretary to: (1) establish new MA payment areas for urban areas based on the Core Based Statistical Area; and (2) make monthly care coordination and management performance bonus payments, quality performance bonus payments, and

quality bonuses for new and low enrollment MA plans, to MA plans that meet certain criteria.

Directs the Secretary to provide transitional rebates for the provision of extra benefits to enrollees.

(Sec. 3202) Prohibits MA plans from charging beneficiaries cost sharing for chemotherapy administration services, renal dialysis services, or skilled nursing care that is greater than what is charged under the traditional fee-for-service program.

Requires MA plans to apply the full amount of rebates, bonuses, and supplemental premiums according to the following order: (1) reduction of cost sharing, (2) coverage of preventive care and wellness benefits, and (3) other benefits not covered under the original Medicare fee-for-service program.

(Sec. 3203) Requires the Secretary to analyze the differences in coding patterns between MA and the original Medicare fee-for-service programs. Authorizes the Secretary to incorporate the results of the analysis into risk scores for 2014 and subsequent years.

(Sec. 3204) Allows beneficiaries to disenroll from an MA plan and return to the traditional Medicare fee-for-service program from January 1 to March 15 of each year.

Revises requirements for annual beneficiary election periods.

(Sec. 3205) Amends SSA title XVIII (Medicare), as modified by MIPPA, to extend special needs plan (SNP) authority through December 31, 2013.

Authorizes the Secretary to establish a frailty payment adjustment under PACE payment rules for fully-integrated, dual-eligible SNPs.

Extends authority through calendar 2012 for SNPs that do not have contracts with state Medicaid programs to continue to operate, but not to expand their service areas.

Directs the Secretary to require an MA organization offering a specialized MA plan for special needs individuals to be approved by the National Committee for Quality Assurance.

Requires the Secretary to use a risk score reflecting the known underlying risk profile and chronic health status of similar individuals, instead of the default risk score, for new enrollees in MA plans that are not specialized MA SNPs.

(Sec. 3206) Extends through calendar 2012 the length of time reasonable cost plans may continue operating regardless of any other MA plans serving the area.

(Sec. 3208) Creates a new type of MA plan called an MA Senior Housing Facility Plan, which would be allowed to limit its service area to a senior housing facility (continuing care retirement community) within a geographic area.

(Sec. 3209) Declares that the Secretary is not required to accept any or every bid submitted by an MA plan or Medicare part D prescription drug plan that proposes to increase significantly any beneficiary cost sharing or decrease benefits offered.

(Sec. 3210) Directs the Secretary to request the National Association of Insurance Commissioners (NAIC) to develop new standards for certain Medigap plans.

Subtitle D: Medicare Part D Improvements for Prescription Drug Plans and MA-PD Plans - (Sec. 3301) Amends Medicare part D (Voluntary Prescription Drug Benefit Program) to establish conditions for the availability of coverage for part D drugs. Requires the manufacturer to participate in the Medicare coverage gap discount program. Directs the Secretary to establish such a program.

(Sec. 3302) Excludes the MA rebate amounts and quality bonus payments from calculation of the regional low-income subsidy benchmark premium for MA monthly prescription drug beneficiaries.

(Sec. 3303) Directs the Secretary to permit a prescription drug plan or an MA-PD plan to waive the monthly beneficiary premium for a subsidy eligible individual if the amount of such premium is *de minimis*. Provides that, if such premium is waived, the Secretary shall not reassign subsidy eligible individuals enrolled in the plan to other plans based on the fact that the monthly beneficiary premium under the plan was greater than the low-income benchmark premium amount.

Authorizes the Secretary to auto-enroll subsidy eligible individuals in plans that waive *de minimis* premiums.

(Sec. 3304) Sets forth a special rule for widows and widowers regarding eligibility for low-income assistance. Allows the surviving spouse of an eligible couple to delay redetermination of eligibility for one year after the death of a spouse.

(Sec. 3305) Directs the Secretary, in the case of a subsidy eligible individual enrolled in one prescription drug plan but subsequently reassigned by the Secretary to a new prescription drug plan, to provide the individual with: (1) information on formulary differences between the individual's former plan and the new plan with respect to the individual's drug regimens; and (2) a description of the individual's right to request a coverage determination, exception, or reconsideration, bring an appeal, or resolve a grievance.

(Sec. 3306) Amends MIPPA to provide additional funding for FY2010-FY2012 for outreach and education activities related to specified Medicare low-income assistance programs.

(Sec. 3307) Authorizes the Secretary to identify classes of clinical concern through rulemaking, including anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection.

Requires prescription drug plan sponsors to include all drugs in these classes in their formularies.

(Sec. 3308) Requires part D enrollees who exceed certain income thresholds to pay higher premiums. Revises the current authority of the IRS to disclose income information to the Social Security Administration for purposes of adjusting the part B subsidy.

(Sec. 3309) Eliminates cost sharing for certain dual eligible individuals receiving care under a home and community-based waiver program who would otherwise require institutional care.

(Sec. 3310) Directs the Secretary to require sponsors of prescription drug plans to utilize specific, uniform techniques for dispensing covered part D drugs to enrollees who reside in an long-term care facility in order to reduce waste associated with 30-day refills.

(Sec. 3311) Directs the Secretary to develop and maintain an easy to use complaint system to collect and maintain information on MA-PD plan and prescription drug complaints received by the Secretary until the complaint is resolved.

(Sec. 3312) Requires a prescription drug plan sponsor to: (1) use a single, uniform exceptions and appeals process for determination of a plan enrollee's prescription drug coverage; and (2) provide instant access to this process through a toll-free telephone number and an Internet website.

(Sec. 3313) Requires the HHS Inspector General to study and report to Congress on the inclusion in formularies of: (1) drugs commonly used by dual eligibles; and (2) prescription drug prices under Medicare part D and Medicaid.

(Sec. 3314) Allows the costs incurred by AIDS drug assistance programs and by IHS in providing prescription drugs to count toward the annual out-of-pocket threshold.

(Sec. 3315) Increases by $500 the 2010 standard initial coverage limit (thus decreasing the time that a part D enrollee would be in the coverage gap).

Subtitle E: Ensuring Medicare Sustainability - (Sec. 3401, as modified by Sec. 10319 and Sec. 10322) Revises certain market basket updates and incorporates a full productivity adjustment into any updates that do not already incorporate such adjustments, including inpatient hospitals, home health providers, nursing homes, hospice providers, inpatient psychiatric facilities, long-term care hospitals, inpatient rehabilitation facilities, and Part B providers.

Establishes a quality measure reporting program for psychiatric hospitals beginning in FY2014.

(Sec. 3402) Revises requirements for reduction of the Medicare part B premium subsidy based on income. Maintains the current 2010 income thresholds for the period of 2011 through 2019.

(Sec. 3403, as modified by Sec. 10320) Establishes an Independent Payment Advisory Board to develop and submit detailed proposals to reduce the per capita rate of growth in Medicare spending to the President for Congress to consider. Establishes a consumer advisory council to advise the Board on the impact of payment policies under this title on consumers.

Subtitle F: Health Care Quality Improvements - (Sec. 3501) Amends the Public Health Service Act to direct the Center for Quality Improvement and Patient Safety of the Agency for Healthcare Research and Quality (AHRQ) to conduct or support activities for best practices in the delivery of health care services and support research on the development of tools to facilitate adoption of best practices that improve the quality, safety, and efficiency of health care delivery services. Authorizes appropriations for FY2010-FY2014.

Requires the AHRQ Director, through the AHRQ Center for Quality Improvement and Patient Safety, to award grants or contracts to eligible entities to provide technical support or to implement models and practices identified in the research conducted by the Center.

(Sec. 3502, as modified by Sec. 10321) Directs the Secretary to establish a program to provide grants to or enter into contracts with eligible entities to establish community-based interdisciplinary, interprofessional teams to support primary care practices, including obstetrics and gynecology practices, within the hospital service areas served by the eligible entities.

(Sec. 3503) Directs the Secretary, acting through the Patient Safety Research Center, to establish a program to provide grants or contracts to eligible entities to implement medication management services provided by licensed pharmacists, as a collaborative multidisciplinary, inter-professional approach to the treatment of chronic diseases for targeted individuals, to improve the quality of care and reduce overall cost in the treatment of such disease.

(Sec. 3504) Directs the Secretary, acting through the Assistant Secretary for Preparedness and Response, to award at least four multiyear contracts or competitive grants to eligible entities to support pilot projects that design, implement, and evaluate innovative models of regionalized, comprehensive, and accountable emergency care and trauma systems.

Requires the Secretary to support federal programs administered by the National Institutes of Health (NIH), the AHRQ, the Health Resources and Services Administration (HRSA), the CMS, and other agencies involved in improving the emergency care

system to expand and accelerate research in emergency medical care systems and emergency medicine.

Directs the Secretary to support federal programs administered by the such agencies to coordinate and expand research in pediatric emergency medical care systems and pediatric emergency medicine.

Authorizes appropriations for FY2010-FY2014.

(Sec. 3505) Requires the Secretary to establish three programs to award grants to qualified public, nonprofit IHS, Indian tribal, and urban Indian trauma centers to: (1) assist in defraying substantial uncompensated care costs; (2) further the core missions of such trauma centers, including by addressing costs associated with patient stabilization and transfer; and (3) provide emergency relief to ensure the continued and future availability of trauma services. Authorizes appropriations for FY2010-FY2015.

Directs the Secretary to provide funding to states to enable them to award grants to eligible entities for trauma services. Authorizes appropriations for FY2010-FY2015.

(Sec. 3506) Directs the Secretary to: (1) establish a program to award grants or contracts to develop, update, and produce patient decision aids to assist health care providers and patients; (2) establish a program to provide for the phased-in development, implementation, and evaluation of shared decision making using patient decision aids to meet the objective of improving the understanding of patients of their medical treatment options; and (3) award grants for establishment and support of Shared Decisionmaking Resource Centers. Authorizes appropriations for FY2010 and subsequent fiscal years.

(Sec. 3507) Requires the Secretary, acting through the Commissioner of Food and Drugs, to determine whether the addition of quantitative summaries of the benefits and risks of prescription drugs in a standardized format to the promotional labeling or print advertising of such drugs would improve heath care decisionmaking by clinicians and patients and consumers.

(Sec. 3508) Authorizes the Secretary to award grants to eligible entities or consortia to carry out demonstration projects to develop and implement academic curricula that integrate quality improvement and patient safety in the clinical education of health professionals.

(Sec. 3509) Establishes an Office on Women's Health within the Office of the Secretary, the Office of the Director of the Centers for Disease Control and Prevention (CDC), the Office of the AHRQ Director, the Office of the Administrator of HRSA, and the Office of the Commissioner of Food and Drugs.

Authorizes appropriations for FY2010-FY2014 for all such Offices on Women's Health.

(Sec. 3510) Extends from three years to four years the duration of a patient navigator grant.

Prohibits the Secretary from awarding such a grant unless the recipient entity provides assurances that patient navigators recruited, assigned, trained, or employed using grant funds meet minimum core proficiencies tailored for the main focus or intervention of the navigator involved.

Authorizes appropriations for FY2010-FY2015.

(Sec. 3511) Authorizes appropriations to carry out this title, except where otherwise provided in the title.

(Sec. 3512, as added by Sec. 10201) Directs the Comptroller General to study and report to Congress on whether the development, recognition, or implementation of any guideline or other standards under specified provisions of this Act would result in the establishment of a new cause of action or claim.

Subtitle G: Protecting and Improving Guaranteed Medicare Benefits - (Sec. 3601) Provides that nothing in this Act shall result in a reduction of guaranteed benefits under the Medicare program.

States that savings generated for the Medicare program under this Act shall extend the solvency of the Medicare trust funds, reduce Medicare premiums and other cost-sharing for beneficiaries, and improve or expand guaranteed Medicare benefits and protect access to Medicare providers.

(Sec. 3602) Declares that nothing in this Act shall result in the reduction or elimination of any benefits guaranteed by law to participants in MA plans.

Title IV: Prevention of Chronic Disease and Improving Public Health - Subtitle A: Modernizing Disease Prevention and Public Health Systems - (Sec. 4001, as modified by Sec. 10401) Requires the President to: (1) establish the National Prevention, Health Promotion and Public Health Council; (2) establish the Advisory Group on Prevention, Health Promotion, and Integrative and Public Health; and (3) appoint the Surgeon General as Chairperson of the Council in order to develop a national prevention, health promotion, and public health strategy.

Requires the Secretary and the Comptroller General to conduct periodic reviews and evaluations of every federal disease prevention and health promotion initiative, program, and agency.

(Sec. 4002, as modified by Sec. 10401) Establishes a Prevention and Public Health Fund to provide for expanded and sustained national investment in prevention and public health programs to improve health and help restrain the rate of growth in private and public sector health care costs. Authorizes appropriations and appropriates money to such Fund.

(Sec. 4003) Requires (currently, allows) the Director of AHRQ to convene the Preventive Services Task Force to review scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations for the health care community.

Requires the Director of CDC to convene an independent Community Preventive Services Task Force to review scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of community preventive interventions for the purpose of developing recommendations for individuals and organizations delivering populations-based services and other policy makers

(Sec. 4004, as modified by Sec. 10401) Requires the Secretary to provide for the planning and implementation of a national public-private partnership for a prevention and health promotion outreach and education campaign to raise public awareness of health improvement across the life span.

Requires the Secretary, acting through the Director of CDC, to: (1) establish and implement a national science-based media campaign on health promotion and disease prevention; and (2) enter into a contract for the development and operation of a federal website personalized prevention plan tool.

Subtitle B: Increasing Access to Clinical Preventive Services - (Sec. 4101, as modified by Sec. 10402) Requires the Secretary to establish a program to award grants to eligible entities to support the operation of school-based health centers.

(Sec. 4102) Requires the Secretary, acting through the Director of CDC, to carry out oral health activities, including: (1) establishing a national public education campaign that is focused on oral health care prevention and education; (2) awarding demonstration grants for research-based dental caries disease management activities; (3) awarding grants for the development of school-based dental sealant programs; and (4) entering into cooperative agreements with state, territorial, and Indian tribes or tribal organizations for oral health data collection and interpretation, a delivery system for oral health, and science-based programs to improve oral health.

Requires the Secretary to: (1) update and improve the Pregnancy Risk Assessment Monitoring System as it relates to oral health care; (2) develop oral health care components for inclusion in the National Health and Nutrition Examination Survey; and (3) ensure that the Medical Expenditures Panel Survey by AHRQ includes the verification of dental utilization, expenditure, and coverage findings through conduct of a look-back analysis.

(Sec. 4103, as modified by Sec. 10402) Amends SSA title XVIII (Medicare) to provide coverage of personalized prevention plan services, including a health risk assessment, for individuals. Prohibits cost-sharing for such services.

(Sec. 4104, as modified by Sec. 10406) Eliminates cost-sharing for certain preventive services recommended by the United States Preventive Services Task Force.

(Sec. 4105) Authorizes the Secretary to modify Medicare coverage of any preventive service consistent with the recommendations of such Task Force.

(Sec. 4106) Amends SSA title XIX (Medicaid) to provide Medicaid coverage of preventive services and approved vaccines. Increases the FMAP for such services and vaccines.

(Sec. 4107) Provides for Medicaid coverage of counseling and pharmacotherapy for cessation of tobacco use by pregnant women.

(Sec. 4108) Requires the Secretary to award grants to states to carry out initiatives to provide incentives to Medicaid beneficiaries who participate in programs to lower health risk and demonstrate changes in health risk and outcomes.

Subtitle C: Creating Healthier Communities - (Sec. 4201, as modified by Sec. 10403) Requires the Secretary, acting through the Director of CDC, to award grants to state and local governmental agencies and community-based organizations for the implementation, evaluation, and dissemination of evidence-based community preventive health activities in order to reduce chronic disease rates, prevent the development of secondary conditions, address health disparities, and develop a stronger evidence base of effective prevention programming.

(Sec. 4202) Requires the Secretary, acting through the Director of CDC, to award grants to state or local health departments and Indian tribes to carry out pilot programs to provide public health community interventions, screenings, and clinical referrals for individuals who are between 55 and 64 years of age.

Requires the Secretary to: (1) conduct an evaluation of community-based prevention and wellness programs and develop a plan for promoting healthy lifestyles and chronic disease self-management for Medicare beneficiaries; and (2) evaluate community prevention and wellness programs that have demonstrated potential to help Medicare beneficiaries reduce their risk of disease, disability, and injury by making healthy lifestyle choices.

(Sec. 4203) Amends the Rehabilitation Act of 1973 to require the Architectural and Transportation Barriers Compliance Board to promulgate standards setting forth the minimum technical criteria for medical diagnostic equipment used in medical settings to ensure that such equipment is accessible to, and usable by, individuals with accessibility needs.

(Sec. 4204) Authorizes the Secretary to negotiate and enter into contracts with vaccine manufacturers for the purchase and delivery of vaccines for adults. Allows a state to purchase additional quantities of adult vaccines from manufacturers at the applicable price negotiated by the Secretary. Requires the Secretary, acting through the Director of

CDC, to establish a demonstration program to award grants to states to improve the provision of recommended immunizations for children and adults through the use of evidence-based, population-based interventions for high-risk populations.

Reauthorizes appropriations for preventive health service programs to immunize children and adults against vaccine-preventable diseases without charge.

Requires the Comptroller General to study the ability of Medicare beneficiaries who are 65 years or older to access routinely recommended vaccines covered under the prescription drug program since its establishment.

(Sec. 4205) Amends the Federal Food, Drug, and Cosmetic Act to require the labeling of a food item offered for sale in a retail food establishment that is part of a chain with 20 or more locations under the same name to disclose on the menu and menu board: (1) the number of calories contained in the standard menu item; (2) the suggested daily caloric intake; and (3) the availability on the premises and upon request of specified additional nutrient information. Requires self-service facilities to place adjacent to each food offered a sign that lists calories per displayed food item or per serving. Requires vending machine operators who operate 20 or more vending machines to provide a sign disclosing the number of calories contained in each article of food.

(Sec. 4206) Requires the Secretary to establish a pilot program to test the impact of providing at-risk populations who utilize community health centers an individualized wellness plan designed to reduce risk factors for preventable conditions as identified by a comprehensive risk-factor assessment.

(Sec. 4207) Amends the Fair Labor Standards Act of 1938 to require employers to provide a reasonable break time and a suitable place, other than a bathroom, for an employee to express breast milk for her nursing child. Excludes an employer with fewer than 50 employees if such requirements would impose an undue hardship.

Subtitle D: Support for Prevention and Public Health Innovation - (Sec. 4301) Requires the Secretary, acting through the Director of CDC, to provide funding for research in the area of public health services and systems.

(Sec. 4302) Requires the Secretary to ensure that any federally conduced or supported health care or public health program, activity, or survey collects and reports specified demographic data regarding health disparities.

Requires the Secretary, acting through the National Coordinator for Health Information Technology, to develop: (1) national standards for the management of data collected; and (2) interoperability and security systems for data management.

(Sec. 4303, as modified by Sec. 10404) Requires the Director of CDC to: (1) provide employers with technical assistance, consultation, tools, and other resources in evaluating employer-based wellness programs; and (2) build evaluation capacity among

workplace staff by training employers on how to evaluate such wellness programs and ensuring that evaluation resources, technical assistance, and consultation are available.

Requires the Director of CDC to conduct a national worksite health policies and programs survey to assess employer-based health policies and programs.

(Sec. 4304) Requires the Secretary, acting through the Director of CDC, to establish an Epidemiology and Laboratory Capacity Grant Program to award grants to assist public health agencies in improving surveillance for, and response to, infectious diseases and other conditions of public health importance.

(Sec. 4305) Requires the Secretary to: (1) enter into an agreement with the Institute of Medicine to convene a Conference on Pain, the purposes of which shall include to increase the recognition of pain as a significant public health problem in the United States; and (2) establish the Interagency Pain Research Coordinating Committee.

(Sec. 4306) Appropriates funds to carry out childhood obesity demonstration projects.

Subtitle E: Miscellaneous Provisions - (Sec. 4402) Requires the Secretary to evaluate programs to determine whether existing federal health and wellness initiatives are effective in achieving their stated goals.

Title V: Health Care Workforce - Subtitle A: Purpose and Definitions - (Sec. 5001) Declares that the purpose of this title is to improve access to and the delivery of health care services for all individuals, particularly low-income, underserved, uninsured, minority, health disparity, and rural populations.

Subtitle B: Innovations in the Health Care Workforce - (Sec. 5101, as modified by Sec. 10501) Establishes a National Health Care Workforce Commission to: (1) review current and projected health care workforce supply and demand; and (2) make recommendations to Congress and the Administration concerning national health care workforce priorities, goals, and policies.

(Sec. 5102) Establishes a health care workforce development grant program.

(Sec. 5103) Requires the Secretary to establish the National Center for Health Care Workforce Analysis to provide for the development of information describing and analyzing the health care workforce and workforce related issues. Transfers the responsibilities and resources of the National Center for Health Workforce Analysis to the Center created under this section.

(Sec. 5104, as added by Sec. 10501) Establishes the Interagency Access to Health Care in Alaska Task Force to: (1) assess access to health care for beneficiaries of federal health care systems in Alaska; and (2) develop a strategy to improve delivery to such beneficiaries.

Subtitle C: Increasing the Supply of the Health Care Workforce - (Sec. 5201) Revises student loan repayment provisions related to the length of service requirement for the primary health care loan repayment program.

(Sec. 5202) Increases maximum amount of loans made by schools of nursing to students.

(Sec. 5203) Directs the Secretary to establish and carry out a pediatric specialty loan repayment program.

(Sec. 5204) Requires the Secretary to establish the Public Health Workforce Loan Repayment Program to assure an adequate supply of public health professionals to eliminate critical public health workforce shortages in federal, state, local, and tribal public health agencies.

(Sec. 5205) Amends the Higher Education Act of 1965 to expand student loan forgiveness to include allied health professionals employed in public health agencies.

(Sec. 5206) Includes public health workforce loan repayment programs as permitted activities under a grant program to increase the number of individuals in the public health workforce.

Authorizes the Secretary to provide for scholarships for mid-career professionals in the public health and allied health workforce to receive additional training in the field of public health and allied health.

(Sec. 5207) Authorizes appropriations for the National Health Service Corps Scholarship Program and the National Health Service Corps Loan Repayment Program.

(Sec. 5208) Requires the Secretary to award grants for the cost of the operation of nurse-managed health clinics.

(Sec. 5209) Eliminates the cap on the number of commissioned officers in the Public Health Service Regular Corps.

(Sec. 5210) Revises the Regular Corps and the Reserve Corps (renamed the Ready Reserve Corps) in the Public Health Service. Sets forth the uses of the Ready Reserve Corps.

Subtitle D: Enhancing Health Care Workforce Education and Training - (Sec. 5301) Sets forth provisions providing for health care professional training programs.

(Sec. 5302) Requires the Secretary to award grants for new training opportunities for direct care workers who are employed in long-term care settings.

(Sec. 5303) Sets forth provisions providing for dentistry professional training programs.

(Sec. 5304) Authorizes the Secretary to award grants for demonstration programs to establish training programs for alternative dental health care providers in order to increase access to dental health services in rural and other underserved communities.

(Sec. 5305) Requires the Secretary to award grants or contracts to entities that operate a geriatric education center to offer short-term, intensive courses that focus on geriatrics, chronic care management, and long-term care.

Expands geriatric faculty fellowship programs to make dentists eligible.

Reauthorizes and revises the geriatric education programs to allow grant funds to be used for the establishment of traineeships for individuals who are preparing for advanced education nursing degrees in areas that specialize in the care of elderly populations.

(Sec. 5306) Authorizes the Secretary to award grants to institutions of higher education to support the recruitment of students for, and education and clinical experience of the students in, social work programs, psychology programs, child and adolescent mental health, and training of paraprofessional child and adolescent mental health workers.

(Sec. 5307) Authorizes the Secretary, acting through the Administrator of HRSA, to award grants, contracts, or cooperative agreements for the development, evaluation, and dissemination of research, demonstration projects, and model curricula for health professions training in cultural competency, prevention, public health proficiency, reducing health disparities, and working with individuals with disabilities.

(Sec. 5308) Requires nurse-midwifery programs, in order to be eligible for advanced education nursing grants, to have as their objective the education of midwives and to be accredited by the American College of Nurse-Midwives Accreditation Commission for Midwifery Education.

(Sec. 5309) Authorizes the Secretary to award grants or enter into contracts to enhance the nursing workforce by initiating and maintaining nurse retention programs.

(Sec. 5310) Makes nurse faculty at an accredited school of nursing eligible for the nursing education loan repayment program.

(Sec. 5311) Revises the nurse faculty loan repayment program, including to increase the amount of such loans.

Authorizes the Secretary, acting through the Administrator of HRSA, to enter into an agreement for the repayment of education loans in exchange for service as a member of a faculty at an accredited school of nursing.

(Sec. 5312) Authorizes appropriations for carrying out nursing workforce programs.

(Sec. 5313, as modified by Sec. 10501) Requires the Director of CDC to award grants to eligible entities to promote positive health behaviors and outcomes for populations in medically underserved communities through the use of community health workers.

(Sec. 5314) Authorizes the Secretary to carry out activities to address documented workforce shortages in state and local health departments in the critical areas of applied public health epidemiology and public health laboratory science and informatics.

(Sec. 5315) Authorizes the establishment of the United States Public Health Sciences Track, which is authorized to award advanced degrees in public health, epidemiology, and emergency preparedness and response.

Directs the Surgeon General to develop: (1) an integrated longitudinal plan for health professions continuing education; and (2) faculty development programs and curricula in decentralized venues of health care to balance urban, tertiary, and inpatient venues.

(Sec. 5316, as added by Sec. 10501) Requires the Secretary to establish a training demonstration program for family nurse practitioners to employ and provide one-year training for nurse practitioners serving as primary care providers in federally qualified health centers or nurse-managed health centers.

Subtitle E: Supporting the Existing Health Care Workforce - (Sec. 5401) Revises the allocation of funds to assist schools in supporting programs of excellence in health professions education for underrepresented minority individuals and schools designated as centers of excellence.

(Sec. 5402, as modified by Sec. 10501) Makes schools offering physician assistant education programs eligible for loan repayment for health profession faculty. Increases the amount of loan repayment for such program.

Authorizes appropriations for: (1) scholarships for disadvantaged students attending health professions or nursing schools; (2) loan repayment for health professions faculty; and (3) grants to health professions school to assist individuals from disadvantaged backgrounds.

(Sec. 5403) Requires the Secretary to: (1) make awards for area health education center programs; and (2) provide for timely dissemination of research findings using relevant resources.

(Sec. 5404) Makes revisions to the grant program to increase nursing education opportunities for individuals from disadvantaged backgrounds to include providing: (1) stipends for diploma or associate degree nurses to enter a bridge or degree completion program; (2) student scholarships or stipends for accelerated nursing degree programs; and (3) advanced education preparation.

(Sec. 5405, as modified by Sec. 10501) Requires the Secretary, acting through the Director of AHRQ, to establish a Primary Care Extension Program to provide support

and assistance to educate primary care providers about preventive medicine, health promotion, chronic disease management, mental and behavioral health services, and evidence-based and evidence-informed therapies and techniques.

Requires the Secretary to award grants to states for the establishment of Primary Care Extension Program State Hubs to coordinate state health care functions with quality improvement organizations and area health education centers.

Subtitle F: Strengthening Primary Care and Other Workforce Improvements - (Sec. 5501, as modified by Sec. 10501) Requires Medicare incentive payments to: (1) primary care practitioners providing primary care services on or after January 1, 2011, and before January 1, 2016; and (2) general surgeons performing major surgical procedures on or after January 1, 2011, and before January 1, 2016, in a health professional shortage area.

(Sec. 5502, deleted by Sec. 10501)

(Sec. 5503) Reallocates unused residency positions to qualifying hospitals for primary care residents for purposes of payments to hospitals for graduate medical education costs.

(Sec. 5504) Revises provisions related to graduate medical education costs to count the time residents spend in nonprovider settings toward the full-time equivalency if the hospital incurs the costs of the stipends and fringe benefits of such residents during such time.

(Sec. 5505, as modified by Sec. 10501) Includes toward the determination of full-time equivalency for graduate medical education costs time spent by an intern or resident in an approved medical residency training program in a nonprovider setting that is primarily engaged in furnishing patient care in nonpatient care activities.

(Sec. 5506) Directs the Secretary, when a hospital with an approved medical residency program closes, to increase the resident limit for other hospitals based on proximity criteria.

(Sec. 5507) Requires the Secretary to: (1) award grants for demonstration projects that are designed to provide certain low-income individuals with the opportunity to obtain education and training for health care occupations that pay well and that are expected to experience labor shortages or be in high demand; and (2) award grants to states to conduct demonstration projects for purposes of developing core training competencies and certification programs for personal or home care aides.

Authorizes appropriations for FY2009-FY2012 for family-to-family health information centers.

(Sec. 5508) Authorizes the Secretary to award grants to teaching health centers for the purpose of establishing new accredited or expanded primary care residency programs.

Allows up to 50% of time spent teaching by a member of the National Health Service Corps to be considered clinical practice for purposes of fulfilling the service obligation.

Requires the Secretary to make payments for direct and indirect expenses to qualified teaching health centers for expansion or establishment of approved graduate medical residency training programs.

(Sec. 5509) Requires the Secretary to establish a graduate nurse education demonstration under which a hospital may receive payment for the hospital's reasonable costs for the provision of qualified clinical training to advance practice nurses.

Subtitle G: Improving Access to Health Care Services - (Sec. 5601) Reauthorizes appropriations for health centers to serve medically underserved populations.

(Sec. 5602) Requires the Secretary to establish through the negotiated rulemaking process a comprehensive methodology and criteria for designation of medically underserved populations and health professions shortage areas.

(Sec. 5603) Reauthorizes appropriations for FY2010-FY2014 for the expansion and improvement of emergency medical services for children who need treatment for trauma or critical care.

(Sec. 5604) Authorizes the Secretary, acting through the Administrator of the Substance Abuse and Mental Health Services Administration, to award grants and cooperative agreements for demonstration projects for the provision of coordinated and integrated services to special populations through the co-location of primary and specialty care services in community-based mental and behavioral health settings.

(Sec. 5605) Establishes a Commission on Key National Indicators to: (1) conduct comprehensive oversight of a newly established key national indicators system; and (2) make recommendations on how to improve such system. Directs the National Academy of Sciences to enable the establishment of such system by creating its own institutional capability or by partnering with an independent private nonprofit organization to implement such system. Directs the Comptroller General to study previous work conducted by all public agencies, private organizations, or foreign countries with respect to best practices for such systems.

(Sec. 5606, as added by Sec. 10501) Authorizes a state to award grants to health care providers who treat a high percentage of medically underserved populations or other special populations in the state.

Subtitle H: General Provisions - (Sec. 5701) Requires the Secretary to submit to the appropriate congressional committees a report on activities carried out under this title and the effectiveness of such activities.

Title VI: Transparency and Program Integrity - Subtitle A: Physician Ownership and Other Transparency - (Sec. 6001, as modified by Sec. 10601) Amends SSA title XVIII (Medicare) to prohibit physician-owned hospitals that do not have a provider agreement by August 1, 2010, to participate in Medicare. Allows their participation in Medicare under a rural provider and hospital exception to the ownership or investment prohibition if they meet certain requirements addressing conflict of interest, bona fide investments, patient safety issues, and expansion limitations.

(Sec. 6002) Amends SSA title XI to require drug, device, biological and medical supply manufacturers to report to the Secretary transfers of value made to a physician, physician medical practice, a physician group practice, and/or teaching hospital, as well as information on any physician ownership or investment interest in the manufacturer. Provides penalties for noncompliance. Preempts duplicative state or local laws.

(Sec. 6003) Amends SSA title XVIII (Medicare), with respect to the Medicare in-office ancillary exception to the prohibition against physician self-referrals, to require a referring physician to inform the patient in writing that the patient may obtain a specified imaging service from a person other than the referring physician, a physician who is a member of the same group practice as the referring physician, or an individual directly supervised by the physician or by another physician in the group practice. Requires the referring physician also to provide the patient with a written list of suppliers who furnish such services in the area in which the patient resides.

(Sec. 6004) Amends SSA title XI to require prescription drug manufacturers and authorized distributors of record to report to the Secretary specified information pertaining to drug samples.

(Sec. 6005) Amends SSA title XI to require a pharmacy benefit manager (PBM) or a health benefits plan that manages prescription drug coverage under a contract with a Medicare or Exchange health plan to report to the Secretary information regarding the generic dispensing rate, the rebates, discounts, or price concessions negotiated by the PBM, and the payment difference between health plans and PBMs and the PBMs and pharmacies.

Subtitle B: Nursing Home Transparency and Improvement - Part I: Improving Transparency of Information - (Sec. 6101) Amends SSA title XI to require SNFs under Medicare and nursing facilities (NFs) under Medicaid to make available, upon request by the Secretary, the HHS Inspector General, the states, or a state long-term care ombudsman, information on ownership of the SNF or NF, including a description of the facility's governing body and organizational structure, as well as information regarding additional disclosable parties.

(Sec. 6102) Requires SNFs and NFs to operate a compliance and ethics program effective in preventing and detecting criminal, civil, and administrative violations.

Directs the Secretary to establish and implement a quality assurance and performance improvement program for SNFs and NFs, including multi-unit chains of facilities.

(Sec. 6103) Amends SSA title XVIII (Medicare) to require the Secretary to publish on the Nursing Home Compare Medicare website: (1) standardized staffing data; (2) links to state websites regarding state survey and certification programs; (3) the model standardized complaint form; (4) a summary of substantiated complaints; and (5) the number of adjudicated instances of criminal violations by a facility or its employees.

(Sec. 6104) Requires SNFs to report separately expenditures on wages and benefits for direct care staff, breaking out registered nurses, licensed professional nurses, certified nurse assistants, and other medical and therapy staff.

(Sec. 6105) Requires the Secretary to develop a standardized complaint form for use by residents (or a person acting on a resident's behalf) in filing complaints with a state survey and certification agency and a state long-term care ombudsman program. Requires states to to establish complaint resolution processes.

(Sec. 6106) Amends SSA title XI to require the Secretary to develop a program for facilities to report direct care staffing information on payroll and other verifiable and auditable data in a uniform format based.

(Sec. 6107) Requires the Comptroller General to study and report to Congress on the Five-Star Quality Rating System for nursing homes of CMS.

Part II: Targeting Enforcement - (Sec. 6111) Amends SSA title XVIII (Medicare) to authorize the Secretary to reduce civil monetary penalties by 50% for certain SNFs and NFs that self-report and promptly correct deficiencies within 10 calendar days of imposition of the penalty. Directs the Secretary to issue regulations providing for an informal dispute resolution process after imposition of a penalty, as well as an escrow account for money penalties pending resolution of any appeals.

(Sec. 6112) Directs the Secretary to establish a demonstration project for developing, testing, and implementing a national independent monitor program to oversee interstate and large intrastate chains of SNFs and NFs.

(Sec. 6113) Requires the administrator of a SNF or a NF that is preparing to close to notify in writing residents, legal representatives of residents or other responsible parties, the Secretary, and the state long-term care ombudsman program in advance of the closure by at least 60 days. Requires the notice to include a plan for the transfer and adequate relocation of residents to another facility or alternative setting. Requires the state to ensure a successful relocation of residents.

(Sec. 6114) Requires the Secretary to conduct two SNF- and NF-based demonstration projects to develop best practice models in two areas: (1) one for facilities involved in the "culture change" movement; and (2) one for the use of information technology to improve resident care.

Part III: Improving Staff Training - (Sec. 6121) Requires SNFs and NFs to include dementia management and abuse prevention training as part of pre-employment initial training and, if appropriate, as part of ongoing in-service training for permanent and contract or agency staff.

Subtitle C: Nationwide Program for National and State Background Checks on Direct Patient Access Employees of Long Term Care Facilities and Providers - (Sec. 6201) Requires the Secretary to establish a nationwide program for national and state background checks on prospective direct patient access employees of long-term care facilities and providers.

Subtitle D: Patient-Centered Outcomes Research - (Sec. 6301, as modified by Sec. 10602) Amends SSA title XI to establish the Patient-Centered Outcomes Research Institute to identify priorities for, and establish, update, and carry out, a national comparative outcomes research project agenda. Provides for a peer review process for primary research.

Prohibits the Institute from allowing the subsequent use of data from original research in work-for-hire contracts with individuals, entities, or instrumentalities that have a financial interest in the results, unless approved by the Institute under a data use agreement.

Amends the Public Health Service Act to direct the Office of Communication and Knowledge Transfer at AHRQ to disseminate broadly the research findings published by the Institute and other government-funded research relevant to comparative clinical effective research.

Prohibits the Secretary from using evidence and findings from Institute research to make a determination regarding Medicare coverage unless such use is through an iterative and transparent process which includes public comment and considers the effect on subpopulations.

Amends the Internal Revenue Code to establish in the Treasury the Patient-Centered Outcomes Research Trust Fund. Directs the Secretary to make transfers to that Trust Fund from the Medicare Trust Funds.

Imposes annual fees of $2 times the number of insured lives on each specified health insurance policy and on self-insured health plans.

(Sec. 6302) Terminates the Federal Coordinating Council for Comparative Effectiveness Research upon enactment of this Act.

Subtitle E: Medicare, Medicaid, and CHIP Program Integrity Provisions - (Sec. 6401, as modified by Sec. 10603) Amends SSA title XVIII (Medicare) to require the Secretary to: (1) establish procedures for screening providers and suppliers participating in Medicare, Medicaid, and CHIP; and (2) determine the level of screening according to the risk of fraud, waste, and abuse with respect to each category of provider or supplier.

Requires providers and suppliers applying for enrollment or revalidation of enrollment in Medicare, Medicaid, or CHIP to disclose current or previous affiliations with any provider or supplier that: (1) has uncollected debt; (2) has had its payments suspended; (3) has been excluded from participating in a federal health care program; or (4) has had billing privileges revoked. Authorizes the Secretary to deny enrollment in a program if these affiliations pose an undue risk to it.

Requires providers and suppliers to establish a compliance program containing specified core elements.

Directs the CMS Administrator to establish a process for making available to each state agency with responsibility for administering a state Medicaid plan or a child health plan under SSA title XXI the identity of any provider or supplier under Medicare or CHIP who is terminated.

(Sec. 6402) Requires CMS to include in the integrated data repository claims and payment data from Medicare, Medicaid, CHIP, and health-related programs administered by the Departments of Veterans Affairs (VA) and DOD, the Social Security Administration, and IHS.

Directs the Secretary to enter into data-sharing agreements with the Commissioner of Social Security, the VA and DOD Secretaries, and the IHS Director to help identity fraud, waste, and abuse.

Requires that overpayments be reported and returned within 60 days from the date the overpayment was identified or by the date a corresponding cost report was due, whichever is later.

Directs the Secretary to issue a regulation requiring all Medicare, Medicaid, and CHIP providers to include their National Provider Identifier on enrollment applications.

Authorizes the Secretary to withhold the federal matching payment to states for medical assistance expenditures whenever a state does not report enrollee encounter data in a timely manner to the state’s Medicaid Management Information System.

Authorizes the Secretary to exclude providers and suppliers participation in any federal health care program for providing false information on any application to enroll or participate.

Subjects to civil monetary penalties excluded individuals who: (1) order or prescribe an item or service; (2) make false statements on applications or contracts to participate in a federal health care program; or (3) know of an overpayment and do not return it. Subjects the latter offense to civil monetary penalties of up to $50,000 or triple the total amount of the claim involved.

Authorizes the Secretary to issue subpoenas and require the attendance and testimony of witnesses and the production of any other evidence that relates to matters under investigation or in question.

Requires the Secretary take into account the volume of billing for a durable medical equipment (DME) supplier or home health agency when determining the size of the supplier's and agency's surety bond. Authorizes the Secretary to require other providers and suppliers to post a surety bond if the Secretary considers them to be at risk.

Authorizes the Secretary to suspend payments to a provider or supplier pending a fraud investigation.

Appropriates an additional $10 million, adjusted for inflation, to the Health Care Fraud and Abuse Control each of FY2011-FY2020. Applies inflation adjustments as well to Medicare Integrity Program funding.

Requires the Medicaid Integrity Program and Program contractors to provide the Secretary and the HHS Office of Inspector General with performance statistics, including the number and amount of overpayments recovered, the number of fraud referrals, and the return on investment for such activities.

(Sec. 6403) Requires the Secretary to furnish the National Practitioner Data Bank (NPDB) with all information reported to the national health care fraud and abuse data collection program on certain final adverse actions taken against health care providers, suppliers, and practitioners.

Requires the Secretary to establish a process to terminate the Healthcare Integrity and Protection Databank (HIPDB) and ensure that the information formerly collected in it is transferred to the NPDB.

(Sec. 6404) Reduces from three years to one year after the date of service the maximum period for submission of Medicare claims.

(Sec. 6405, as modified by Sec. 10604) Requires DME or home health services to be ordered by an enrolled Medicare eligible professional or physician. Authorizes the Secretary to extend these requirements to other Medicare items and services to reduce fraud, waste, and abuse.

(Sec. 6406) Authorizes the Secretary to disenroll, for up to one year, a Medicare enrolled physician or supplier that fails to maintain and provide access to written orders or requests for payment for DME, certification for home health services, or referrals for other items and services.

Authorizes the Secretary to exclude from participation in any federal health care program any individual or entity ordering, referring for furnishing, or certifying the need for an item or service that fails to provide adequate documentation to verify payment.

(Sec. 6407, as modified by Sec. 10605) Requires a physician, nurse practitioner, clinical nurse specialist, certified nurse-midwife, or physician assistant to have a face-to-face encounter with an individual before issuing a certification for home health services or DME.

Authorizes the Secretary to apply the same face-to-face encounter requirement to other items and services based upon a finding that doing so would reduce the risk of fraud, waste, and abuse. Applies the same requirement, as well, to physicians making certifications for home health services under Medicaid.

(Sec. 6408) Revises civil monetary penalties for making false statements or delaying inspections.

Applies specified enhanced sanctions and civil monetary penalties to MA or Part D plans that: (1) enroll individuals in an MA or Part D plan without their consent; (2) transfer an individual from one plan to another for the purpose of earning a commission; (3) fail to comply with marketing requirements and CMS guidance; or (4) employ or contract with an individual or entity that commits a violation.

(Sec. 6409) Requires the Secretary to establish a self-referral disclosure protocol to enable health care providers and suppliers to disclose actual or potential violations of the physician self-referral law.

Authorizes the Secretary to reduce the amount due and owing for all violations of such law.

(Sec. 6410) Requires the Secretary to: (1) expand the number of areas to be included in round two of the competitive bidding program from 79 to 100 of the largest metropolitan statistical areas; and (2) use competitively bid prices in all areas by 2016.

(Sec. 6411) Requires states to establish contracts with one or more Recovery Audit Contractors (RACs), which shall identify underpayments and overpayments and recoup overpayments made for services provided under state Medicaid plans as well as state plan waivers.

Requires the Secretary to expand the RAC program to Medicare parts C (Medicare+Choice) and D (Prescription Drug Program).

Subtitle F: Additional Medicaid Program Integrity Provisions - (Sec. 6501) Amends SSA title XIX (Medicaid) to require states to terminate individuals or entities (providers) from their Medicaid programs if they were terminated from Medicare or another state's Medicaid program.

(Sec. 6502) Requires Medicaid agencies to exclude individuals or entities from participating in Medicaid for a specified period of time if the entity or individual owns, controls, or manages an entity that: (1) has failed to repay overpayments during a specified period; (2) is suspended, excluded, or terminated from participation in any

Medicaid program; or (3) is affiliated with an individual or entity that has been suspended, excluded, or terminated from Medicaid participation.

(Sec. 6503) Requires state Medicaid plans to require any billing agents, clearinghouses, or other alternate payees that submit claims on behalf of health care providers to register with the state and the Secretary.

(Sec. 6504) Requires states to submit data elements from the state mechanized claims processing and information retrieval system (under the Medicaid Statistical Information System) that the Secretary determines necessary for program integrity, program oversight, and administration.

Requires a Medicaid managed care entity contract to provide for maintenance of sufficient patient encounter data to identify the physician who delivers services to patients (as under current law) at a frequency and level of detail to be specified by the Secretary.

(Sec. 6505) Requires a state Medicaid plan to prohibit the state from making any payments for items or services under a Medicaid state plan or a waiver to any financial institution or entity located outside of the United States.

(Sec. 6506) Extends the period for states to recover overpayments from 60 days to one year after discovery of the overpayment. Declares that, when overpayments due to fraud are pending, state repayments of the federal portion of such overpayments shall not be due until 30 days after the date of the final administrative or judicial judgment on the matter.

(Sec. 6507) Requires state mechanized Medicaid claims processing and information retrieval systems to incorporate methodologies compatible with Medicare's National Correct Coding Initiative.

Subtitle G: Additional Program Integrity Provisions - (Sec. 6601) Amends the Employee Retirement Income Security Act of 1974 (ERISA) to prohibit employees and agents of multiple employer welfare arrangements (MEWAs), subject to criminal penalties, from making false statements in marketing materials regarding an employee welfare benefit plan's financial solvency, benefits, or regulatory status.

(Sec. 6603) Amends the Public Health Service Act to direct the Secretary to request NAIC to develop a model uniform report form for a private health insurance issuer seeking to refer suspected fraud and abuse to state insurance departments or other responsible state agencies for investigation.

(Sec. 6604) Amends ERISA to direct the Secretary of Labor to adopt regulatory standards and/or issue orders to subject MEWAs to state law relating to fraud and abuse.

(Sec. 6605) Authorizes the Secretary of Labor to: (1) issue cease-and-desist orders to shut down temporarily the operations of MEWAs conducting fraudulent activities or posing a serious threat to the public, until hearings can be completed; and (2) seize a plan's assets if it appears that the plan is in a financially hazardous condition.

(Sec. 6606) Directs the Secretary of Labor to require MEWAs which are not group health plans to register with the Department of Labor before operating in a state.

(Sec. 6607) Authorizes the Secretary of Labor to promulgate a regulation providing an evidentiary privilege that allows confidential communication among specified federal and state officials relating to investigation of fraud and abuse.

Subtitle H: Elder Justice Act - Elder Justice Act of 2009 - (Sec. 6702) Amends SSA title XX (Block Grants to States for Social Services) with respect to elder abuse, neglect, and exploitation and their prevention. Requires the HHS Secretary to award grants and carry out activities that provide: (1) greater protection to those individuals seeking care in facilities that provide long-term care services and supports; and (2) greater incentives for individuals to train and seek employment at such facilities.

Requires facility owners, operators, and certain employees to report suspected crimes committed at a facility.

Requires facility owners or operators also to: (1) submit to the Secretary and to the state written notification of an impending closure of a facility within 60 days before the closure; and (2) include a plan for transfer and adequate relocation of all residents.

Establishes an Elder Justice Coordinating Council.

Subtitle I: Sense of the Senate Regarding Medical Malpractice - (Sec. 6801) Expresses the sense of the Senate that: (1) health reform presents an opportunity to address issues related to medical malpractice and medical liability insurance; (2) states should be encouraged to develop and test alternative models to the existing civil litigation system; and (3) Congress should consider state demonstration projects to evaluate such alternatives.

Title VII: Improving Access to Innovative Medical Therapies - Subtitle A: Biologics Price Competition and Innovation - Biologics Price Competition and Innovation Act of 2009 - (Sec. 7002) Amends the Public Health Service Act to allow a person to submit an application for licensure of a biological product based on its similarity to a licensed biological product (the reference product). Requires the Secretary to license the biological product if it is biosimilar to or interchangeable with the reference product.

Prohibits the Secretary from determining that a second or subsequent biological product is interchangeable with a reference product for any condition of use for specified periods based on the marketing of, and the presence or status of litigation involving, the first biosimilar biological product deemed interchangeable with the same reference product.

Prohibits the Secretary from making approval of an application under this Act effective until 12 years after the date on which the reference product was first licensed.

Subtitle B: More Affordable Medicine for Children and Underserved Communities - (Sec. 7101) Expands the 340B drug discount program (a program limiting the cost of covered outpatient drugs to certain federal grantees) to allow participation as a covered entity by certain: (1) children's hospitals; (2) freestanding cancer hospitals; (3) critical access hospitals; (4) rural referral centers; and (5) sole community hospitals. Expands the program to include drugs used in connection with an inpatient or outpatient service by enrolled hospitals (currently, only outpatient drugs are covered under the program).

Requires the Secretary to establish reasonable exceptions to the prohibition on enrolled hospitals obtaining covered outpatient drugs through a group purchasing organization or other group purchasing arrangement, including for drugs unavailable through the program and to facilitate generic substitution when a generic covered drug is available at a lower price. Allows such hospitals to purchase covered drugs for inpatients through any such arrangement.

Requires a hospital enrolled in the 340B drug discount program to issue a credit to a state Medicaid program for inpatient covered drugs provided to Medicaid recipients.

(Sec. 7102) Requires the Secretary to: (1) provide for improvements in compliance by manufacturers and covered entities with the requirements of the 340B drug discount program; and (2) establish and implement an administrative process for resolving claims by covered entities and manufacturers of violations of such requirements.

Requires manufacturers to offer each covered entity covered drugs for purchase at or below the applicable ceiling price if such a drug is made available to any other purchaser at any price.

(Sec. 7103) Requires the Comptroller General to report to Congress on whether those individuals served by the covered entities under the 340B drug discount program are receiving optimal health care services.

Title VIII: Class Act - Community Living Assistance Services and Supports Act or the CLASS Act - (Sec. 8002, as modified by Sec. 10801) Establishes a national, voluntary insurance program for purchasing community living assistance services and supports (CLASS program) under which: (1) all employees are automatically enrolled, but are allowed to waive enrollment; (2) payroll deductions pay monthly premiums; and (3) benefits under a CLASS Independence Benefit Plan provide individuals with functional limitations with tools that will allow them to maintain their personal and financial independence and live in the community.

Title IX: Revenue Provisions - Subtitle A: Revenue Offset Provisions - (Sec. 9001, as modified by section 10901) Amends the Internal Revenue Code to impose an excise

tax of 40% of the excess benefit from certain high cost employer-sponsored health coverage. Deems any amount which exceeds payment of $8,500 for an employee self-only coverage plan and $23,000 for employees with other than self-only coverage (family plans) as an excess benefit. Increases such amounts for certain retirees and employees who are engaged in high-risk professions (e.g., law enforcement officers, emergency medical first responders, or longshore workers). Imposes a penalty on employers and coverage providers for failure to calculate the proper amount of an excess benefit.

(Sec. 9002) Requires employers to include in the W-2 form of each employee the aggregate cost of applicable employer-sponsored group health coverage that is excludable from the employee's gross income (excluding the value of contributions to flexible spending arrangements).

(Sec. 9003) Restricts payments from health savings accounts, medical savings accounts, and health flexible spending arrangements for medications to prescription drugs or insulin.

(Sec. 9004) Increases to 20% the penalty for distributions from a health savings account or Archer medical savings account not used for qualified medical expenses.

(Sec. 9005, as modified by section 10902) Limits annual salary reduction contributions by an employee to a health flexible spending arrangement under a cafeteria plan to $2,500. Allows an annual inflation adjustment to such amount after 2011.

(Sec. 9006) Applies to corporations reporting requirements for payments of $600 or more to persons engaged in a trade or business.

(Sec. 9007, as modified by section 10903) Requires tax-exempt charitable hospitals to: (1) conduct a community health needs assessment every two years; (2) adopt a written financial assistance policy for patients who require financial assistance for hospital care; and (3) refrain from taking extraordinary collection actions against a patient until the hospital has made reasonable efforts to determine whether the patient is eligible for financial assistance. Imposes a penalty tax on hospitals who fail to comply with the requirements of this Act.

Requires the Secretary of the Treasury to report to Congress on information with respect to private tax-exempt, taxable, and government-owned hospitals regarding levels of charity care provided, bad debt expenses, unreimbursed costs, and costs for community benefit activities.

(Sec. 9008) Imposes an annual fee on the branded prescription drug sales exceeding $5 million of manufacturers and importers of such drugs beginning in 2010. Requires the HHS, VA, and DOD Secretaries to report to the Secretary of the Treasury on the total branded prescription drug sales within government programs within their departments.

(Sec. 9009, as modified by section 10904) Imposes an annual fee on the gross sales receipts exceeding $5 million of manufacturers and importers of certain medical devices beginning in 2011.

(Sec. 9010, as modified by section 10905) Imposes on any entity that provides health insurance for any United States health risk an annual fee beginning in 2011. Defines "United States health risk" as the health risk of an individual who is a U.S. citizen or resident or is located in the United States with respect to the period the individual is so located. Exempts entities whose net premiums written are not more than $25 million. Requires all entities subject to such fee to report to the Secretary of the Treasury on their net written premiums and imposes a penalty for failure to report.

(Sec. 9011) Requires the VA Secretary to study and report to Congress by December 31, 2012, on the effect of fees assessed by this Act on the cost of medical care provided to veterans and on veterans' access to medical devices and branded prescription drugs.

(Sec. 9012) Eliminates the tax deduction for expenses for determining the subsidy for employers who maintain prescription drug plans for Medicare Part D eligible retirees.

(Sec. 9013) Increases the adjusted gross income threshold for claiming the itemized deduction for medical expenses from 7.5% to 10% beginning after 2012. Retains the 7.5% threshold through 2016 for individual taxpayers who have attained age 65 before the close of an applicable taxable year.

(Sec. 9014) Imposes a limitation after December 31, 2012, of $500,000 on the deductibility of remuneration paid to officers, directors, employees, and service providers of health insurance issuers who derive at least 25% of their gross premiums from providing health insurance coverage that meets the minimum essential coverage requirements established by this Act.

(Sec. 9015, as modified by section 10906) Increases after December 31, 2012, the hospital insurance tax rate by .9% for individual taxpayers earning over $200,000 ($250,000 for married couples filing joint tax returns).

(Sec. 9016) Requires Blue Cross or Blue Shield organizations or other nonprofit organizations that provide health insurance to reimburse at least 85% of the cost of clinical services provided to their enrollees to be eligible for special tax benefits currently provided to such organizations.

Subtitle B: Other Provisions - (Sec. 9021) Excludes from gross income the value of certain health benefits provided to members of Indian tribes, including: (1) health services or benefits provided or purchased by IHS; (2) medical care provided by an Indian tribe or tribal organization to a member of an Indian tribe; (3) accident or health plan coverage provided by an Indian tribe or tribal organization for medical care to a member of an Indian tribe and dependents; and (4) any other medical care provided by an Indian tribe that supplements, replaces, or substitutes for federal programs.

(Sec. 9022) Establishes a new employee benefit cafeteria plan to be known as a Simple Cafeteria Plan, defined as a plan that: (1) is established and maintained by an employer with an average of 100 or fewer employees during a two-year period; (2) requires employers to make contributions or match employee contributions to the plan; and (3) requires participating employees to have at least 1,000 hours of service for the preceding plan year; and (4) allows such employees to elect any benefit available under the plan.

(Sec. 9023) Allows a 50% tax credit for investment in any qualifying therapeutic discovery project, defined as a project that is designed to: (1) treat or prevent diseases by conducting pre-clinical activities, clinical trials, and clinical studies, or carrying out research projects to approve new drugs or other biologic products; (2) diagnose diseases or conditions to determine molecular factors related to diseases or conditions; or (3) develop a product, process, or technology to further the delivery or administration of therapeutics. Directs the Secretary of the Treasury to award grants for 50% of the investment in 2009 or 2010 in such a project, in lieu of the tax credit.

Title X: Strengthening Quality, Affordable Health Care for All Americans - Subtitle A: Provisions Relating to Title I - (Sec. 10101) Revises provisions of or related to Subtitles A, B, and C of Title I of this Act (as reflected in the summary of those provisions).

(Sec. 10104) Revises provisions of or related to Subtitle D of Title I of this Act (as reflected in the summary of those provisions). Makes changes to the False Claims Act related to the public disclosure bar on filing civil claims.

(Sec. 10105) Revises provisions of or related to Subtitles E, F, and G of Title I of this Act (as reflected in the summary of those provisions).

(Sec. 10108) Requires an offering employer to provide free choice vouchers to each qualified employee. Defines "offering employer" to mean any employer who offers minimum essential coverage to its employees consisting of coverage through an eligible employer-sponsored plan and who pays any portion of the costs of such plan. Defines "qualified employee" as an employee whose required contribution for such coverage and household income fall within a specified range. Requires: (1) a Health Insurance Exchange to credit the amount of any free choice voucher to the monthly premium of any qualified health plan in which the employee is enrolled; and (2) the offering employer to pay any amounts so credited to the Exchange. Excludes the amount of any free choice voucher from the gross income of the employee. Permits a deduction by employers for such costs.

(Sec. 10109) Amends the SSA to require the HHS Secretary to seek input to determine if there could be greater uniformity in financial and administrative health care activities and items.

Requires the Secretary to: (1) task the ICD-9-CM Coordination and Maintenance Committee to convene a meeting to receive input regarding and recommend revisions to the crosswalk between the Ninth and Tenth Revisions of the International Classification of Diseases; and (2) make appropriate revisions to such crosswalk.

Subtitle B: Provisions Relating to Title II - Part I: Medicaid and CHIP - (Sec. 10201) Revises provisions of Subtitles A through L of Title II of this Act (as reflected in the summary of those provisions).

Amends SSA title XIX (Medicaid) to set the FMAP for the state of Nebraska, with respect to all or any portion of a fiscal year that begins on or after January 1, 2017, at 100% (thus requiring the federal government to pay 100% of the cost of covering newly-eligible individuals in Nebraska).

Directs the Comptroller General to study and report to Congress on whether the development, recognition, or implementation of any specified health care quality guideline or other standards would result in the establishment of a new cause of action or claim.

(Sec. 10202) Creates a State Balancing Incentive Payments Program to increase the FMAP for states which offer home and community-based services as a long-term care alternative to nursing homes.

(Sec. 10203) Amends SSA title XXI (CHIP) to make appropriations for CHIP through FY2015 and revise other CHIP-related requirements.

Part II: Support for Pregnant and Parenting Teens and Women - (Sec. 10212) Requires the Secretary to establish a Pregnancy Assistance Fund for grants to states to assist pregnant and parenting teens and women.

(Sec. 10214) Authorizes appropriations for FY2010-FY2019.

Part III: Indian Health Care Improvement - (Sec. 10221) Enacts into law the Indian Health Care Improvement Reauthorization and Extension Act of 2009 (S. 1790) as reported by the Senate Committee on Indian Affairs in December 2009 and with the following changes.

Amends the Indian Health Care Improvement Act, as amended by the Indian Health Care Improvement Reauthorization and Extension Act of 2009, to make an exception to the requirement that a national Community Health Aide Program exclude dental health aide therapist services. Declares that the exclusion of dental health aide therapist services from services covered under the national program shall not apply where an Indian tribe or tribal organization, located in a state (other than Alaska) in which state law authorizes the use of dental health aide therapist services or midlevel dental health provider services, elects to supply such services in accordance with state law.

Subtitle C: Provisions Relating to Title III - (Sec. 10301) Revises provisions of Subtitles A through G of Title III of this Act (as reflected in the summary of those provisions).

(Sec. 10323) Amends SSA title XVIII (Medicare) to deem eligible for Medicare coverage certain individuals exposed to environmental health hazards.

Directs the Secretary to establish a pilot program for care of certain individuals residing in emergency declaration areas.

Amends SSA title XX (Block Grants to States for Social Services) to direct the Secretary to establish a program for early detection of certain medical conditions related to environmental health hazards. Makes appropriations for FY2012-FY2019.

(Sec. 10324) Establishes floors: (1) on the area wage index for hospitals in frontier states; (2) on the area wage adjustment factor for hospital outpatient department services in frontier states; and (3) for the practice expense index for services furnished in frontier states.

(Sec. 10325) Revises the SNF prospective payment system to delay specified changes until FY2011.

(Sec. 10326) Directs the Secretary to conduct separate pilot programs, for specified kinds of hospitals and hospice programs, to test the implementation of a value-based purchasing program for payments to the provider.

(Sec. 10327) Authorizes an additional incentive payment under the physician quality reporting system in 2011 through 2014 to eligible professionals who report quality measures to CMS via a qualified Maintenance of Certification program. Eliminates the MedicareAdvantage Regional Plan Stabilization Fund.

(Sec. 10328) Requires Medicare part D prescription drug plans to include a comprehensive review of medications as part of their medication therapy management programs. Requires automatic quarterly enrollment of qualified beneficiaries, with an allowance for them to opt out.

(Sec. 10329) Requires the Secretary to develop a methodology to measure health plan value.

(Sec. 10330) Directs the Secretary to develop a plan to modernize CMS computer and data systems.

(Sec. 10331) Requires the Secretary to: (1) develop a Physician Compare website with information on physicians enrolled in the Medicare program and other eligible professionals who participate in the Physician Quality Reporting Initiative; and (2) implement a plan to make information on physician performance public through Physician Compare, particularly quality and patient experience measures.

Authorizes the Secretary to provide financial incentives to Medicare beneficiaries furnished services by high quality physicians.

(Sec. 10332) Directs the Secretary to make available to qualified entities standardized extracts of Medicare claims data for the evaluation of the performance of service providers and suppliers.

(Sec. 10333) Amends the Public Health Service Act to authorize the Secretary to award grants to eligible entities to support community-based collaborative care networks for low-income populations.

(Sec. 10334) Transfers the Office of Minority Health to the Office of the Secretary. Authorizes appropriations for FY2011-FY2016.

Establishes individual offices of minority health within HHS.

Redesignates the National Center on Minority Health and Health Disparities in NIH as the National Institute on Minority Health and Health Disparities.

(Sec. 10336) Directs the Comptroller General to study and report to Congress on the impact on Medicare beneficiary access to high-quality dialysis services of including specified oral drugs furnished to them for the treatment of end stage renal disease in the related bundled prospective payment system.

Subtitle D: Provisions Relating to Title IV - (Sec. 10401) Revises provisions of or related to Subtitles A, B, C, D, and E of Title IV of this Act (as reflected in the summary of those provisions).

(Sec. 10407) Catalyst to Better Diabetes Care Act of 2009 - Requires the Secretary to prepare biennially a national diabetes report card and, to the extent possible, one for each state.

Requires the Secretary, acting through the Director of CDC, to: (1) promote the education and training of physicians on the importance of birth and death certificate data and on how to properly complete these documents; (2) encourage state adoption of the latest standard revisions of birth and death certificates; and (3) work with states to reengineer their vital statistics systems in order to provide cost-effective, timely, and accurate vital systems data. Allows the Secretary to promote improvements to the collection of diabetes mortality data.

Directs the Secretary to conduct a study of the impact of diabetes on the practice of medicine in the United States and the level of diabetes medical education that should be required prior to licensure, board certification, and board recertification.

(Sec. 10408) Requires the Secretary to award grants to eligible employers to provide their employees with access to comprehensive workplace wellness programs.

(Sec. 10409) Cures Acceleration Network Act of 2009 - Amends the Public Health Service Act to require the Secretary, acting through the Director of NIH, to implement the Cures Acceleration Network under which grants and contracts will be awarded to accelerate the development of high need cures. Defines "high need cure" as a drug, biological product, or device: (1) that is a priority to diagnose, mitigate, prevent, or treat harm from any disease or condition; and (2) for which the incentives of the commercial market are unlikely to result in its adequate or timely development. Establishes a Cures Acceleration Network Review Board.

(Sec. 10410) Establishing a Network of Health-Advancing National Centers of Excellence for Depression Act of 2009 or the ENHANCED Act of 2009 - Requires the Secretary, acting through the Administrator of the Substance Abuse and Mental Health Services Administration, to: (1) award grants to establish national centers of excellence for depression; and (2) designate one such center as a coordinating center. Requires the coordinating center to establish and maintain a national, publicly available database to improve prevention programs, evidence-based interventions, and disease management programs for depressive disorders using data collected from the national centers.

(Sec. 10411) Congenital Heart Futures Act - Authorizes the Secretary, acting through the Director of CDC, to: (1) enhance and expand infrastructure to track the epidemiology of congenital heart disease and to organize such information into the National Congenital Heart Disease Surveillance System; or (2) award a grant to an eligible entity to undertake such activities.

Authorizes the Director of the National Heart, Lung, and Blood Institute to expand, intensify, and coordinate research and related Institute activities on congenital heart disease.

(Sec. 10412) Reauthorizes appropriations for grants for public access defibrillation programs. Requires an information clearinghouse to increase public access to defibrillation in schools established under such program to be administered by an organization that has substantial expertise in pediatric education, pediatric medicine, and electrophysiology and sudden death.

(Sec. 10413) Young Women's Breast Health Education and Awareness Requires Learning Young Act of 2009 or the EARLY Act - Requires the Secretary, acting through the Director of CDC, to conduct: (1) a national education campaign to increase awareness of young women's knowledge regarding breast health and breast cancer; (2) an education campaign among physicians and other health care professionals to increase awareness of breast health of young women; and (3) prevention research on breast cancer in younger women.

Requires the Secretary, acting through the Director of NIH, to conduct research to develop and validate new screening tests and methods for prevention and early detection of breast cancer in young women.

Directs the Secretary to award grants for the provision of health information to young women diagnosed with breast cancer and pre-neoplastic breast diseases.

Subtitle E: Provisions Relating to Title V - (Sec. 10501) Revises provisions of or related to Title V of this Act (as reflected in the summary of those provisions).

Requires the Secretary, acting through the Director of CDC, to establish a national diabetes prevention program targeted at adults at high risk for diabetes.

Directs the Secretary to develop a Medicare prospective payment system for payment for services furnished by federally qualified health centers.

Requires the Secretary, acting through the Administrator of the HRSA, to establish a grant program to assist accredited schools of allopathic or osteopathic medicine in: (1) recruiting students most likely to practice medicine in underserved rural communities; (2) providing rural-focused training and experience; and (3) increasing the number of recent allopathic and osteopathic medical school graduates who practice in underserved rural communities.

Directs the Secretary, acting through the Administrator of HRSA, to award grants or enter into contracts with eligible entities to provide training to graduate medical residents in preventive medicine specialties.

Reauthorizes appropriations for public health workforce activities.

Revises provisions related to fulfillment of service obligations under the National Health Service Corps related to half-time clinical practice and teaching.

(Sec. 10502) Authorizes appropriations to HHS for debt service on, or direct construction or renovation of, a health care facility that provides research, inpatient tertiary care, or outpatient clinical services and that meets certain requirements, including that it is critical for the provision of greater access to health care within the state.

(Sec. 10503) Establishes a Community Health Center Fund to provide for expanded and sustained national investment in community health centers. Authorizes appropriations to such Fund.

(Sec. 10504) Requires the Secretary, acting through the Administrator of HRSA, to establish a demonstration project to provide access to comprehensive health care services to the uninsured at reduced fees.

Subtitle F: Provisions Relating to Title VI - (Sec. 10601) Revises provisions of Subtitles A through E of Title IV of this Act (as reflected in the summary of those provisions).

(Sec. 10606) Directs the U.S. Sentencing Commission to amend the Federal Sentencing Guidelines to provide two-level, three-level, and four-level increases in the offense level for any defendant convicted of a federal health care offense relating to a government health care program of a loss between $1 million and $7 million, between $7 million and $20 million, and at least $20 million, respectively.

Provides that a person need not have actual knowledge of the prohibition against health care fraud nor specific intent to violate it in order to commit health care fraud.

Expands the scope of violations constituting a federal health care offense.

Amends the Civil Rights of Institutionalized Persons Act to authorize the Attorney General to require access to an institution by subpoena to investigate conditions depriving residents of specified constitutional or federal rights.

(Sec. 10607) Authorizes the Secretary to award demonstration grants to states for the development, implementation, and evaluation of alternatives to current tort litigation for resolving disputes over injuries allegedly caused by health care providers or health care organizations.

(Sec. 10608) Amends the Public Health Service Act to extend medical malpractice coverage to free clinics by deeming their officers, employees, board members, and contractors to be employees of the Public Health Service.

(Sec. 10609) Amends the Federal Food, Drug, and Cosmetic Act to set forth circumstances under which a generic drug may be approved with a label different from the listed drug.

Subtitle G: Provisions Relating to Title VIII - (Sec. 10801) Revises provisions of or related to Title VIII of this Act (as reflected in the summary of those provisions).

Subtitle H: Provisions Relating to Title IX: (Sec. 10901) Revises provisions of or related to Title IX of this Act (as reflected in the summary of those provisions).

(Sec. 10907) Amends the Internal Revenue Code to impose a 10% excise tax on any amount paid for indoor tanning services on or after July 1, 2010. Exempts phototherapy services performed by a licensed medical professional from the definition of "indoor tanning services."

(Sec. 10908) Excludes from gross income any payments under the National Health Service Corps Loan Repayment Program and any other state loan repayment or forgiveness programs intended to increase the availability of health care services in underserved or health professional shortage areas.

(Sec. 10909) Increases from $10,000 to $13,170 the dollar limitation on: (1) the tax credit for adoption expenses; and (2) the tax exclusion for employer-provided adoption assistance. Allows an inflation adjustment to such limitation after 2010. Makes such credit refundable. Extends through 2011 the general terminating date of the Economic Growth and Tax Relief Reconciliation Act of 2001 with respect to such credit and exclusion.

Key Elements of the Affordable Care Act

Arguably for brokers, the ACA has 3 'most important' features:

1. Redefining health insurance to include certain essential benefits and exclude certain restrictions l pre-existing condition coverage considerations, annual or lifetime maximum payouts and pol rescission;
2. Establishing individual and employer coverage mandates and exchanges and subsidies in the individ market; and
3. Expanding Medicaid

We present below the original texts of **Title 1** that addresses the first 2 features above and **Title 2** that addresses the third. This will allow readers to grasp the essence and intent of the lawmakers without any potential interpretive biases from me.

Title 1

Title I: Quality, Affordable Health Care for All Americans - Subtitle A: Immediate Improvements in Health Care Coverage for All Americans - (Sec. 1001, as modified by Sec. 10101) Amends the Public Health Service Act to prohibit a health plan ("health plan" under this subtitle excludes any "grandfathered health plan" as defined in section 1251) from establishing lifetime limits or annual limits on the dollar value of benefits for any participant or beneficiary after January 1, 2014. Permits a restricted annual limit for plan years beginning prior to January 1, 2014. Declares that a health plan shall not be prevented from placing annual or lifetime per-beneficiary limits on covered benefits that are not essential health benefits to the extent that such limits are otherwise permitted.

Prohibits a health plan from rescinding coverage of an enrollee except in the case of fraud or intentional misrepresentation of material fact.

Requires health plans to provide coverage for, and to not impose any cost sharing requirements for: (1) specified preventive items or services; (2) recommended immunizations; and (3) recommended preventive care and screenings for women and children.

Requires a health plan that provides dependent coverage of children to make such coverage available for an unmarried, adult child until the child turns 26 years of age.

Requires the Secretary of Health and Human Services (HHS) to develop standards for health plans (including grandfathered health plans) to provide an accurate summary of benefits and coverage explanation. Directs each such health plan, prior to any enrollment restriction, to provide such a summary of benefits and coverage explanation to: (1) the applicant at the time of application; (2) an enrollee prior to the time of enrollment or re-enrollment; and (3) a policy or certificate holder at the time of issuance of the policy or delivery of the certificate.

Requires group health plans to comply with requirements relating to the prohibition against discrimination in favor of highly compensated individuals.

Requires the Secretary to develop reporting requirements for health plans on benefits or reimbursement structures that: (1) improve health outcomes; (2) prevent hospital readmissions; (3) improve patient safety and reduce medical errors; and (4) promote wellness and health.

Prohibits: (1) a wellness and health promotion activity implemented by a health plan or any data collection activity authorized under this Act from requiring the disclosure or collection of any information relating to the lawful use, possession, or storage of a

firearm or ammunition by an individual; (2) any authority provided to the Secretary under this Act from being construed to authorize the collection of such information or the maintenance of records of individual ownership or possession of a firearm or ammunition; or (3) any health insurance premium increase, denial of coverage, or reduction of any reward for participation in a wellness program on the basis of the lawful use, possession, or storage of a firearm or ammunition.

Requires a health plan (including a grandfathered health plan) to: (1) submit to the Secretary a report concerning the ratio of the incurred loss (or incurred claims) plus the loss adjustment expense (or change in contract reserves) to earned premiums; and (2) provide an annual rebate to each enrollee if the ratio of the amount of premium revenue expended by the issuer on reimbursement for clinical services provided to enrollees and activities that improve health care quality to the total amount of premium revenue for the plan year is less than a 85% for large group markets or 80% for small group or individual markets.

Requires each U.S. hospital to establish and make public a list of its standard charges for items and services.

Requires a health plan to implement an effective process for appeals of coverage determinations and claims.

Sets forth requirements for health plans related to: (1) designation of a primary care provider; (2) coverage of emergency services; and (3) elimination of referral requirements for obstetrical or gynecological care.

(Sec. 1002) Requires the Secretary to award grants to states for offices of health insurance consumer assistance or health insurance ombudsman programs.

(Sec. 1003, as modified by Sec. 10101) Requires the Secretary to establish a process for the annual review of unreasonable increases in premiums for health insurance coverage.

(Sec. 1004) Makes this subtitle effective for plan years beginning six months after enactment of this Act, with certain exceptions.

Subtitle B: Immediate Actions to Preserve and Expand Coverage - (Sec. 1101) Requires the Secretary to establish a temporary high risk health insurance pool program to provide health insurance coverage to eligible individuals with a preexisting condition. Terminates such coverage on January 1, 2014, and provides for a transition to an American Health Benefit Exchange (Exchange).

(Sec. 1102, as modified by Sec. 10102) Requires the Secretary to establish a temporary reinsurance program to provide reimbursement to participating employment-based plans for a portion of the cost of providing health insurance coverage to early retirees before January 1, 2014.

(Sec. 1103, as modified by Sec. 10102) Requires the Secretary to establish a mechanism, including an Internet website, through which a resident of, or small business in, any state may identify affordable health insurance coverage options in that state.

(Sec. 1104) Sets forth provisions governing electronic health care transactions. Establishes penalties for health plans failing to comply with requirements.

(Sec. 1105) Makes this subtitle effective on the date of enactment of this Act.

Subtitle C: Quality Health Insurance Coverage for All Americans - Part I: Health Insurance Market Reforms - (Sec. 1201, as modified by Sec. 10103) Prohibits a health plan ("health plan" under this subtitle excludes any "grandfathered health plan" as defined in section 1251) from: (1) imposing any preexisting condition exclusion; or (2) discriminating on the basis of any health status-related factor. Allows premium rates to vary only by individual or family coverage, rating area, age, or tobacco use.

Requires health plans in a state to: (1) accept every employer and individual in the state that applies for coverage; and (2) renew or continue coverage at the option of the plan sponsor or the individual, as applicable.

Prohibits a health plan from establishing individual eligibility rules based on health status-related factors, including medical condition, claims experience, receipt of health care, medical history, genetic information, and evidence of insurability.

Sets forth provisions governing wellness programs under the health plan, including allowing cost variances for coverage for participation in such a program.

Prohibits a health plan from discriminating with respect to participation under the plan or coverage against any health care provider who is acting within the scope of that provider's license or certification under applicable state law.

Requires health plans that offer health insurance coverage in the individual or small group market to ensure that such coverage includes the essential health benefits package. Requires a group health plan to ensure that any annual cost-sharing imposed under the plan does not exceed specified limitations.

Prohibits a health plan from: (1) applying any waiting period for coverage that exceeds 90 days; or (2) discriminating against individual participation in clinical trials with respect to treatment of cancer or any other life-threatening disease or condition.

Part II: Other Provisions - (Sec. 1251, as modified by Sec. 10103) Provides that nothing in this Act shall be construed to require that an individual terminate coverage under a group health plan or health insurance coverage in which such individual was enrolled on the date of enactment of this Act. Allows family members of individuals currently enrolled in a plan to enroll in such plan or coverage if such enrollment was

permitted under the terms of the plan. Allows new employees and their families to enroll in a group health plan that provides coverage on the date of enactment of this Act.

Defines a "grandfathered health plan" as a group health plan or health insurance coverage in which an individual was enrolled on the date of enactment of this Act.

States that this subtitle and subtitle A shall not apply to: (1) a group health plan or health insurance coverage in which an individual was enrolled on the date of enactment of this Act, regardless of whether the individual renews such coverage after such date of enactment; (2) an existing group health plan that enrolls new employees under this section; and (3) health insurance coverage maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers that was ratified before the date of enactment of this Act until the date on which the last of the collective bargaining agreements relating to the coverage terminates.

Applies provisions related to uniform coverage documents and medical loss ratios to grandfathered health plans for plan years beginning after enactment of this Act.

(Sec. 1252) Requires uniform application of standards or requirements adopted by states to all health plans in each applicable insurance market.

(Sec. 1253, as added by Sec. 10103) Directs the Secretary of Labor to prepare an annual report on self-insured group health plans and self-insured employers.

(Sec. 1254, as added by Sec. 10103) Requires the HHS Secretary to conduct a study of the fully-insured and self-insured group health plan markets related to financial solvency and the effect of insurance market reforms.

(Sec. 1255, as modified by Sec. 10103) Sets forth effective dates for specified provisions of this subtitle.

Subtitle D: Available Coverage Choices for All Americans - Part I: Establishment of Qualified Health Plans - (Sec. 1301, as modified by Sec. 10104) Defines "qualified health plan" to require that such a plan provides essential health benefits and offers at least one plan in the silver level at one plan in the gold level in each Exchange through which such plan is offered.

(Sec. 1302, as modified by Sec. 10104) Requires the essential health benefits package to provide essential health benefits and limit cost-sharing. Directs the Secretary to: (1) define essential health benefits and include emergency services, hospitalization, maternity and newborn care, mental health and substance use disorder services, prescription drugs, preventive and wellness services and chronic disease management, and pediatric services, including oral and vision care; (2) ensure that the scope of the essential health benefits is equal to the scope of benefits provided under a typical employer plan; and (3) provide notice and an opportunity for public comment in defining

the essential health benefits. Establishes: (1) an annual limit on cost-sharing beginning in 2014; and (2) a limitation on the deductible under a small group market health plan.

Sets forth levels of coverage for health plans defined by a certain percentage of the costs paid by the plan. Allows health plans in the individual market to offer catastrophic coverage for individuals under age 30, with certain limitations.

(Sec. 1303, as modified by Sec. 10104) Sets forth special rules for abortion coverage, including: (1) permitting states to elect to prohibit abortion coverage in qualified health plans offered through an Exchange in the state; (2) prohibiting federal funds from being used for abortion services; and (3) requiring separate accounts for payments for such services. Prohibits any qualified health plan offered through an Exchange from discriminating against any individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions.

(Sec. 1304, as modified by Sec. 10104) Sets forth definitions for terms used in this title.

Part II: Consumer Choices and Insurance Competition Through Health Benefit Exchanges - (Sec. 1311, as modified by Sec. 10104) Requires states to establish an American Health Benefit Exchange that: (1) facilitates the purchase of qualified health plans; and (2) provides for the establishment of a Small Business Health Options Program (SHOP Exchange) that is designed to assist qualified small employers in facilitating the enrollment of their employees in qualified health plans offered in the small group market in the state.

Requires the Secretary to establish criteria for the certification of health plans as qualified health plans, including requirements for: (1) meeting market requirements; and (2) ensuring a sufficient choice of providers.

Sets forth the requirements for an Exchange, including that an Exchange: (1) must be a governmental agency or nonprofit entity that is established by a state; (2) may not make available any health plan that is not a qualified health plan; (3) must implement procedures for certification of health plans as qualified health plans; and (4) must require health plans seeking certification to submit a justification of any premium increase prior to implementation of such increase.

Permits states to require qualified health plans to offer additional benefits. Requires states to pay for the cost of such additional benefits.

Allows a state to establish one or more subsidiary Exchanges for geographically distinct areas of a certain size.

Applies mental health parity provisions to qualified health plans.

(Sec. 1312, as modified by Sec. 10104) Allows an employer to select a level of coverage to be made available to employees through an Exchange. Allows employees to choose to enroll in any qualified health plan that offers that level of coverage.

Restricts the health plans that the federal government may make available to Members of Congress and congressional staff after the effective date of this subtitle to only those health plans that are created under this Act or offered through an Exchange.

Permits states to allow large employers to join an Exchange after 2017.

(Sec. 1313, as modified by Sec. 10104) Requires an Exchange to keep an accurate accounting of all activities, receipts, and expenditures and to submit to the Secretary, annually, a report concerning such accountings. Requires the Secretary to take certain action to reduce fraud and abuse in the administration of this title. Requires the Comptroller General to conduct an ongoing study of Exchange activities and the enrollees in qualified health plans offered through Exchanges.

Part III: State Flexibility Relating to Exchanges - (Sec. 1321) Requires the Secretary to issue regulations setting standards related to: (1) the establishment and operation of Exchanges; (2) the offering of qualified health plans through Exchanges; and (3) the establishment of the reinsurance and risk adjustment programs under part V.

Requires the Secretary to: (1) establish and operate an Exchange within a state if the state does not have one operational by January 1, 2014; and (2) presume that an Exchange operating in a state before January 1, 2010, that insures a specified percentage of its population meets the standards under this section.

(Sec. 1322, as modified by Sec. 10104) Requires the Secretary to establish the Consumer Operated and Oriented Plan (CO-OP) program to foster the creation of qualified nonprofit health insurance issuers to offer qualified health plans in the individual and small group markets. Requires the Secretary to provide for loans and grants to persons applying to become qualified nonprofit health insurance issuers. Sets forth provisions governing the establishment and operation of CO-OP program plans.

(Sec. 1323, deleted by Sec. 10104)

(Sec. 1324, as modified by Sec. 10104) Declares that health insurance coverage offered by a private health insurance issuer shall not be subject to federal or state laws if a qualified health plan offered under the CO-OP program is not subject to such law.

Part IV: State Flexibility to Establish Alternative Programs - (Sec. 1331, as modified by Sec. 10104) Requires the Secretary to establish a basic health program under which a state may enter into contracts to offer one or more standard health plans providing at least the essential health benefits to eligible individuals in lieu of offering such individuals coverage through an Exchange. Sets forth requirements for such a plan. Transfers funds that would have gone to the Exchange for such individuals to the state.

(Sec. 1332) Authorizes a state to apply to the Secretary for the waiver of specified requirements under this Act with respect to health insurance coverage within that state for plan years beginning on or after January 1, 2017. Directs the Secretary to provide for an alternative means by which the aggregate amounts of credits or reductions that

would have been paid on behalf of participants in the Exchange will be paid to the state for purposes of implementing the state plan.

(Sec. 1333, as modified by Sec. 10104) Requires the Secretary to issue regulations for the creation of health care choice compacts under which two or more states may enter into an agreement that: (1) qualified health plans could be offered in the individual markets in all such states only subject to the laws and regulations of the state in which the plan was written or issued; and (2) the issuer of any qualified health plan to which the compact applies would continue to be subject to certain laws of the state in which the purchaser resides, would be required to be licensed in each state, and must clearly notify consumers that the policy may not be subject to all the laws and regulations of the state in which the purchaser resides. Sets forth provisions regarding the Secretary's approval of such compacts.

(Sec. 1334, as added by Sec. 10104) Requires the Director of the Office of Personnel Management (OPM) to: (1) enter into contracts with health insurance issuers to offer at least two multistate qualified health plans through each Exchange in each state to provide individual or group coverage; and (2) implement this subsection in a manner similar to the manner in which the Director implements the Federal Employees Health Benefits Program. Sets forth requirements for a multistate qualified health plan.

Part V: Reinsurance and Risk Adjustment - (Sec. 1341, as modified by Sec. 10104) Directs each state, not later than January 1, 2014, to establish one or more reinsurance entities to carry out the reinsurance program under this section. Requires the Secretary to establish standards to enable states to establish and maintain a reinsurance program under which: (1) health insurance issuers and third party administrators on behalf of group health plans are required to make payments to an applicable reinsurance entity for specified plan years; and (2) the applicable reinsurance entity uses amounts collected to make reinsurance payments to health insurance issuers that cover high risk individuals in the individual market. Directs the state to eliminate or modify any state high-risk pool to the extent necessary to carry out the reinsurance program established under this section.

(Sec. 1342) Requires the Secretary to establish and administer a program of risk corridors for calendar years 2014 through 2016 under which a qualified health plan offered in the individual or small group market shall participate in a payment adjusted system based on the ratio of the allowable costs of the plan to the plan's aggregate premiums. Directs the Secretary to make payments when a plan's allowable costs exceed the target amount by a certain percentage and directs a plan to make payments to the Secretary when its allowable costs are less than target amount by a certain percentage.

(Sec. 1343) Requires each state to assess a charge on health plans and health insurance issuers if the actuarial risk of the enrollees of such plans or coverage for a year is less than the average actuarial risk of all enrollees in all plans or coverage in the

state for the year. Requires each state to provide a payment to health plans and health insurance issuers if the actuarial risk of the enrollees of such plan or coverage for a year is greater than the average actuarial risk of all enrollees in all plans and coverage in the state for the year. Excludes self-insured group health plans from this section.

Subtitle E: Affordable Coverage Choices for All Americans - Part I: Premium Tax Credits and Cost-sharing Reductions - Subpart A: Premium Tax Credits and Cost-sharing Reductions - (Sec. 1401, as modified by section 10105) Amends the Internal Revenue Code to allow individual taxpayers whose household income equals or exceeds 100%, but does not exceed 400%, of the federal poverty line (as determined in the Social Security Act [SSA]) a refundable tax credit for a percentage of the cost of premiums for coverage under a qualified health plan. Sets forth formulae and rules for the calculation of credit amounts based upon taxpayer household income as a percentage of the poverty line.

Directs the Comptroller General, not later than five years after enactment of this Act, to conduct a study and report to specified congressional committees on the affordability of health insurance coverage.

(Sec. 1402) Requires reductions in the maximum limits for out-of-pocket expenses for individuals enrolled in qualified health plans whose incomes are between 100% and 400% of the poverty line.

Subpart B: Eligibility Determinations - (Sec. 1411) - Requires the Secretary to establish a program for verifying the eligibility of applicants for participation in a qualified health plan offered through an Exchange or for a tax credit for premium assistance based upon their income or their citizenship or immigration status. Requires an Exchange to submit information received from an applicant to the Secretary for verification of applicant eligibility. Provides for confidentiality of applicant information and for an appeals and redetermination process for denials of eligibility. Imposes civil penalties on applicants for providing false or fraudulent information relating to eligibility.

Requires the Secretary to study and report to Congress by January 1, 2013, on procedures necessary to ensure the protection of privacy and due process rights in making eligibility and other determinations under this Act.

(Sec. 1412) Requires the Secretary to establish a program for advance payments of the tax credit for premium assistance and for reductions of cost-sharing. Prohibits any federal payments, tax credit, or cost-sharing reductions for individuals who are not lawfully present in the United States.

(Sec. 1413) Requires the Secretary to establish a system to enroll state residents who apply to an Exchange in state health subsidy programs, including Medicaid or the Children's Health Insurance Program (CHIP, formerly known as SCHIP), if such residents are found to be eligible for such programs after screening.

(Sec. 1414) Requires the Secretary of the Treasury to disclose to HHS personnel certain taxpayer information to determine eligibility for programs under this Act or certain other social security programs.

(Sec. 1415) Disregards the premium assistance tax credit and cost-sharing reductions in determining eligibility for federal and federally-assisted programs.

(Sec. 1416, as added by section 10105) Directs the HHS Secretary to study and report to Congress by January 1, 2013, on the feasibility and implication of adjusting the application of the federal poverty level under this subtitle for different geographic areas in the United States, including its territories.

Part II: Small Business Tax Credit - (Sec. 1421, as modified by section 10105) Allows qualified small employers to elect, beginning in 2010, a tax credit for 50% of their employee health care coverage expenses. Defines "qualified small employer" as an employer who has no more than 25 employees with average annual compensation levels not exceeding $50,000. Requires a phase-out of such credit based on employer size and employee compensation.

Subtitle F: Shared Responsibility for Health Care - Part I: Individual Responsibility - (Sec. 1501, as modified by section 10106) Requires individuals to maintain minimal essential health care coverage beginning in 2014. Imposes a penalty for failure to maintain such coverage beginning in 2014, except for certain low-income individuals who cannot afford coverage, members of Indian tribes, and individuals who suffer hardship. Exempts from the coverage requirement individuals who object to health care coverage on religious grounds, individuals not lawfully present in the United States, and individuals who are incarcerated.

(Sec. 1502) Requires providers of minimum essential coverage to file informational returns providing identifying information of covered individuals and the dates of coverage. Requires the IRS to send a notice to taxpayers who are not enrolled in minimum essential coverage about services available through the Exchange operating in their state.

Part II: Employer Responsibilities - (Sec. 1511) Amends the Fair Labor Standards Act of 1938 to: (1) require employers with more than 200 full-time employees to automatically enroll new employees in a health care plan and provide notice of the opportunity to opt-out of such coverage; and (2) provide notice to employees about an Exchange, the availability of a tax credit for premium assistance, and the loss of an employer's contribution to an employer-provided health benefit plan if the employee purchases a plan through an Exchange.

(Sec. 1513, as modified by section 10106) Imposes fines on large employers (employers with more than 50 full-time employees) who fail to offer their full-time employees the opportunity to enroll in minimum essential coverage or who have a waiting period for enrollment of more than 60 days.

Requires the Secretary of Labor to study and report to Congress on whether employees' wages are reduced due to fines imposed on employers.

(Sec. 1514, as modified by section 10106) Requires large employers to file a report with the Secretary of the Treasury on health insurance coverage provided to their full-time employees. Requires such reports to contain: (1) a certification as to whether such employers provide their full-time employees (and their dependents) the opportunity to enroll in minimum essential coverage under an eligible employer-sponsored plan; (2) the length of any waiting period for such coverage; (3) the months during which such coverage was available; (4) the monthly premium for the lowest cost option in each of the enrollment categories under the plan; (5) the employer's share of the total allowed costs of benefits provided under the plan; and (6) identifying information about the employer and full-time employees. Imposes a penalty on employers who fail to provide such report. Authorizes the Secretary of the Treasury to review the accuracy of information provided by large employers.

(Sec. 1515) Allows certain small employers to include as a benefit in a tax-exempt cafeteria plan a qualified health plan offered through an Exchange.

Subtitle G: Miscellaneous Provisions - (Sec. 1551) Applies the definitions under the Public Health Service Act related to health insurance coverage to this title.

(Sec. 1552) Requires the HHS Secretary to publish on the HHS website a list of all of the authorities provided to the Secretary under this Act.

(Sec. 1553) Prohibits the federal government, any state or local government or health care provider that receives federal financial assistance under this Act, or any health plan created under this Act from discriminating against an individual or institutional health care entity on the basis that such individual or entity does not provide a health care item or service furnished for the purpose of causing, or assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy killing.

(Sec. 1554) Prohibits the Secretary from promulgating any regulation that: (1) creates an unreasonable barrier to the ability of individuals to obtain appropriate medical care; (2) impedes timely access to health care services; (3) interferes with communications regarding a full range of treatment options between the patient and the health care provider; (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions; (5) violates the principle of informed consent and the ethical standards of health care professionals; or (6) limits the availability of health care treatment for the full duration of a patient's medical needs.

(Sec. 1555) Declares that no individual, company, business, nonprofit entity, or health insurance issuer offering group or individual health insurance coverage shall be required to participate in any federal health insurance program created by or expanded under this Act. Prohibits any penalty from being imposed upon any such issuer for choosing not to participate in any such program.

(Sec. 1556) Amends the Black Lung Benefits Act, with respect to claims filed on or after the effective date of the Black Lung Benefits Amendments of 1981, to eliminate exceptions to: (1) the applicability of certain provisions regarding rebuttable presumptions; and (2) the prohibition against requiring eligible survivors of a miner determined to be eligible for black lung benefits to file a new claim or to refile or otherwise revalidate the miner's claim.

(Sec. 1557) Prohibits discrimination by any federal health program or activity on the grounds of race, color, national origin, sex, age, or disability.

(Sec. 1558) Amends the Fair Labor Standards Act of 1938 to prohibit an employer from discharging or discriminating against any employee because the employee: (1) has received a health insurance credit or subsidy; (2) provides information relating to any violation of any provision of such Act; or (3) objects to, or refuses to participate in, any activity, policy, practice, or assigned task that the employee reasonably believed to be in violation of such Act.

(Sec. 1559) Gives the HHS Inspector General oversight authority with respect to the administration and implementation of this title.

(Sec. 1560) Declares that nothing in this title shall be construed to modify, impair, or supersede the operation of any antitrust laws.

(Sec. 1561) Amends the Public Health Service Act to require the Secretary to: (1) develop interoperable and secure standards and protocols that facilitate enrollment of individuals in federal and state health and human services programs; and (2) award grants to develop and adapt technology systems to implement such standards and protocols.

(Sec. 1562, as added by Sec. 10107) Directs the Comptroller General to study denials by health plans of coverage for medical services and of applications to enroll in health insurance.

(Sec. 1563, as added by Sec. 10107) Disallows the waiver of laws or regulations establishing procurement requirements relating to small business concerns with respect to any contract awarded under any program or other authority under this Act.

(Sec. 1563 [*sic*], as modified by Sec. 10107) Makes technical and conforming amendments.

(Sec. 1563 [*sic*]) Expresses the sense of the Senate that: (1) the additional surplus in the Social Security trust fund generated by this Act should be reserved for Social Security; and (2) the net savings generated by the CLASS program (established under Title VIII of this Act) should be reserved for such program

Title 2

Medicaid expansion

Title II: Role of Public Programs - Subtitle A: Improved Access to Medicaid - (Sec. 2001, as modified by Sec. 10201) Amends title XIX (Medicaid) of the SSA to extend Medicaid coverage, beginning in calendar 2014, to individuals under age 65 who are not entitled to or enrolled in Medicare and have incomes at or below 133% of the federal poverty line. Grants a state the option to expand Medicaid eligibility to such individuals as early as April 1, 2010. Provides that, for between 2014 and 2016, the federal government will pay 100% of the cost of covering newly-eligible individuals.

Increases the federal medical assistance percentage (FMAP): (1) with respect to newly eligible individuals; and (2) between January 1, 2014, and December 31, 2016, for states meeting certain eligibility requirements.

Requires Medicaid benchmark benefits to include coverage of prescription drugs and mental health services.

Grants states the option to extend Medicaid coverage to individuals who have incomes that exceed 133% of the federal poverty line beginning January 1, 2014.

(Sec. 2002) Requires a state to use an individual's or household's modified gross income to determine income eligibility for Medicaid for non-elderly individuals, without applying any income or expense disregards or assets or resources test.

Exempts from this requirement: (1) individuals eligible for Medicaid through another program; (2) the elderly or Social Security Disability Insurance (SSDI) program beneficiaries; (3) the medically needy; (4) enrollees in a Medicare Savings Program; and (5) the disabled.

(Sec. 2003) Revises state authority to offer a premium assistance subsidy for qualified employer-sponsored coverage to children under age 19 to extend such a subsidy to all individuals, regardless of age.

Prohibits a state from requiring, as a condition of Medicaid eligibility, that an individual (or the individual's parent) apply for enrollment in qualified employer-sponsored coverage.

(Sec. 2004, as modified by Sec. 10201) Extends Medicaid coverage to former foster care children who are under 26 years of age.

(Sec. 2005, as modified by Sec. 10201) Revises requirements for Medicaid payments to territories, including an increase in the limits on payments for FY2011 and thereafter.

(Sec. 2006, as modified by Sec. 10201) Prescribes an adjustment to the FMAP determination for certain states recovering from a major disaster.

(Sec. 2007) Rescinds any unobligated amounts available to the Medicaid Improvement Fund for FY2014-FY2018.

Subtitle B: Enhanced Support for the Children's Health Insurance Program - (Sec. 2101, as modified by Sec. 10201) Amends SSA title XXI (State Children's Health Insurance Program) (CHIP, formerly known as SCHIP) to increase the FY2016-FY2019 enhanced FMAP for states, subject to a 100% cap.

Prohibits states from applying, before the end of FY2019, CHIP eligibility standards that are more restrictive than those under this Act.

Deems ineligible for CHIP any targeted low-income children who cannot enroll in CHIP because allotments are capped, but who are therefore eligible for tax credits in the Exchanges.

Requires the Secretary to: (1) review benefits offered for children, and related cost-sharing imposed, by qualified health plans offered through an Exchange; and (2) certify those plans whose benefits and cost-sharing are at least comparable to those provided under the particular state's CHIP plan.

Prohibits enrollment bonus payments for children enrolled in CHIP after FY2013.

Requires a state CHIP plan, beginning January 1, 2014, to use modified gross income and household income to determine CHIP eligibility.

Requires a state to treat as a targeted low-income child eligible for CHIP any child determined ineligible for Medicaid as a result of the elimination of an income disregard based on expense or type of income.

(Sec. 2102) Makes technical corrections to the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA).

Subtitle C: Medicaid and CHIP Enrollment Simplification - (Sec. 2201) Amends SSA title XIX (Medicaid) to require enrollment application simplification and coordination with state health insurance Exchanges and CHIP via state-run websites.

(Sec. 2202) Permits hospitals to provide Medicaid services during a period of presumptive eligibility to members of all Medicaid eligibility categories.

Subtitle D: Improvements to Medicaid Services - (Sec. 2301) Requires Medicaid coverage of: (1) freestanding birth center services; and (2) concurrent care for children receiving hospice care.

(Sec. 2303) Gives states the option of extending Medicaid coverage to family planning services and supplies under a presumptive eligibility period for a categorically needy group of individuals.

Subtitle E: New Options for States to Provide Long-Term Services and Supports - (Sec. 2401) Authorizes states to offer home and community-based attendant services and supports to Medicaid beneficiaries with disabilities who would otherwise require

care in a hospital, nursing facility, intermediate care facility for the mentally retarded, or an institution for mental diseases.

(Sec. 2402) Gives states the option of: (1) providing home and community-based services to individuals eligible for services under a waiver; and (2) offering home and community-based services to specific, targeted populations

Creates an optional eligibility category to provide full Medicaid benefits to individuals receiving home and community-based services under a state plan amendment.

(Sec. 2403) Amends the Deficit Reduction Act of 2005 to: (1) extend through FY2016 the Money Follows the Person Rebalancing Demonstration; and (2) reduce to 90 days the institutional residency period.

(Sec. 2404) Applies Medicaid eligibility criteria to recipients of home and community-based services, during calendar 2014 through 2019, in such a way as to protect against spousal impoverishment.

(Sec. 2405) Makes appropriations for FY2010-FY2014 to the Secretary, acting through the Assistant Secretary for Aging, to expand state aging and disability resource centers.

(Sec. 2406) Expresses the sense of the Senate that: (1) during the 111th session of Congress, Congress should address long-term services and supports in a comprehensive way that guarantees elderly and disabled individuals the care they need; and (2) long-term services and supports should be made available in the community in addition to institutions.

Subtitle F: Medicaid Prescription Drug Coverage - (Sec. 2501) Amends SSA title XIX (Medicaid) to: (1) increase the minimum rebate percentage for single source drugs and innovator multiple source drugs; (2) increase the rebate for other drugs; (3) require contracts with Medicaid managed care organizations to extend prescription drug rebates (discounts) to their enrollees; (4) provide an additional rebate for new formulations of existing drugs; and (5) set a maximum rebate amount.

(Sec. 2502) Eliminates the exclusion from Medicaid coverage of, thereby extending coverage to, certain drugs used to promote smoking cessation, as well as barbiturates and benzodiazepines.

(Sec. 2503) Revises requirements with respect to pharmacy reimbursements.

Subtitle G: Medicaid Disproportionate Share Hospital (DSH) Payments - (Sec. 2551, as modified by Sec. 10201) Reduces state disproportionate share hospital (DSH) allotments, except for Hawaii, by 50% or 35% once a state's uninsured rate decreases by 45%, depending on whether they have spent at least or more than 99.9% of their allotments on average during FY2004-FY2008. Requires a reduction of only 25% or 17.5% for low DSH states, depending on whether they have spent at least or more than

99.9% of their allotments on average during FY2004-FY2008. Prescribes allotment reduction requirements for subsequent fiscal years.

Revises DSH allotments for Hawaii for the last three quarters of FY2012 and for FY2013 and succeeding fiscal years.

Subtitle H: Improved Coordination for Dual Eligible Beneficiaries - (Sec. 2601) Declares that any Medicaid waiver for individuals dually eligible for both Medicaid and Medicare may be conducted for a period of five years, with a five-year extension, upon state request, unless the Secretary determines otherwise for specified reasons.

(Sec. 2602) Directs the Secretary to establish a Federal Coordinated Health Care Office to bring together officers and employees of the Medicare and Medicaid programs at the Centers for Medicare and Medicaid Services (CMS) to: (1) integrate Medicaid and Medicare benefits more effectively; and (2) improve the coordination between the federal government and states for dual eligible individuals to ensure that they get full access to the items and services to which they are entitled.

Subtitle I: Improving the Quality of Medicaid for Patients and Providers - (Sec. 2701) Amends SSA title XI, as modified by CHIPRA, to direct the Secretary to: (1) identify and publish a recommended core set of adult health quality measures for Medicaid eligible adults; and (2) establish a Medicaid Quality Measurement Program.

(Sec. 2702) Requires the Secretary to identify current state practices that prohibit payment for health care-acquired conditions and to incorporate them, or elements of them, which are appropriate for application in regulations to the Medicaid program. Requires such regulations to prohibit payments to states for any amounts expended for providing medical assistance for specified health care-acquired conditions.

(Sec. 2703) Gives states the option to provide coordinated care through a health home for individuals with chronic conditions. Authorizes the Secretary to award planning grants to states to develop a state plan amendment to that effect.

(Sec. 2704) Directs the Secretary to establish a demonstration project to evaluate the use of bundled payments for the provision of integrated care for a Medicaid beneficiary: (1) with respect to an episode of care that includes a hospitalization; and (2) for concurrent physicians services provided during a hospitalization.

(Sec. 2705) Requires the Secretary to establish a Medicaid Global Payment System Demonstration Project under which a participating state shall adjust payments made to an eligible safety net hospital or network from a fee-for-service payment structure to a global capitated payment model. Authorizes appropriations.

(Sec. 2706) Directs the Secretary to establish the Pediatric Accountable Care Organization Demonstration Project to authorize a participating state to allow pediatric medical providers meeting specified requirements to be recognized as an accountable

care organization for the purpose of receiving specified incentive payments. Authorizes appropriations.

(Sec. 2707) Requires the Secretary to establish a three-year Medicaid emergency psychiatric demonstration project. Makes appropriations for FY2011.

Subtitle J: Improvements to the Medicaid and CHIP Payment and Access Commission (MACPAC) - (Sec. 2801) Revises requirements with respect to the Medicaid and CHIP Payment and Access Commission (MACPAC) and the Medicare Payment Advisory Commission (MEDPAC), including those for MACPAC membership, topics to be reviewed, and MEDPAC review of Medicaid trends in spending, utilization, and financial performance.

Requires MACPAC and MEDPAC to consult with one another on related issues.

Makes appropriations to MACPAC for FY2010.

Subtitle K: Protections for American Indians and Alaska Natives - (Sec. 2901) Sets forth special rules relating to Indians.

Declares that health programs operated by the Indian Health Service (IHS), Indian tribes, tribal organizations, and Urban Indian organizations shall be the payer of last resort for services they provide to eligible individuals.

Makes such organizations Express Lane agencies for determining Medicaid and CHIP eligibility.

(Sec. 2902) Makes permanent the requirement that the Secretary reimburse certain Indian hospitals and clinics for all Medicare part B services.

Subtitle L: Maternal and Child Health Services - (Sec. 2951) Amends SSA title V (Maternal and Child Health Services) to direct the Secretary to make grants to eligible entities for early childhood home visitation programs. Makes appropriations for FY2010-FY2014.

(Sec. 2952) Encourages the Secretary to continue activities on postpartum depression or postpartum psychosis, including research to expand the understanding of their causes and treatment.

Authorizes the Secretary to make grants to eligible entities for projects to establish, operate, and coordinate effective and cost-efficient systems for the delivery of essential services to individuals with or at risk for postpartum conditions and their families. Authorizes appropriations for FY2010-FY2012.

(Sec. 2953, as modified by Sec. 10201) Directs the Secretary to allot funds to states to award grants to local organizations and other specified entities to carry out personal responsibility education programs to educate adolescents on both abstinence and contraception for the prevention of pregnancy and sexually transmitted infections, as

well as on certain adulthood preparation subjects. Makes appropriations for FY2010-FY2014.

(Sec. 2954) Makes appropriations for FY2010-FY2014 for abstinence education.

(Sec. 2955) Requires the case review system for children aging out of foster care and independent living programs to include information about the importance of having a health care power of attorney in transition planning.

Title 3

Improving the Quality and Efficiency of Healthcare

Subtitle A: Transforming the Health Care Delivery System - Part I: Linking Payment to Quality Outcomes under the Medicare Program - (Sec. 3001) Amends SSA title XVIII (Medicare) to direct the Secretary to establish a hospital value-based purchasing program under which value-based incentive payments are made in a fiscal year to hospitals that meet specified performance standards for a certain performance period.

Directs the Secretary to establish value-based purchasing demonstration programs for: (1) inpatient critical access hospital services; and (2) hospitals excluded from the program because of insufficient numbers of measures and cases.

(Sec. 3002) Extends through 2013 the authority for incentive payments under the physician quality reporting system. Prescribes an incentive (penalty) for providers who do not report quality measures satisfactorily, beginning in 2015.

Requires the Secretary to integrate reporting on quality measures with reporting requirements for the meaningful use of electronic health records.

(Sec. 3003) Requires specified new types of reports and data analysis under the physician feedback program.

(Sec. 3004) Requires long-term care hospitals, inpatient rehabilitation hospitals, and hospices, starting in rate year 2014, to submit data on specified quality measures. Requires reduction of the annual update of entities which do not comply.

(Sec. 3005) Directs the Secretary, starting FY2014, to establish quality reporting programs for inpatient cancer hospitals exempt from the prospective payment system.

(Sec. 3006, as modified by Sec. 10301) Directs the Secretary to develop a plan to implement value-based purchasing programs for Medicare payments for skilled nursing facilities (SNFs), home health agencies, and ambulatory surgical centers.

(Sec. 3007) Directs the Secretary to establish a value-based payment modifier, under the physician fee schedule, based upon the quality of care furnished compared to cost.

(Sec. 3008) Subjects hospitals to a penalty adjustment to hospital payments for high rates of hospital acquired conditions.

Part II: National Strategy to Improve Health Care Quality - (Sec. 3011, as modified by Sec. 10302) Amends the Public Health Service Act to direct the Secretary, through a transparent collaborative process, to establish a National Strategy for Quality Improvement in health care services, patient health outcomes, and population health, taking into consideration certain limitations on the use of comparative effectiveness data.

(Sec. 3012) Directs the President to convene an Interagency Working Group on Health Care Quality.

(Sec. 3013, as modified by Sec. 10303) Directs the Secretary, at least triennially, to identify gaps where no quality measures exist as well as existing quality measures that need improvement, updating, or expansion, consistent with the national strategy for use in federal health programs.

Directs the Secretary to award grants, contracts, or intergovernmental agreements to eligible entities for purposes of developing, improving, updating, or expanding such quality measures.

Requires the Secretary to develop and update periodically provider-level outcome measures for hospitals and physicians, as well as other appropriate providers.

(Sec. 3014, as modified by Sec. 10304) Requires the convening of multi-stakeholder groups to provide input into the selection of quality and efficiency measures.

(Sec. 3015, as modified by Sec. 10305) Directs the Secretary to: (1) establish an overall strategic framework to carry out the public reporting of performance information; and (2) collect and aggregate consistent data on quality and resource use measures from information systems used to support health care delivery. Authorizes the Secretary to award grants for such purpose.

Directs the Secretary to make available to the public, through standardized Internet websites, performance information summarizing data on quality measures.

Part III: Encouraging Development of New Patient Care Models - (Sec. 3021, as modified by Sec. 10306) Creates within CMS a Center for Medicare and Medicaid Innovation to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to individuals. Makes appropriations for FY2010-FY2019.

(Sec. 3022, as modified by Sec. 10307) Directs the Secretary to establish a shared savings program that: (1) promotes accountability for a patient population; (2) coordinates items and services under Medicare parts A and B; and (3) encourages

investment in infrastructure and redesigned care processes for high quality and efficient service delivery.

(Sec. 3023, as modified by Sec. 10308) Directs the Secretary to establish a pilot program for integrated care (involving payment bundling) during an episode of care provided to an applicable beneficiary around a hospitalization in order to improve the coordination, quality, and efficiency of health care services.

(Sec. 3024) Directs the Secretary to conduct a demonstration program to test a payment incentive and service delivery model that utilizes physician and nurse practitioner directed home-based primary care teams designed to reduce expenditures and improve health outcomes in the provision of items and services to applicable beneficiaries.

(Sec. 3025, as modified by Sec. 10309) Requires the Secretary to establish a hospital readmissions reduction program involving certain payment adjustments, effective for discharges on or after October 1, 2012, for certain potentially preventable Medicare inpatient hospital readmissions.

Directs the Secretary to make available a program for hospitals with a high severity adjusted readmission rate to improve their readmission rates through the use of patient safety organizations.

(Sec. 3026) Directs the Secretary to establish a Community-Based Care Transitions Program which provides funding to eligible entities that furnish improved care transitions services to high-risk Medicare beneficiaries.

(Sec. 3027) Amends the Deficit Reduction Act of 2005 to extend certain Gainsharing Demonstration Projects through FY2011.

Subtitle B: Improving Medicare for Patients and Providers - Part 1: Ensuring Beneficiary Access to Physician Care and Other Services - (Sec. 3101, deleted by section 10310) (Sec. 3102) Extends through calendar 2010 the floor on geographic indexing adjustments to the work portion of the physician fee schedule. Revises requirements for calculation of the practice expense portion of the geographic adjustment factor applied in a fee schedule area for services furnished in 2010 or 2011. Directs the Secretary to analyze current methods of establishing practice expense geographic adjustments and make appropriate further adjustments (a new methodology) to such adjustments for 2010 and subsequent years.

(Sec. 3103) Extends the process allowing exceptions to limitations on medically necessary therapy caps through December 31, 2010.

(Sec. 3104) Amends the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 to extend until January 1, 2010, an exception to a payment rule that permits laboratories to receive direct Medicare reimbursement when providing the

technical component of certain physician pathology services that had been outsourced by certain (rural) hospitals.

(Sec. 3105, as modified by Sec. 10311) Amends SSA title XVIII (Medicare) to extend the bonus and increased payments for ground ambulance services until January 1, 2011.

Amends the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) to extend the payment of certain urban air ambulance services until January 1, 2011.

(Sec. 3106, as modified by Sec. 10312) Amends the Medicare, Medicaid, and SCHIP Extension Act of 2007, as modified by the American Recovery and Reinvestment Act, to extend for two years: (1) certain payment rules for long-term care hospital services; and (2) a certain moratorium on the establishment of certain hospitals and facilities.

(Sec. 3107) Amends MIPPA to extend the physician fee schedule mental health add-on payment provision through December 31, 2010.

(Sec. 3108) Allows a physician assistant who does not have an employment relationship with a SNF, but who is working in collaboration with a physician, to certify the need for post-hospital extended care services for Medicare payment purposes.

(Sec. 3109) Amends title XVIII, as modified by MIPPA, to exempt certain pharmacies from accreditation requirements until the Secretary develops pharmacy-specific standards.

(Sec. 3110) Creates a special part B enrollment period for military retirees, their spouses (including widows/ widowers), and dependent children, who are otherwise eligible for TRICARE (the health care plan under the Department of Defense [DOD]) and entitled to Medicare part A (Hospital Insurance) based on disability or end stage renal disease, but who have declined Medicare part B (Supplementary Medical Insurance).

(Sec. 3111) Sets payments for dual-energy x-ray absorptiometry services in 2010 and 2011 at 70% of the 2006 reimbursement rates. Directs the Secretary to arrange with the Institute of Medicine of the National Academies to study and report to the Secretary and Congress on the ramifications of Medicare reimbursement reductions for such services on beneficiary access to bone mass measurement benefits.

(Sec. 3112) Eliminates funding in the Medicare Improvement Fund FY2014.

(Sec. 3113) Directs the Secretary to conduct a demonstration project under Medicare part B of separate payments for complex diagnostic laboratory tests provided to individuals.

(Sec. 3114) Increases from 65% to 100% of the fee schedule amount provided for the same service performed by a physician the fee schedule for certified-midwife services provided on or after January 1, 2011.

Part II: Rural Protections - (Sec. 3121) Extends through 2010 hold harmless provisions under the prospective payment system for hospital outpatient department services.

Removes the 100-bed limitation for sole community hospitals so all such hospitals receive an 85% increase in the payment difference in 2010.

(Sec. 3122) Amends the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, as modified by other federal law, to extend from July 1, 2010, until July 1, 2011, the reasonable cost reimbursement for clinical diagnostic laboratory service for qualifying rural hospitals with under 50 beds.

(Sec. 3123, as modified by Sec. 10313) Extends the Rural Community Hospital Demonstration Program for five additional years. Expands the maximum number of participating hospitals to 30, and to 20 the number of demonstration states with low population densities.

(Sec. 3124) Extends the Medicare-dependent Hospital Program through FY2012.

(Sec. 3125, as modified by Sec. 10314) Modifies the Medicare inpatient hospital payment adjustment for low-volume hospitals for FY2011-FY2012.

(Sec. 3126) Revises requirements for the Demonstration Project on Community Health Integration Models in Certain Rural Counties to allow additional counties as well as physicians to participate.

(Sec. 3127) Directs MEDPAC to study and report to Congress on the adequacy of payments for items and services furnished by service providers and suppliers in rural areas under the Medicare program.

(Sec. 3128) Allows a critical access hospital to continue to be eligible to receive 101% of reasonable costs for providing: (1) outpatient care regardless of the eligible billing method such hospital uses; and (2) qualifying ambulance services.

(Sec. 3129) Extends through FY2012 FLEX grants under the Medicare Rural Hospital Flexibility Program. Allows the use of grant funding to assist small rural hospitals to participate in delivery system reforms.

Part III: Improving Payment Accuracy - (Sec. 3131, as modified by Sec. 10315) Requires the Secretary, starting in 2014, to rebase home health payments by an appropriate percentage, among other things, to reflect the number, mix, and level of intensity of home health services in an episode, and the average cost of providing care.

Directs the Secretary to study and report to Congress on home health agency costs involved with providing ongoing access to care to low-income Medicare beneficiaries or beneficiaries in medically underserved areas, and in treating beneficiaries with varying levels of severity of illness. Authorizes a Medicare demonstration project based on the study results.

(Sec. 3132) Requires the Secretary, by January 1, 2011, to begin collecting additional data and information needed to revise payments for hospice care.

Directs the Secretary, not earlier than October 1, 2013, to implement, by regulation, budget neutral revisions to the methodology for determining hospice payments for routine home care and other services, which may include per diem payments reflecting changes in resource intensity in providing such care and services during the course of an entire episode of hospice care.

Requires the Secretary to impose new requirements on hospice providers participating in Medicare, including requirements for: (1) a hospice physician or nurse practitioner to have a face-to-face encounter with the individual regarding eligibility and recertification; and (2) a medical review of any stays exceeding 180 days, where the number of such cases exceeds a specified percentage of them for all hospice programs.

(Sec. 3133, as modified by Sec. 10316) Specifies reductions to Medicare DSH payments for FY2015 and ensuing fiscal years, especially to subsection (d) hospitals, to reflect lower uncompensated care costs relative to increases in the number of insured. (Generally, a subsection [d] hospital is an acute care hospital, particularly one that receives payments under Medicare's inpatient prospective payment system when providing covered inpatient services to eligible beneficiaries.)

(Sec. 3134) Directs the Secretary periodically to identify physician services as being potentially misvalued and make appropriate adjustments to the relative values of such services under the Medicare physician fee schedule.

(Sec. 3135) Increases the presumed utilization rate for calculating the payment for advanced imaging equipment other than low-tech imaging such as ultrasound, x-rays and EKGs.

Increases the technical component payment "discount" for sequential imaging services on contiguous body parts during the same visit.

(Sec. 3136) Restricts the lump-sum payment option for new or replacement chairs to the complex, rehabilitative power-driven wheelchairs only. Eliminates the lump-sum payment option for all other power-driven wheelchairs. Makes the rental payment for power-driven wheelchairs 15% of the purchase price for each of the first three months (instead of 10%), and 6% of the purchase price for each of the remaining 10 months of the rental period (instead of 7.5%).

(Sec. 3137, as modified by Sec. 10317) Amends the Tax Relief and Health Care Act of 2006, as modified by other federal law, to extend "Section 508" hospital reclassifications until September 30, 2010, with a special rule for FY2010. ("Section 508" refers to Section 508 of the Medicare Modernization Act of 2003, which allows the temporary reclassification of a hospital with a low Medicare area wage index, for reimbursement

purposes, to a nearby location with a higher Medicare area wage index, so that the "Section 508 hospital" will receive the higher Medicare reimbursement rate.)

Directs the Secretary to report to Congress a plan to reform the hospital wage index system.

(Sec. 3138) Requires the Secretary to determine if the outpatient costs incurred by inpatient prospective payment system-exempt cancer hospitals, including those for drugs and biologicals, with respect to Medicare ambulatory payment classification groups, exceed those costs incurred by other hospitals reimbursed under the outpatient prospective payment system (OPPS). Requires the Secretary, if this is so, to provide for an appropriate OPPS adjustment to reflect such higher costs for services furnished on or after January 1, 2011.

(Sec. 3139) Allows a biosimilar biological product to be reimbursed at 6% of the average sales price of the brand biological product.

(Sec. 3140) Directs the Secretary to establish a Medicare Hospice Concurrent Care demonstration program under which Medicare beneficiaries are furnished, during the same period, hospice care and any other Medicare items or services from Medicare funds otherwise paid to such hospice programs.

(Sec. 3141) Requires application of the budget neutrality requirement associated with the effect of the imputed rural floor on the area wage index under the Balanced Budget Act of 1997 through a uniform national, instead of state-by-state, adjustment to the area hospital wage index floor.

(Sec. 3142) Directs the Secretary to study and report to Congress on the need for an additional payment for urban Medicare-dependent hospitals for inpatient hospital services under Medicare.

(Sec. 3143) Declares that nothing in this Act shall result in the reduction of guaranteed home health benefits under the Medicare program.

Subtitle C: Provisions Relating to Part C - (Sec. 3201, as modified by Sec. 10318) Bases the MedicareAdvantage (MA) benchmark on the average of the bids from MA plans in each market.

Revises the formula for calculating the annual Medicare+Choice capitation rate to reduce the national MA per capita Medicare+Choice growth percentage used to increase benchmarks in 2011.

Increases the monthly MA plan rebates from 75% to 100% of the average per capita savings.

Requires that bid information which MA plans are required to submit to the Secretary be certified by a member of the American Academy of Actuaries and meet actuarial guidelines and rules established by the Secretary.

Directs the Secretary, acting through the CMS Chief Actuary, to establish actuarial guidelines for the submission of bid information and bidding rules that are appropriate to ensure accurate bids and fair competition among MA plans.

Directs the Secretary to: (1) establish new MA payment areas for urban areas based on the Core Based Statistical Area; and (2) make monthly care coordination and management performance bonus payments, quality performance bonus payments, and quality bonuses for new and low enrollment MA plans, to MA plans that meet certain criteria.

Directs the Secretary to provide transitional rebates for the provision of extra benefits to enrollees.

(Sec. 3202) Prohibits MA plans from charging beneficiaries cost sharing for chemotherapy administration services, renal dialysis services, or skilled nursing care that is greater than what is charged under the traditional fee-for-service program.

Requires MA plans to apply the full amount of rebates, bonuses, and supplemental premiums according to the following order: (1) reduction of cost sharing, (2) coverage of preventive care and wellness benefits, and (3) other benefits not covered under the original Medicare fee-for-service program.

(Sec. 3203) Requires the Secretary to analyze the differences in coding patterns between MA and the original Medicare fee-for-service programs. Authorizes the Secretary to incorporate the results of the analysis into risk scores for 2014 and subsequent years.

(Sec. 3204) Allows beneficiaries to disenroll from an MA plan and return to the traditional Medicare fee-for-service program from January 1 to March 15 of each year.

Revises requirements for annual beneficiary election periods.

(Sec. 3205) Amends SSA title XVIII (Medicare), as modified by MIPPA, to extend special needs plan (SNP) authority through December 31, 2013.

Authorizes the Secretary to establish a frailty payment adjustment under PACE payment rules for fully-integrated, dual-eligible SNPs.

Extends authority through calendar 2012 for SNPs that do not have contracts with state Medicaid programs to continue to operate, but not to expand their service areas.

Directs the Secretary to require an MA organization offering a specialized MA plan for special needs individuals to be approved by the National Committee for Quality Assurance.

Requires the Secretary to use a risk score reflecting the known underlying risk profile and chronic health status of similar individuals, instead of the default risk score, for new enrollees in MA plans that are not specialized MA SNPs.

(Sec. 3206) Extends through calendar 2012 the length of time reasonable cost plans may continue operating regardless of any other MA plans serving the area.

(Sec. 3208) Creates a new type of MA plan called an MA Senior Housing Facility Plan, which would be allowed to limit its service area to a senior housing facility (continuing care retirement community) within a geographic area.

(Sec. 3209) Declares that the Secretary is not required to accept any or every bid submitted by an MA plan or Medicare part D prescription drug plan that proposes to increase significantly any beneficiary cost sharing or decrease benefits offered.

(Sec. 3210) Directs the Secretary to request the National Association of Insurance Commissioners (NAIC) to develop new standards for certain Medigap plans.

Subtitle D: Medicare Part D Improvements for Prescription Drug Plans and MA-PD Plans - (Sec. 3301) Amends Medicare part D (Voluntary Prescription Drug Benefit Program) to establish conditions for the availability of coverage for part D drugs. Requires the manufacturer to participate in the Medicare coverage gap discount program. Directs the Secretary to establish such a program.

(Sec. 3302) Excludes the MA rebate amounts and quality bonus payments from calculation of the regional low-income subsidy benchmark premium for MA monthly prescription drug beneficiaries.

(Sec. 3303) Directs the Secretary to permit a prescription drug plan or an MA-PD plan to waive the monthly beneficiary premium for a subsidy eligible individual if the amount of such premium is *de minimis*. Provides that, if such premium is waived, the Secretary shall not reassign subsidy eligible individuals enrolled in the plan to other plans based on the fact that the monthly beneficiary premium under the plan was greater than the low-income benchmark premium amount.

Authorizes the Secretary to auto-enroll subsidy eligible individuals in plans that waive *de minimis* premiums.

(Sec. 3304) Sets forth a special rule for widows and widowers regarding eligibility for low-income assistance. Allows the surviving spouse of an eligible couple to delay redetermination of eligibility for one year after the death of a spouse.

(Sec. 3305) Directs the Secretary, in the case of a subsidy eligible individual enrolled in one prescription drug plan but subsequently reassigned by the Secretary to a new prescription drug plan, to provide the individual with: (1) information on formulary differences between the individual's former plan and the new plan with respect to the individual's drug regimens; and (2) a description of the individual's right to request a coverage determination, exception, or reconsideration, bring an appeal, or resolve a grievance.

(Sec. 3306) Amends MIPPA to provide additional funding for FY2010-FY2012 for outreach and education activities related to specified Medicare low-income assistance programs.

(Sec. 3307) Authorizes the Secretary to identify classes of clinical concern through rulemaking, including anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection. Requires prescription drug plan sponsors to include all drugs in these classes in their formularies.

(Sec. 3308) Requires part D enrollees who exceed certain income thresholds to pay higher premiums. Revises the current authority of the IRS to disclose income information to the Social Security Administration for purposes of adjusting the part B subsidy.

(Sec. 3309) Eliminates cost sharing for certain dual eligible individuals receiving care under a home and community-based waiver program who would otherwise require institutional care.

(Sec. 3310) Directs the Secretary to require sponsors of prescription drug plans to utilize specific, uniform techniques for dispensing covered part D drugs to enrollees who reside in an long-term care facility in order to reduce waste associated with 30-day refills.

(Sec. 3311) Directs the Secretary to develop and maintain an easy to use complaint system to collect and maintain information on MA-PD plan and prescription drug complaints received by the Secretary until the complaint is resolved.

(Sec. 3312) Requires a prescription drug plan sponsor to: (1) use a single, uniform exceptions and appeals process for determination of a plan enrollee's prescription drug coverage; and (2) provide instant access to this process through a toll-free telephone number and an Internet website.

(Sec. 3313) Requires the HHS Inspector General to study and report to Congress on the inclusion in formularies of: (1) drugs commonly used by dual eligibles; and (2) prescription drug prices under Medicare part D and Medicaid.

(Sec. 3314) Allows the costs incurred by AIDS drug assistance programs and by IHS in providing prescription drugs to count toward the annual out-of-pocket threshold.

(Sec. 3315) Increases by $500 the 2010 standard initial coverage limit (thus decreasing the time that a part D enrollee would be in the coverage gap).

Subtitle E: Ensuring Medicare Sustainability - (Sec. 3401, as modified by Sec. 10319 and Sec. 10322) Revises certain market basket updates and incorporates a full productivity adjustment into any updates that do not already incorporate such adjustments, including inpatient hospitals, home health providers, nursing homes,

hospice providers, inpatient psychiatric facilities, long-term care hospitals, inpatient rehabilitation facilities, and Part B providers.

Establishes a quality measure reporting program for psychiatric hospitals beginning in FY2014.

(Sec. 3402) Revises requirements for reduction of the Medicare part B premium subsidy based on income. Maintains the current 2010 income thresholds for the period of 2011 through 2019.

(Sec. 3403, as modified by Sec. 10320) Establishes an Independent Payment Advisory Board to develop and submit detailed proposals to reduce the per capita rate of growth in Medicare spending to the President for Congress to consider. Establishes a consumer advisory council to advise the Board on the impact of payment policies under this title on consumers.

Subtitle F: Health Care Quality Improvements - (Sec. 3501) Amends the Public Health Service Act to direct the Center for Quality Improvement and Patient Safety of the Agency for Healthcare Research and Quality (AHRQ) to conduct or support activities for best practices in the delivery of health care services and support research on the development of tools to facilitate adoption of best practices that improve the quality, safety, and efficiency of health care delivery services. Authorizes appropriations for FY2010-FY2014.

Requires the AHRQ Director, through the AHRQ Center for Quality Improvement and Patient Safety, to award grants or contracts to eligible entities to provide technical support or to implement models and practices identified in the research conducted by the Center.

(Sec. 3502, as modified by Sec. 10321) Directs the Secretary to establish a program to provide grants to or enter into contracts with eligible entities to establish community-based interdisciplinary, interprofessional teams to support primary care practices, including obstetrics and gynecology practices, within the hospital service areas served by the eligible entities.

(Sec. 3503) Directs the Secretary, acting through the Patient Safety Research Center, to establish a program to provide grants or contracts to eligible entities to implement medication management services provided by licensed pharmacists, as a collaborative multidisciplinary, inter-professional approach to the treatment of chronic diseases for targeted individuals, to improve the quality of care and reduce overall cost in the treatment of such disease.

(Sec. 3504) Directs the Secretary, acting through the Assistant Secretary for Preparedness and Response, to award at least four multiyear contracts or competitive grants to eligible entities to support pilot projects that design, implement, and evaluate

innovative models of regionalized, comprehensive, and accountable emergency care and trauma systems.

Requires the Secretary to support federal programs administered by the National Institutes of Health (NIH), the AHRQ, the Health Resources and Services Administration (HRSA), the CMS, and other agencies involved in improving the emergency care system to expand and accelerate research in emergency medical care systems and emergency medicine.

Directs the Secretary to support federal programs administered by the such agencies to coordinate and expand research in pediatric emergency medical care systems and pediatric emergency medicine.

Authorizes appropriations for FY2010-FY2014.

(Sec. 3505) Requires the Secretary to establish three programs to award grants to qualified public, nonprofit IHS, Indian tribal, and urban Indian trauma centers to: (1) assist in defraying substantial uncompensated care costs; (2) further the core missions of such trauma centers, including by addressing costs associated with patient stabilization and transfer; and (3) provide emergency relief to ensure the continued and future availability of trauma services. Authorizes appropriations for FY2010-FY2015.

Directs the Secretary to provide funding to states to enable them to award grants to eligible entities for trauma services. Authorizes appropriations for FY2010-FY2015.

(Sec. 3506) Directs the Secretary to: (1) establish a program to award grants or contracts to develop, update, and produce patient decision aids to assist health care providers and patients; (2) establish a program to provide for the phased-in development, implementation, and evaluation of shared decision making using patient decision aids to meet the objective of improving the understanding of patients of their medical treatment options; and (3) award grants for establishment and support of Shared Decisionmaking Resource Centers. Authorizes appropriations for FY2010 and subsequent fiscal years.

(Sec. 3507) Requires the Secretary, acting through the Commissioner of Food and Drugs, to determine whether the addition of quantitative summaries of the benefits and risks of prescription drugs in a standardized format to the promotional labeling or print advertising of such drugs would improve heath care decisionmaking by clinicians and patients and consumers.

(Sec. 3508) Authorizes the Secretary to award grants to eligible entities or consortia to carry out demonstration projects to develop and implement academic curricula that integrate quality improvement and patient safety in the clinical education of health professionals.

(Sec. 3509) Establishes an Office on Women's Health within the Office of the Secretary, the Office of the Director of the Centers for Disease Control and Prevention (CDC), the

Office of the AHRQ Director, the Office of the Administrator of HRSA, and the Office of the Commissioner of Food and Drugs.

Authorizes appropriations for FY2010-FY2014 for all such Offices on Women's Health.

(Sec. 3510) Extends from three years to four years the duration of a patient navigator grant.

Prohibits the Secretary from awarding such a grant unless the recipient entity provides assurances that patient navigators recruited, assigned, trained, or employed using grant funds meet minimum core proficiencies tailored for the main focus or intervention of the navigator involved.

Authorizes appropriations for FY2010-FY2015.

(Sec. 3511) Authorizes appropriations to carry out this title, except where otherwise provided in the title.

(Sec. 3512, as added by Sec. 10201) Directs the Comptroller General to study and report to Congress on whether the development, recognition, or implementation of any guideline or other standards under specified provisions of this Act would result in the establishment of a new cause of action or claim.

Subtitle G: Protecting and Improving Guaranteed Medicare Benefits - (Sec. 3601) Provides that nothing in this Act shall result in a reduction of guaranteed benefits under the Medicare program.

States that savings generated for the Medicare program under this Act shall extend the solvency of the Medicare trust funds, reduce Medicare premiums and other cost-sharing for beneficiaries, and improve or expand guaranteed Medicare benefits and protect access to Medicare providers.

(Sec. 3602) Declares that nothing in this Act shall result in the reduction or elimination of any benefits guaranteed by law to participants in MA plans.

Title IV

Prevention of Chronic Disease and Improving Public Health

Subtitle A: Modernizing Disease Prevention and Public Health Systems - (Sec. 4001, as modified by Sec. 10401) Requires the President to: (1) establish the National Prevention, Health Promotion and Public Health Council; (2) establish the Advisory Group on Prevention, Health Promotion, and Integrative and Public Health; and (3) appoint the Surgeon General as Chairperson of the Council in order to develop a national prevention, health promotion, and public health strategy.

Requires the Secretary and the Comptroller General to conduct periodic reviews and evaluations of every federal disease prevention and health promotion initiative, program, and agency.

(Sec. 4002, as modified by Sec. 10401) Establishes a Prevention and Public Health Fund to provide for expanded and sustained national investment in prevention and public health programs to improve health and help restrain the rate of growth in private and public sector health care costs. Authorizes appropriations and appropriates money to such Fund.

(Sec. 4003) Requires (currently, allows) the Director of AHRQ to convene the Preventive Services Task Force to review scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations for the health care community.

Requires the Director of CDC to convene an independent Community Preventive Services Task Force to review scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of community preventive interventions for the purpose of developing recommendations for individuals and organizations delivering populations-based services and other policy makers

(Sec. 4004, as modified by Sec. 10401) Requires the Secretary to provide for the planning and implementation of a national public-private partnership for a prevention and health promotion outreach and education campaign to raise public awareness of health improvement across the life span.

Requires the Secretary, acting through the Director of CDC, to: (1) establish and implement a national science-based media campaign on health promotion and disease prevention; and (2) enter into a contract for the development and operation of a federal website personalized prevention plan tool.

Subtitle B: Increasing Access to Clinical Preventive Services - (Sec. 4101, as modified by Sec. 10402) Requires the Secretary to establish a program to award grants to eligible entities to support the operation of school-based health centers.

(Sec. 4102) Requires the Secretary, acting through the Director of CDC, to carry out oral health activities, including: (1) establishing a national public education campaign that is focused on oral health care prevention and education; (2) awarding demonstration grants for research-based dental caries disease management activities; (3) awarding grants for the development of school-based dental sealant programs; and (4) entering into cooperative agreements with state, territorial, and Indian tribes or tribal organizations for oral health data collection and interpretation, a delivery system for oral health, and science-based programs to improve oral health.

Requires the Secretary to: (1) update and improve the Pregnancy Risk Assessment Monitoring System as it relates to oral health care; (2) develop oral health care components for inclusion in the National Health and Nutrition Examination Survey; and (3) ensure that the Medical Expenditures Panel Survey by AHRQ includes the verification of dental utilization, expenditure, and coverage findings through conduct of a look-back analysis.

(Sec. 4103, as modified by Sec. 10402) Amends SSA title XVIII (Medicare) to provide coverage of personalized prevention plan services, including a health risk assessment, for individuals. Prohibits cost-sharing for such services.

(Sec. 4104, as modified by Sec. 10406) Eliminates cost-sharing for certain preventive services recommended by the United States Preventive Services Task Force.

(Sec. 4105) Authorizes the Secretary to modify Medicare coverage of any preventive service consistent with the recommendations of such Task Force.

(Sec. 4106) Amends SSA title XIX (Medicaid) to provide Medicaid coverage of preventive services and approved vaccines. Increases the FMAP for such services and vaccines.

(Sec. 4107) Provides for Medicaid coverage of counseling and pharmacotherapy for cessation of tobacco use by pregnant women.

(Sec. 4108) Requires the Secretary to award grants to states to carry out initiatives to provide incentives to Medicaid beneficiaries who participate in programs to lower health risk and demonstrate changes in health risk and outcomes.

Subtitle C: Creating Healthier Communities - (Sec. 4201, as modified by Sec. 10403) Requires the Secretary, acting through the Director of CDC, to award grants to state and local governmental agencies and community-based organizations for the implementation, evaluation, and dissemination of evidence-based community preventive health activities in order to reduce chronic disease rates, prevent the development of secondary conditions, address health disparities, and develop a stronger evidence base of effective prevention programming.

(Sec. 4202) Requires the Secretary, acting through the Director of CDC, to award grants to state or local health departments and Indian tribes to carry out pilot programs to provide public health community interventions, screenings, and clinical referrals for individuals who are between 55 and 64 years of age.

Requires the Secretary to: (1) conduct an evaluation of community-based prevention and wellness programs and develop a plan for promoting healthy lifestyles and chronic disease self-management for Medicare beneficiaries; and (2) evaluate community prevention and wellness programs that have demonstrated potential to help Medicare beneficiaries reduce their risk of disease, disability, and injury by making healthy lifestyle choices.

(Sec. 4203) Amends the Rehabilitation Act of 1973 to require the Architectural and Transportation Barriers Compliance Board to promulgate standards setting forth the minimum technical criteria for medical diagnostic equipment used in medical settings to ensure that such equipment is accessible to, and usable by, individuals with accessibility needs.

(Sec. 4204) Authorizes the Secretary to negotiate and enter into contracts with vaccine manufacturers for the purchase and delivery of vaccines for adults. Allows a state to purchase additional quantities of adult vaccines from manufacturers at the applicable price negotiated by the Secretary. Requires the Secretary, acting through the Director of CDC, to establish a demonstration program to award grants to states to improve the provision of recommended immunizations for children and adults through the use of evidence-based, population-based interventions for high-risk populations.

Reauthorizes appropriations for preventive health service programs to immunize children and adults against vaccine-preventable diseases without charge.

Requires the Comptroller General to study the ability of Medicare beneficiaries who are 65 years or older to access routinely recommended vaccines covered under the prescription drug program since its establishment.

(Sec. 4205) Amends the Federal Food, Drug, and Cosmetic Act to require the labeling of a food item offered for sale in a retail food establishment that is part of a chain with 20 or more locations under the same name to disclose on the menu and menu board: (1) the number of calories contained in the standard menu item; (2) the suggested daily caloric intake; and (3) the availability on the premises and upon request of specified additional nutrient information. Requires self-service facilities to place adjacent to each food offered a sign that lists calories per displayed food item or per serving. Requires vending machine operators who operate 20 or more vending machines to provide a sign disclosing the number of calories contained in each article of food.

(Sec. 4206) Requires the Secretary to establish a pilot program to test the impact of providing at-risk populations who utilize community health centers an individualized wellness plan designed to reduce risk factors for preventable conditions as identified by a comprehensive risk-factor assessment.

(Sec. 4207) Amends the Fair Labor Standards Act of 1938 to require employers to provide a reasonable break time and a suitable place, other than a bathroom, for an employee to express breast milk for her nursing child. Excludes an employer with fewer than 50 employees if such requirements would impose an undue hardship.

Subtitle D: Support for Prevention and Public Health Innovation - (Sec. 4301) Requires the Secretary, acting through the Director of CDC, to provide funding for research in the area of public health services and systems.

(Sec. 4302) Requires the Secretary to ensure that any federally conduced or supported health care or public health program, activity, or survey collects and reports specified demographic data regarding health disparities.

Requires the Secretary, acting through the National Coordinator for Health Information Technology, to develop: (1) national standards for the management of data collected; and (2) interoperability and security systems for data management.

(Sec. 4303, as modified by Sec. 10404) Requires the Director of CDC to: (1) provide employers with technical assistance, consultation, tools, and other resources in evaluating employer-based wellness programs; and (2) build evaluation capacity among workplace staff by training employers on how to evaluate such wellness programs and ensuring that evaluation resources, technical assistance, and consultation are available.

Requires the Director of CDC to conduct a national worksite health policies and programs survey to assess employer-based health policies and programs.

(Sec. 4304) Requires the Secretary, acting through the Director of CDC, to establish an Epidemiology and Laboratory Capacity Grant Program to award grants to assist public health agencies in improving surveillance for, and response to, infectious diseases and other conditions of public health importance.

(Sec. 4305) Requires the Secretary to: (1) enter into an agreement with the Institute of Medicine to convene a Conference on Pain, the purposes of which shall include to increase the recognition of pain as a significant public health problem in the United States; and (2) establish the Interagency Pain Research Coordinating Committee.

(Sec. 4306) Appropriates funds to carry out childhood obesity demonstration projects.

Subtitle E: Miscellaneous Provisions - (Sec. 4402) Requires the Secretary to evaluate programs to determine whether existing federal health and wellness initiatives are effective in achieving their stated goals.

Title 5

Healthcare Workforce

Title V: Health Care Workforce - Subtitle A: Purpose and Definitions - (Sec. 5001) Declares that the purpose of this title is to improve access to and the delivery of health care services for all individuals, particularly low-income, underserved, uninsured, minority, health disparity, and rural populations.

Subtitle B: Innovations in the Health Care Workforce - (Sec. 5101, as modified by Sec. 10501) Establishes a National Health Care Workforce Commission to: (1) review current and projected health care workforce supply and demand; and (2) make recommendations to Congress and the Administration concerning national health care workforce priorities, goals, and policies.

(Sec. 5102) Establishes a health care workforce development grant program.

(Sec. 5103) Requires the Secretary to establish the National Center for Health Care Workforce Analysis to provide for the development of information describing and analyzing the health care workforce and workforce related issues. Transfers the responsibilities and resources of the National Center for Health Workforce Analysis to the Center created under this section.

(Sec. 5104, as added by Sec. 10501) Establishes the Interagency Access to Health Care in Alaska Task Force to: (1) assess access to health care for beneficiaries of federal health care systems in Alaska; and (2) develop a strategy to improve delivery to such beneficiaries.

Subtitle C: Increasing the Supply of the Health Care Workforce - (Sec. 5201) Revises student loan repayment provisions related to the length of service requirement for the primary health care loan repayment program.

(Sec. 5202) Increases maximum amount of loans made by schools of nursing to students.

(Sec. 5203) Directs the Secretary to establish and carry out a pediatric specialty loan repayment program.

(Sec. 5204) Requires the Secretary to establish the Public Health Workforce Loan Repayment Program to assure an adequate supply of public health professionals to eliminate critical public health workforce shortages in federal, state, local, and tribal public health agencies.

(Sec. 5205) Amends the Higher Education Act of 1965 to expand student loan forgiveness to include allied health professionals employed in public health agencies.

(Sec. 5206) Includes public health workforce loan repayment programs as permitted activities under a grant program to increase the number of individuals in the public health workforce.

Authorizes the Secretary to provide for scholarships for mid-career professionals in the public health and allied health workforce to receive additional training in the field of public health and allied health.

(Sec. 5207) Authorizes appropriations for the National Health Service Corps Scholarship Program and the National Health Service Corps Loan Repayment Program.

(Sec. 5208) Requires the Secretary to award grants for the cost of the operation of nurse-managed health clinics.

(Sec. 5209) Eliminates the cap on the number of commissioned officers in the Public Health Service Regular Corps.

(Sec. 5210) Revises the Regular Corps and the Reserve Corps (renamed the Ready Reserve Corps) in the Public Health Service. Sets forth the uses of the Ready Reserve Corps.

Subtitle D: Enhancing Health Care Workforce Education and Training - (Sec. 5301) Sets forth provisions providing for health care professional training programs.

(Sec. 5302) Requires the Secretary to award grants for new training opportunities for direct care workers who are employed in long-term care settings.

(Sec. 5303) Sets forth provisions providing for dentistry professional training programs.

(Sec. 5304) Authorizes the Secretary to award grants for demonstration programs to establish training programs for alternative dental health care providers in order to increase access to dental health services in rural and other underserved communities.

(Sec. 5305) Requires the Secretary to award grants or contracts to entities that operate a geriatric education center to offer short-term, intensive courses that focus on geriatrics, chronic care management, and long-term care.

Expands geriatric faculty fellowship programs to make dentists eligible.

Reauthorizes and revises the geriatric education programs to allow grant funds to be used for the establishment of traineeships for individuals who are preparing for advanced education nursing degrees in areas that specialize in the care of elderly populations.

(Sec. 5306) Authorizes the Secretary to award grants to institutions of higher education to support the recruitment of students for, and education and clinical experience of the students in, social work programs, psychology programs, child and adolescent mental health, and training of paraprofessional child and adolescent mental health workers.

(Sec. 5307) Authorizes the Secretary, acting through the Administrator of HRSA, to award grants, contracts, or cooperative agreements for the development, evaluation, and dissemination of research, demonstration projects, and model curricula for health professions training in cultural competency, prevention, public health proficiency, reducing health disparities, and working with individuals with disabilities.

(Sec. 5308) Requires nurse-midwifery programs, in order to be eligible for advanced education nursing grants, to have as their objective the education of midwives and to be accredited by the American College of Nurse-Midwives Accreditation Commission for Midwifery Education.

(Sec. 5309) Authorizes the Secretary to award grants or enter into contracts to enhance the nursing workforce by initiating and maintaining nurse retention programs.

(Sec. 5310) Makes nurse faculty at an accredited school of nursing eligible for the nursing education loan repayment program.

(Sec. 5311) Revises the nurse faculty loan repayment program, including to increase the amount of such loans.

Authorizes the Secretary, acting through the Administrator of HRSA, to enter into an agreement for the repayment of education loans in exchange for service as a member of a faculty at an accredited school of nursing.

(Sec. 5312) Authorizes appropriations for carrying out nursing workforce programs.

(Sec. 5313, as modified by Sec. 10501) Requires the Director of CDC to award grants to eligible entities to promote positive health behaviors and outcomes for populations in medically underserved communities through the use of community health workers.

(Sec. 5314) Authorizes the Secretary to carry out activities to address documented workforce shortages in state and local health departments in the critical areas of applied public health epidemiology and public health laboratory science and informatics.

(Sec. 5315) Authorizes the establishment of the United States Public Health Sciences Track, which is authorized to award advanced degrees in public health, epidemiology, and emergency preparedness and response.

Directs the Surgeon General to develop: (1) an integrated longitudinal plan for health professions continuing education; and (2) faculty development programs and curricula in decentralized venues of health care to balance urban, tertiary, and inpatient venues.

(Sec. 5316, as added by Sec. 10501) Requires the Secretary to establish a training demonstration program for family nurse practitioners to employ and provide one-year training for nurse practitioners serving as primary care providers in federally qualified health centers or nurse-managed health centers.

Subtitle E: Supporting the Existing Health Care Workforce - (Sec. 5401) Revises the allocation of funds to assist schools in supporting programs of excellence in health professions education for underrepresented minority individuals and schools designated as centers of excellence.

(Sec. 5402, as modified by Sec. 10501) Makes schools offering physician assistant education programs eligible for loan repayment for health profession faculty. Increases the amount of loan repayment for such program.

Authorizes appropriations for: (1) scholarships for disadvantaged students attending health professions or nursing schools; (2) loan repayment for health professions faculty; and (3) grants to health professions school to assist individuals from disadvantaged backgrounds.

(Sec. 5403) Requires the Secretary to: (1) make awards for area health education center programs; and (2) provide for timely dissemination of research findings using relevant resources.

(Sec. 5404) Makes revisions to the grant program to increase nursing education opportunities for individuals from disadvantaged backgrounds to include providing: (1) stipends for diploma or associate degree nurses to enter a bridge or degree completion program; (2) student scholarships or stipends for accelerated nursing degree programs; and (3) advanced education preparation.

(Sec. 5405, as modified by Sec. 10501) Requires the Secretary, acting through the Director of AHRQ, to establish a Primary Care Extension Program to provide support

and assistance to educate primary care providers about preventive medicine, health promotion, chronic disease management, mental and behavioral health services, and evidence-based and evidence-informed therapies and techniques.

Requires the Secretary to award grants to states for the establishment of Primary Care Extension Program State Hubs to coordinate state health care functions with quality improvement organizations and area health education centers.

Subtitle F: Strengthening Primary Care and Other Workforce Improvements - (Sec. 5501, as modified by Sec. 10501) Requires Medicare incentive payments to: (1) primary care practitioners providing primary care services on or after January 1, 2011, and before January 1, 2016; and (2) general surgeons performing major surgical procedures on or after January 1, 2011, and before January 1, 2016, in a health professional shortage area.

(Sec. 5502, deleted by Sec. 10501)

(Sec. 5503) Reallocates unused residency positions to qualifying hospitals for primary care residents for purposes of payments to hospitals for graduate medical education costs.

(Sec. 5504) Revises provisions related to graduate medical education costs to count the time residents spend in nonprovider settings toward the full-time equivalency if the hospital incurs the costs of the stipends and fringe benefits of such residents during such time.

(Sec. 5505, as modified by Sec. 10501) Includes toward the determination of full-time equivalency for graduate medical education costs time spent by an intern or resident in an approved medical residency training program in a nonprovider setting that is primarily engaged in furnishing patient care in nonpatient care activities.

(Sec. 5506) Directs the Secretary, when a hospital with an approved medical residency program closes, to increase the resident limit for other hospitals based on proximity criteria.

(Sec. 5507) Requires the Secretary to: (1) award grants for demonstration projects that are designed to provide certain low-income individuals with the opportunity to obtain education and training for health care occupations that pay well and that are expected to experience labor shortages or be in high demand; and (2) award grants to states to conduct demonstration projects for purposes of developing core training competencies and certification programs for personal or home care aides.

Authorizes appropriations for FY2009-FY2012 for family-to-family health information centers.

(Sec. 5508) Authorizes the Secretary to award grants to teaching health centers for the purpose of establishing new accredited or expanded primary care residency programs.

Allows up to 50% of time spent teaching by a member of the National Health Service Corps to be considered clinical practice for purposes of fulfilling the service obligation.

Requires the Secretary to make payments for direct and indirect expenses to qualified teaching health centers for expansion or establishment of approved graduate medical residency training programs.

(Sec. 5509) Requires the Secretary to establish a graduate nurse education demonstration under which a hospital may receive payment for the hospital's reasonable costs for the provision of qualified clinical training to advance practice nurses.

Subtitle G: Improving Access to Health Care Services - (Sec. 5601) Reauthorizes appropriations for health centers to serve medically underserved populations.

(Sec. 5602) Requires the Secretary to establish through the negotiated rulemaking process a comprehensive methodology and criteria for designation of medically underserved populations and health professions shortage areas.

(Sec. 5603) Reauthorizes appropriations for FY2010-FY2014 for the expansion and improvement of emergency medical services for children who need treatment for trauma or critical care.

(Sec. 5604) Authorizes the Secretary, acting through the Administrator of the Substance Abuse and Mental Health Services Administration, to award grants and cooperative agreements for demonstration projects for the provision of coordinated and integrated services to special populations through the co-location of primary and specialty care services in community-based mental and behavioral health settings.

(Sec. 5605) Establishes a Commission on Key National Indicators to: (1) conduct comprehensive oversight of a newly established key national indicators system; and (2) make recommendations on how to improve such system. Directs the National Academy of Sciences to enable the establishment of such system by creating its own institutional capability or by partnering with an independent private nonprofit organization to implement such system. Directs the Comptroller General to study previous work conducted by all public agencies, private organizations, or foreign countries with respect to best practices for such systems.

(Sec. 5606, as added by Sec. 10501) Authorizes a state to award grants to health care providers who treat a high percentage of medically underserved populations or other special populations in the state.

Subtitle H: General Provisions - (Sec. 5701) Requires the Secretary to submit to the appropriate congressional committees a report on activities carried out under this title and the effectiveness of such activities.

Title 6

Transparency and Program Integrity

Subtitle A: Physician Ownership and Other Transparency - (Sec. 6001, as modified by Sec. 10601) Amends SSA title XVIII (Medicare) to prohibit physician-owned hospitals that do not have a provider agreement by August 1, 2010, to participate in Medicare. Allows their participation in Medicare under a rural provider and hospital exception to the ownership or investment prohibition if they meet certain requirements addressing conflict of interest, bona fide investments, patient safety issues, and expansion limitations.

(Sec. 6002) Amends SSA title XI to require drug, device, biological and medical supply manufacturers to report to the Secretary transfers of value made to a physician, physician medical practice, a physician group practice, and/or teaching hospital, as well as information on any physician ownership or investment interest in the manufacturer. Provides penalties for noncompliance. Preempts duplicative state or local laws.

(Sec. 6003) Amends SSA title XVIII (Medicare), with respect to the Medicare in-office ancillary exception to the prohibition against physician self-referrals, to require a referring physician to inform the patient in writing that the patient may obtain a specified imaging service from a person other than the referring physician, a physician who is a member of the same group practice as the referring physician, or an individual directly supervised by the physician or by another physician in the group practice. Requires the referring physician also to provide the patient with a written list of suppliers who furnish such services in the area in which the patient resides.

(Sec. 6004) Amends SSA title XI to require prescription drug manufacturers and authorized distributors of record to report to the Secretary specified information pertaining to drug samples.

(Sec. 6005) Amends SSA title XI to require a pharmacy benefit manager (PBM) or a health benefits plan that manages prescription drug coverage under a contract with a Medicare or Exchange health plan to report to the Secretary information regarding the generic dispensing rate, the rebates, discounts, or price concessions negotiated by the PBM, and the payment difference between health plans and PBMs and the PBMs and pharmacies.

Subtitle B: Nursing Home Transparency and Improvement - Part I: Improving Transparency of Information - (Sec. 6101) Amends SSA title XI to require SNFs under Medicare and nursing facilities (NFs) under Medicaid to make available, upon request by the Secretary, the HHS Inspector General, the states, or a state long-term care ombudsman, information on ownership of the SNF or NF, including a description of the facility's governing body and organizational structure, as well as information regarding additional disclosable parties.

(Sec. 6102) Requires SNFs and NFs to operate a compliance and ethics program effective in preventing and detecting criminal, civil, and administrative violations.

Directs the Secretary to establish and implement a quality assurance and performance improvement program for SNFs and NFs, including multi-unit chains of facilities.

(Sec. 6103) Amends SSA title XVIII (Medicare) to require the Secretary to publish on the Nursing Home Compare Medicare website: (1) standardized staffing data; (2) links to state websites regarding state survey and certification programs; (3) the model standardized complaint form; (4) a summary of substantiated complaints; and (5) the number of adjudicated instances of criminal violations by a facility or its employees.

(Sec. 6104) Requires SNFs to report separately expenditures on wages and benefits for direct care staff, breaking out registered nurses, licensed professional nurses, certified nurse assistants, and other medical and therapy staff.

(Sec. 6105) Requires the Secretary to develop a standardized complaint form for use by residents (or a person acting on a resident's behalf) in filing complaints with a state survey and certification agency and a state long-term care ombudsman program. Requires states to to establish complaint resolution processes.

(Sec. 6106) Amends SSA title XI to require the Secretary to develop a program for facilities to report direct care staffing information on payroll and other verifiable and auditable data in a uniform format based.

(Sec. 6107) Requires the Comptroller General to study and report to Congress on the Five-Star Quality Rating System for nursing homes of CMS.

Part II: Targeting Enforcement - (Sec. 6111) Amends SSA title XVIII (Medicare) to authorize the Secretary to reduce civil monetary penalties by 50% for certain SNFs and NFs that self-report and promptly correct deficiencies within 10 calendar days of imposition of the penalty. Directs the Secretary to issue regulations providing for an informal dispute resolution process after imposition of a penalty, as well as an escrow account for money penalties pending resolution of any appeals.

(Sec. 6112) Directs the Secretary to establish a demonstration project for developing, testing, and implementing a national independent monitor program to oversee interstate and large intrastate chains of SNFs and NFs.

(Sec. 6113) Requires the administrator of a SNF or a NF that is preparing to close to notify in writing residents, legal representatives of residents or other responsible parties, the Secretary, and the state long-term care ombudsman program in advance of the closure by at least 60 days. Requires the notice to include a plan for the transfer and adequate relocation of residents to another facility or alternative setting. Requires the state to ensure a successful relocation of residents.

(Sec. 6114) Requires the Secretary to conduct two SNF- and NF-based demonstration projects to develop best practice models in two areas: (1) one for facilities involved in the “culture change” movement; and (2) one for the use of information technology to improve resident care.

Part III: Improving Staff Training - (Sec. 6121) Requires SNFs and NFs to include dementia management and abuse prevention training as part of pre-employment initial training and, if appropriate, as part of ongoing in-service training for permanent and contract or agency staff.

Subtitle C: Nationwide Program for National and State Background Checks on Direct Patient Access Employees of Long Term Care Facilities and Providers - (Sec. 6201) Requires the Secretary to establish a nationwide program for national and state background checks on prospective direct patient access employees of long-term care facilities and providers.

Subtitle D: Patient-Centered Outcomes Research - (Sec. 6301, as modified by Sec. 10602) Amends SSA title XI to establish the Patient-Centered Outcomes Research Institute to identify priorities for, and establish, update, and carry out, a national comparative outcomes research project agenda. Provides for a peer review process for primary research.

Prohibits the Institute from allowing the subsequent use of data from original research in work-for-hire contracts with individuals, entities, or instrumentalities that have a financial interest in the results, unless approved by the Institute under a data use agreement.

Amends the Public Health Service Act to direct the Office of Communication and Knowledge Transfer at AHRQ to disseminate broadly the research findings published by the Institute and other government-funded research relevant to comparative clinical effective research.

Prohibits the Secretary from using evidence and findings from Institute research to make a determination regarding Medicare coverage unless such use is through an iterative and transparent process which includes public comment and considers the effect on subpopulations.

Amends the Internal Revenue Code to establish in the Treasury the Patient-Centered Outcomes Research Trust Fund. Directs the Secretary to make transfers to that Trust Fund from the Medicare Trust Funds.

Imposes annual fees of $2 times the number of insured lives on each specified health insurance policy and on self-insured health plans.

(Sec. 6302) Terminates the Federal Coordinating Council for Comparative Effectiveness Research upon enactment of this Act.

Subtitle E: Medicare, Medicaid, and CHIP Program Integrity Provisions - (Sec. 6401, as modified by Sec. 10603) Amends SSA title XVIII (Medicare) to require the Secretary to: (1) establish procedures for screening providers and suppliers participating in Medicare, Medicaid, and CHIP; and (2) determine the level of screening according to the risk of fraud, waste, and abuse with respect to each category of provider or supplier.

Requires providers and suppliers applying for enrollment or revalidation of enrollment in Medicare, Medicaid, or CHIP to disclose current or previous affiliations with any provider or supplier that: (1) has uncollected debt; (2) has had its payments suspended; (3) has been excluded from participating in a federal health care program; or (4) has had billing privileges revoked. Authorizes the Secretary to deny enrollment in a program if these affiliations pose an undue risk to it.

Requires providers and suppliers to establish a compliance program containing specified core elements.

Directs the CMS Administrator to establish a process for making available to each state agency with responsibility for administering a state Medicaid plan or a child health plan under SSA title XXI the identity of any provider or supplier under Medicare or CHIP who is terminated.

(Sec. 6402) Requires CMS to include in the integrated data repository claims and payment data from Medicare, Medicaid, CHIP, and health-related programs administered by the Departments of Veterans Affairs (VA) and DOD, the Social Security Administration, and IHS.

Directs the Secretary to enter into data-sharing agreements with the Commissioner of Social Security, the VA and DOD Secretaries, and the IHS Director to help identity fraud, waste, and abuse.

Requires that overpayments be reported and returned within 60 days from the date the overpayment was identified or by the date a corresponding cost report was due, whichever is later.

Directs the Secretary to issue a regulation requiring all Medicare, Medicaid, and CHIP providers to include their National Provider Identifier on enrollment applications.

Authorizes the Secretary to withhold the federal matching payment to states for medical assistance expenditures whenever a state does not report enrollee encounter data in a timely manner to the state’s Medicaid Management Information System.

Authorizes the Secretary to exclude providers and suppliers participation in any federal health care program for providing false information on any application to enroll or participate.

Subjects to civil monetary penalties excluded individuals who: (1) order or prescribe an item or service; (2) make false statements on applications or contracts to participate in a federal health care program; or (3) know of an overpayment and do not return it. Subjects the latter offense to civil monetary penalties of up to $50,000 or triple the total amount of the claim involved.

Authorizes the Secretary to issue subpoenas and require the attendance and testimony of witnesses and the production of any other evidence that relates to matters under investigation or in question.

Requires the Secretary take into account the volume of billing for a durable medical equipment (DME) supplier or home health agency when determining the size of the supplier's and agency's surety bond. Authorizes the Secretary to require other providers and suppliers to post a surety bond if the Secretary considers them to be at risk.

Authorizes the Secretary to suspend payments to a provider or supplier pending a fraud investigation.

Appropriates an additional $10 million, adjusted for inflation, to the Health Care Fraud and Abuse Control each of FY2011-FY2020. Applies inflation adjustments as well to Medicare Integrity Program funding.

Requires the Medicaid Integrity Program and Program contractors to provide the Secretary and the HHS Office of Inspector General with performance statistics, including the number and amount of overpayments recovered, the number of fraud referrals, and the return on investment for such activities.

(Sec. 6403) Requires the Secretary to furnish the National Practitioner Data Bank (NPDB) with all information reported to the national health care fraud and abuse data collection program on certain final adverse actions taken against health care providers, suppliers, and practitioners.

Requires the Secretary to establish a process to terminate the Healthcare Integrity and Protection Databank (HIPDB) and ensure that the information formerly collected in it is transferred to the NPDB.

(Sec. 6404) Reduces from three years to one year after the date of service the maximum period for submission of Medicare claims.

(Sec. 6405, as modified by Sec. 10604) Requires DME or home health services to be ordered by an enrolled Medicare eligible professional or physician. Authorizes the Secretary to extend these requirements to other Medicare items and services to reduce fraud, waste, and abuse.

(Sec. 6406) Authorizes the Secretary to disenroll, for up to one year, a Medicare enrolled physician or supplier that fails to maintain and provide access to written orders

or requests for payment for DME, certification for home health services, or referrals for other items and services.

Authorizes the Secretary to exclude from participation in any federal health care program any individual or entity ordering, referring for furnishing, or certifying the need for an item or service that fails to provide adequate documentation to verify payment.

(Sec. 6407, as modified by Sec. 10605) Requires a physician, nurse practitioner, clinical nurse specialist, certified nurse-midwife, or physician assistant to have a face-to-face encounter with an individual before issuing a certification for home health services or DME.

Authorizes the Secretary to apply the same face-to-face encounter requirement to other items and services based upon a finding that doing so would reduce the risk of fraud, waste, and abuse. Applies the same requirement, as well, to physicians making certifications for home health services under Medicaid.

(Sec. 6408) Revises civil monetary penalties for making false statements or delaying inspections.

Applies specified enhanced sanctions and civil monetary penalties to MA or Part D plans that: (1) enroll individuals in an MA or Part D plan without their consent; (2) transfer an individual from one plan to another for the purpose of earning a commission; (3) fail to comply with marketing requirements and CMS guidance; or (4) employ or contract with an individual or entity that commits a violation.

(Sec. 6409) Requires the Secretary to establish a self-referral disclosure protocol to enable health care providers and suppliers to disclose actual or potential violations of the physician self-referral law.

Authorizes the Secretary to reduce the amount due and owing for all violations of such law.

(Sec. 6410) Requires the Secretary to: (1) expand the number of areas to be included in round two of the competitive bidding program from 79 to 100 of the largest metropolitan statistical areas; and (2) use competitively bid prices in all areas by 2016.

(Sec. 6411) Requires states to establish contracts with one or more Recovery Audit Contractors (RACs), which shall identify underpayments and overpayments and recoup overpayments made for services provided under state Medicaid plans as well as state plan waivers.

Requires the Secretary to expand the RAC program to Medicare parts C (Medicare+Choice) and D (Prescription Drug Program).

Subtitle F: Additional Medicaid Program Integrity Provisions - (Sec. 6501) Amends SSA title XIX (Medicaid) to require states to terminate individuals or entities (providers)

from their Medicaid programs if they were terminated from Medicare or another state's Medicaid program.

(Sec. 6502) Requires Medicaid agencies to exclude individuals or entities from participating in Medicaid for a specified period of time if the entity or individual owns, controls, or manages an entity that: (1) has failed to repay overpayments during a specified period; (2) is suspended, excluded, or terminated from participation in any Medicaid program; or (3) is affiliated with an individual or entity that has been suspended, excluded, or terminated from Medicaid participation.

(Sec. 6503) Requires state Medicaid plans to require any billing agents, clearinghouses, or other alternate payees that submit claims on behalf of health care providers to register with the state and the Secretary.

(Sec. 6504) Requires states to submit data elements from the state mechanized claims processing and information retrieval system (under the Medicaid Statistical Information System) that the Secretary determines necessary for program integrity, program oversight, and administration.

Requires a Medicaid managed care entity contract to provide for maintenance of sufficient patient encounter data to identify the physician who delivers services to patients (as under current law) at a frequency and level of detail to be specified by the Secretary.

(Sec. 6505) Requires a state Medicaid plan to prohibit the state from making any payments for items or services under a Medicaid state plan or a waiver to any financial institution or entity located outside of the United States.

(Sec. 6506) Extends the period for states to recover overpayments from 60 days to one year after discovery of the overpayment. Declares that, when overpayments due to fraud are pending, state repayments of the federal portion of such overpayments shall not be due until 30 days after the date of the final administrative or judicial judgment on the matter.

(Sec. 6507) Requires state mechanized Medicaid claims processing and information retrieval systems to incorporate methodologies compatible with Medicare's National Correct Coding Initiative.

Subtitle G: Additional Program Integrity Provisions - (Sec. 6601) Amends the Employee Retirement Income Security Act of 1974 (ERISA) to prohibit employees and agents of multiple employer welfare arrangements (MEWAs), subject to criminal penalties, from making false statements in marketing materials regarding an employee welfare benefit plan's financial solvency, benefits, or regulatory status.

(Sec. 6603) Amends the Public Health Service Act to direct the Secretary to request NAIC to develop a model uniform report form for a private health insurance issuer

seeking to refer suspected fraud and abuse to state insurance departments or other responsible state agencies for investigation.

(Sec. 6604) Amends ERISA to direct the Secretary of Labor to adopt regulatory standards and/or issue orders to subject MEWAs to state law relating to fraud and abuse.

(Sec. 6605) Authorizes the Secretary of Labor to: (1) issue cease-and-desist orders to shut down temporarily the operations of MEWAs conducting fraudulent activities or posing a serious threat to the public, until hearings can be completed; and (2) seize a plan's assets if it appears that the plan is in a financially hazardous condition.

(Sec. 6606) Directs the Secretary of Labor to require MEWAs which are not group health plans to register with the Department of Labor before operating in a state.

(Sec. 6607) Authorizes the Secretary of Labor to promulgate a regulation providing an evidentiary privilege that allows confidential communication among specified federal and state officials relating to investigation of fraud and abuse.

Subtitle H: Elder Justice Act - Elder Justice Act of 2009 - (Sec. 6702) Amends SSA title XX (Block Grants to States for Social Services) with respect to elder abuse, neglect, and exploitation and their prevention. Requires the HHS Secretary to award grants and carry out activities that provide: (1) greater protection to those individuals seeking care in facilities that provide long-term care services and supports; and (2) greater incentives for individuals to train and seek employment at such facilities.

Requires facility owners, operators, and certain employees to report suspected crimes committed at a facility.

Requires facility owners or operators also to: (1) submit to the Secretary and to the state written notification of an impending closure of a facility within 60 days before the closure; and (2) include a plan for transfer and adequate relocation of all residents.

Establishes an Elder Justice Coordinating Council.

Subtitle I: Sense of the Senate Regarding Medical Malpractice - (Sec. 6801) Expresses the sense of the Senate that: (1) health reform presents an opportunity to address issues related to medical malpractice and medical liability insurance; (2) states should be encouraged to develop and test alternative models to the existing civil litigation system; and (3) Congress should consider state demonstration projects to evaluate such alternatives.

Title 8

Improving Access to Innovative Medical Therapies

Subtitle A: Biologics Price Competition and Innovation - Biologics Price Competition and Innovation Act of 2009 - (Sec. 7002) Amends the Public Health Service

Act to allow a person to submit an application for licensure of a biological product based on its similarity to a licensed biological product (the reference product). Requires the Secretary to license the biological product if it is biosimilar to or interchangeable with the reference product.

Prohibits the Secretary from determining that a second or subsequent biological product is interchangeable with a reference product for any condition of use for specified periods based on the marketing of, and the presence or status of litigation involving, the first biosimilar biological product deemed interchangeable with the same reference product.

Prohibits the Secretary from making approval of an application under this Act effective until 12 years after the date on which the reference product was first licensed.

Subtitle B: More Affordable Medicine for Children and Underserved Communities - (Sec. 7101) Expands the 340B drug discount program (a program limiting the cost of covered outpatient drugs to certain federal grantees) to allow participation as a covered entity by certain: (1) children's hospitals; (2) freestanding cancer hospitals; (3) critical access hospitals; (4) rural referral centers; and (5) sole community hospitals. Expands the program to include drugs used in connection with an inpatient or outpatient service by enrolled hospitals (currently, only outpatient drugs are covered under the program).

Requires the Secretary to establish reasonable exceptions to the prohibition on enrolled hospitals obtaining covered outpatient drugs through a group purchasing organization or other group purchasing arrangement, including for drugs unavailable through the program and to facilitate generic substitution when a generic covered drug is available at a lower price. Allows such hospitals to purchase covered drugs for inpatients through any such arrangement.

Requires a hospital enrolled in the 340B drug discount program to issue a credit to a state Medicaid program for inpatient covered drugs provided to Medicaid recipients.

(Sec. 7102) Requires the Secretary to: (1) provide for improvements in compliance by manufacturers and covered entities with the requirements of the 340B drug discount program; and (2) establish and implement an administrative process for resolving claims by covered entities and manufacturers of violations of such requirements.

Requires manufacturers to offer each covered entity covered drugs for purchase at or below the applicable ceiling price if such a drug is made available to any other purchaser at any price.

(Sec. 7103) Requires the Comptroller General to report to Congress on whether those individuals served by the covered entities under the 340B drug discount program are receiving optimal health care services.

Title VIII: Class Act - Community Living Assistance Services and Supports Act or the CLASS Act - (Sec. 8002, as modified by Sec. 10801) Establishes a national, voluntary

insurance program for purchasing community living assistance services and supports (CLASS program) under which: (1) all employees are automatically enrolled, but are allowed to waive enrollment; (2) payroll deductions pay monthly premiums; and (3) benefits under a CLASS Independence Benefit Plan provide individuals with functional limitations with tools that will allow them to maintain their personal and financial independence and live in the community.

Title IX

Revenue Provisions

Subtitle A: Revenue Offset Provisions - (Sec. 9001, as modified by section 10901) Amends the Internal Revenue Code to impose an excise tax of 40% of the excess benefit from certain high cost employer-sponsored health coverage. Deems any amount which exceeds payment of $8,500 for an employee self-only coverage plan and $23,000 for employees with other than self-only coverage (family plans) as an excess benefit. Increases such amounts for certain retirees and employees who are engaged in high-risk professions (e.g., law enforcement officers, emergency medical first responders, or longshore workers). Imposes a penalty on employers and coverage providers for failure to calculate the proper amount of an excess benefit.

(Sec. 9002) Requires employers to include in the W-2 form of each employee the aggregate cost of applicable employer-sponsored group health coverage that is excludable from the employee's gross income (excluding the value of contributions to flexible spending arrangements).

(Sec. 9003) Restricts payments from health savings accounts, medical savings accounts, and health flexible spending arrangements for medications to prescription drugs or insulin.

(Sec. 9004) Increases to 20% the penalty for distributions from a health savings account or Archer medical savings account not used for qualified medical expenses.

(Sec. 9005, as modified by section 10902) Limits annual salary reduction contributions by an employee to a health flexible spending arrangement under a cafeteria plan to $2,500. Allows an annual inflation adjustment to such amount after 2011.

(Sec. 9006) Applies to corporations reporting requirements for payments of $600 or more to persons engaged in a trade or business.

(Sec. 9007, as modified by section 10903) Requires tax-exempt charitable hospitals to: (1) conduct a community health needs assessment every two years; (2) adopt a written financial assistance policy for patients who require financial assistance for hospital care; and (3) refrain from taking extraordinary collection actions against a patient until the hospital has made reasonable efforts to determine whether the patient is eligible for financial assistance. Imposes a penalty tax on hospitals who fail to comply with the requirements of this Act.

Requires the Secretary of the Treasury to report to Congress on information with respect to private tax-exempt, taxable, and government-owned hospitals regarding levels of charity care provided, bad debt expenses, unreimbursed costs, and costs for community benefit activities.

(Sec. 9008) Imposes an annual fee on the branded prescription drug sales exceeding $5 million of manufacturers and importers of such drugs beginning in 2010. Requires the HHS, VA, and DOD Secretaries to report to the Secretary of the Treasury on the total branded prescription drug sales within government programs within their departments.

(Sec. 9009, as modified by section 10904) Imposes an annual fee on the gross sales receipts exceeding $5 million of manufacturers and importers of certain medical devices beginning in 2011.

(Sec. 9010, as modified by section 10905) Imposes on any entity that provides health insurance for any United States health risk an annual fee beginning in 2011. Defines "United States health risk" as the health risk of an individual who is a U.S. citizen or resident or is located in the United States with respect to the period the individual is so located. Exempts entities whose net premiums written are not more than $25 million. Requires all entities subject to such fee to report to the Secretary of the Treasury on their net written premiums and imposes a penalty for failure to report.

(Sec. 9011) Requires the VA Secretary to study and report to Congress by December 31, 2012, on the effect of fees assessed by this Act on the cost of medical care provided to veterans and on veterans' access to medical devices and branded prescription drugs.

(Sec. 9012) Eliminates the tax deduction for expenses for determining the subsidy for employers who maintain prescription drug plans for Medicare Part D eligible retirees.

(Sec. 9013) Increases the adjusted gross income threshold for claiming the itemized deduction for medical expenses from 7.5% to 10% beginning after 2012. Retains the 7.5% threshold through 2016 for individual taxpayers who have attained age 65 before the close of an applicable taxable year.

(Sec. 9014) Imposes a limitation after December 31, 2012, of $500,000 on the deductibility of remuneration paid to officers, directors, employees, and service providers of health insurance issuers who derive at least 25% of their gross premiums from providing health insurance coverage that meets the minimum essential coverage requirements established by this Act.

(Sec. 9015, as modified by section 10906) Increases after December 31, 2012, the hospital insurance tax rate by .9% for individual taxpayers earning over $200,000 ($250,000 for married couples filing joint tax returns).

(Sec. 9016) Requires Blue Cross or Blue Shield organizations or other nonprofit organizations that provide health insurance to reimburse at least 85% of the cost of

clinical services provided to their enrollees to be eligible for special tax benefits currently provided to such organizations.

Subtitle B: Other Provisions - (Sec. 9021) Excludes from gross income the value of certain health benefits provided to members of Indian tribes, including: (1) health services or benefits provided or purchased by IHS; (2) medical care provided by an Indian tribe or tribal organization to a member of an Indian tribe; (3) accident or health plan coverage provided by an Indian tribe or tribal organization for medical care to a member of an Indian tribe and dependents; and (4) any other medical care provided by an Indian tribe that supplements, replaces, or substitutes for federal programs.

(Sec. 9022) Establishes a new employee benefit cafeteria plan to be known as a Simple Cafeteria Plan, defined as a plan that: (1) is established and maintained by an employer with an average of 100 or fewer employees during a two-year period; (2) requires employers to make contributions or match employee contributions to the plan; and (3) requires participating employees to have at least 1,000 hours of service for the preceding plan year; and (4) allows such employees to elect any benefit available under the plan.

(Sec. 9023) Allows a 50% tax credit for investment in any qualifying therapeutic discovery project, defined as a project that is designed to: (1) treat or prevent diseases by conducting pre-clinical activities, clinical trials, and clinical studies, or carrying out research projects to approve new drugs or other biologic products; (2) diagnose diseases or conditions to determine molecular factors related to diseases or conditions; or (3) develop a product, process, or technology to further the delivery or administration of therapeutics. Directs the Secretary of the Treasury to award grants for 50% of the investment in 2009 or 2010 in such a project, in lieu of the tax credit.

Title 10

Strengthening Quality, Affordable Health Care for All Americans

Subtitle A: Provisions Relating to Title I - (Sec. 10101) Revises provisions of or related to Subtitles A, B, and C of Title I of this Act (as reflected in the summary of those provisions).

(Sec. 10104) Revises provisions of or related to Subtitle D of Title I of this Act (as reflected in the summary of those provisions). Makes changes to the False Claims Act related to the public disclosure bar on filing civil claims.

(Sec. 10105) Revises provisions of or related to Subtitles E, F, and G of Title I of this Act (as reflected in the summary of those provisions).

(Sec. 10108) Requires an offering employer to provide free choice vouchers to each qualified employee. Defines "offering employer" to mean any employer who offers minimum essential coverage to its employees consisting of coverage through an eligible employer-sponsored plan and who pays any portion of the costs of such plan. Defines

"qualified employee" as an employee whose required contribution for such coverage and household income fall within a specified range. Requires: (1) a Health Insurance Exchange to credit the amount of any free choice voucher to the monthly premium of any qualified health plan in which the employee is enrolled; and (2) the offering employer to pay any amounts so credited to the Exchange. Excludes the amount of any free choice voucher from the gross income of the employee. Permits a deduction by employers for such costs.

(Sec. 10109) Amends the SSA to require the HHS Secretary to seek input to determine if there could be greater uniformity in financial and administrative health care activities and items.

Requires the Secretary to: (1) task the ICD-9-CM Coordination and Maintenance Committee to convene a meeting to receive input regarding and recommend revisions to the crosswalk between the Ninth and Tenth Revisions of the International Classification of Diseases; and (2) make appropriate revisions to such crosswalk.

Subtitle B: Provisions Relating to Title II - Part I: Medicaid and CHIP - (Sec. 10201) Revises provisions of Subtitles A through L of Title II of this Act (as reflected in the summary of those provisions).

Amends SSA title XIX (Medicaid) to set the FMAP for the state of Nebraska, with respect to all or any portion of a fiscal year that begins on or after January 1, 2017, at 100% (thus requiring the federal government to pay 100% of the cost of covering newly-eligible individuals in Nebraska).

Directs the Comptroller General to study and report to Congress on whether the development, recognition, or implementation of any specified health care quality guideline or other standards would result in the establishment of a new cause of action or claim.

(Sec. 10202) Creates a State Balancing Incentive Payments Program to increase the FMAP for states which offer home and community-based services as a long-term care alternative to nursing homes.

(Sec. 10203) Amends SSA title XXI (CHIP) to make appropriations for CHIP through FY2015 and revise other CHIP-related requirements.

Part II: Support for Pregnant and Parenting Teens and Women - (Sec. 10212) Requires the Secretary to establish a Pregnancy Assistance Fund for grants to states to assist pregnant and parenting teens and women.

(Sec. 10214) Authorizes appropriations for FY2010-FY2019.

Part III: Indian Health Care Improvement - (Sec. 10221) Enacts into law the Indian Health Care Improvement Reauthorization and Extension Act of 2009 (S. 1790) as

reported by the Senate Committee on Indian Affairs in December 2009 and with the following changes.

Amends the Indian Health Care Improvement Act, as amended by the Indian Health Care Improvement Reauthorization and Extension Act of 2009, to make an exception to the requirement that a national Community Health Aide Program exclude dental health aide therapist services. Declares that the exclusion of dental health aide therapist services from services covered under the national program shall not apply where an Indian tribe or tribal organization, located in a state (other than Alaska) in which state law authorizes the use of dental health aide therapist services or midlevel dental health provider services, elects to supply such services in accordance with state law.

Subtitle C: Provisions Relating to Title III - (Sec. 10301) Revises provisions of Subtitles A through G of Title III of this Act (as reflected in the summary of those provisions).

(Sec. 10323) Amends SSA title XVIII (Medicare) to deem eligible for Medicare coverage certain individuals exposed to environmental health hazards.

Directs the Secretary to establish a pilot program for care of certain individuals residing in emergency declaration areas.

Amends SSA title XX (Block Grants to States for Social Services) to direct the Secretary to establish a program for early detection of certain medical conditions related to environmental health hazards. Makes appropriations for FY2012-FY2019.

(Sec. 10324) Establishes floors: (1) on the area wage index for hospitals in frontier states; (2) on the area wage adjustment factor for hospital outpatient department services in frontier states; and (3) for the practice expense index for services furnished in frontier states.

(Sec. 10325) Revises the SNF prospective payment system to delay specified changes until FY2011.

(Sec. 10326) Directs the Secretary to conduct separate pilot programs, for specified kinds of hospitals and hospice programs, to test the implementation of a value-based purchasing program for payments to the provider.

(Sec. 10327) Authorizes an additional incentive payment under the physician quality reporting system in 2011 through 2014 to eligible professionals who report quality measures to CMS via a qualified Maintenance of Certification program. Eliminates the MedicareAdvantage Regional Plan Stabilization Fund.

(Sec. 10328) Requires Medicare part D prescription drug plans to include a comprehensive review of medications as part of their medication therapy management programs. Requires automatic quarterly enrollment of qualified beneficiaries, with an allowance for them to opt out.

(Sec. 10329) Requires the Secretary to develop a methodology to measure health plan value.

(Sec. 10330) Directs the Secretary to develop a plan to modernize CMS computer and data systems.

(Sec. 10331) Requires the Secretary to: (1) develop a Physician Compare website with information on physicians enrolled in the Medicare program and other eligible professionals who participate in the Physician Quality Reporting Initiative; and (2) implement a plan to make information on physician performance public through Physician Compare, particularly quality and patient experience measures.

Authorizes the Secretary to provide financial incentives to Medicare beneficiaries furnished services by high quality physicians.

(Sec. 10332) Directs the Secretary to make available to qualified entities standardized extracts of Medicare claims data for the evaluation of the performance of service providers and suppliers.

(Sec. 10333) Amends the Public Health Service Act to authorize the Secretary to award grants to eligible entities to support community-based collaborative care networks for low-income populations.

(Sec. 10334) Transfers the Office of Minority Health to the Office of the Secretary. Authorizes appropriations for FY2011-FY2016.

Establishes individual offices of minority health within HHS.

Redesignates the National Center on Minority Health and Health Disparities in NIH as the National Institute on Minority Health and Health Disparities.

(Sec. 10336) Directs the Comptroller General to study and report to Congress on the impact on Medicare beneficiary access to high-quality dialysis services of including specified oral drugs furnished to them for the treatment of end stage renal disease in the related bundled prospective payment system.

Subtitle D: Provisions Relating to Title IV - (Sec. 10401) Revises provisions of or related to Subtitles A, B, C, D, and E of Title IV of this Act (as reflected in the summary of those provisions).

(Sec. 10407) Catalyst to Better Diabetes Care Act of 2009 - Requires the Secretary to prepare biennially a national diabetes report card and, to the extent possible, one for each state.

Requires the Secretary, acting through the Director of CDC, to: (1) promote the education and training of physicians on the importance of birth and death certificate data and on how to properly complete these documents; (2) encourage state adoption of the latest standard revisions of birth and death certificates; and (3) work with states to

reengineer their vital statistics systems in order to provide cost-effective, timely, and accurate vital systems data. Allows the Secretary to promote improvements to the collection of diabetes mortality data.

Directs the Secretary to conduct a study of the impact of diabetes on the practice of medicine in the United States and the level of diabetes medical education that should be required prior to licensure, board certification, and board recertification.

(Sec. 10408) Requires the Secretary to award grants to eligible employers to provide their employees with access to comprehensive workplace wellness programs.

(Sec. 10409) Cures Acceleration Network Act of 2009 - Amends the Public Health Service Act to require the Secretary, acting through the Director of NIH, to implement the Cures Acceleration Network under which grants and contracts will be awarded to accelerate the development of high need cures. Defines "high need cure" as a drug, biological product, or device: (1) that is a priority to diagnose, mitigate, prevent, or treat harm from any disease or condition; and (2) for which the incentives of the commercial market are unlikely to result in its adequate or timely development. Establishes a Cures Acceleration Network Review Board.

(Sec. 10410) Establishing a Network of Health-Advancing National Centers of Excellence for Depression Act of 2009 or the ENHANCED Act of 2009 - Requires the Secretary, acting through the Administrator of the Substance Abuse and Mental Health Services Administration, to: (1) award grants to establish national centers of excellence for depression; and (2) designate one such center as a coordinating center. Requires the coordinating center to establish and maintain a national, publicly available database to improve prevention programs, evidence-based interventions, and disease management programs for depressive disorders using data collected from the national centers.

(Sec. 10411) Congenital Heart Futures Act - Authorizes the Secretary, acting through the Director of CDC, to: (1) enhance and expand infrastructure to track the epidemiology of congenital heart disease and to organize such information into the National Congenital Heart Disease Surveillance System; or (2) award a grant to an eligible entity to undertake such activities.

Authorizes the Director of the National Heart, Lung, and Blood Institute to expand, intensify, and coordinate research and related Institute activities on congenital heart disease.

(Sec. 10412) Reauthorizes appropriations for grants for public access defibrillation programs. Requires an information clearinghouse to increase public access to defibrillation in schools established under such program to be administered by an organization that has substantial expertise in pediatric education, pediatric medicine, and electrophysiology and sudden death.

(Sec. 10413) Young Women's Breast Health Education and Awareness Requires Learning Young Act of 2009 or the EARLY Act - Requires the Secretary, acting through the Director of CDC, to conduct: (1) a national education campaign to increase awareness of young women's knowledge regarding breast health and breast cancer; (2) an education campaign among physicians and other health care professionals to increase awareness of breast health of young women; and (3) prevention research on breast cancer in younger women.

Requires the Secretary, acting through the Director of NIH, to conduct research to develop and validate new screening tests and methods for prevention and early detection of breast cancer in young women.

Directs the Secretary to award grants for the provision of health information to young women diagnosed with breast cancer and pre-neoplastic breast diseases.

Subtitle E: Provisions Relating to Title V - (Sec. 10501) Revises provisions of or related to Title V of this Act (as reflected in the summary of those provisions).

Requires the Secretary, acting through the Director of CDC, to establish a national diabetes prevention program targeted at adults at high risk for diabetes.

Directs the Secretary to develop a Medicare prospective payment system for payment for services furnished by federally qualified health centers.

Requires the Secretary, acting through the Administrator of the HRSA, to establish a grant program to assist accredited schools of allopathic or osteopathic medicine in: (1) recruiting students most likely to practice medicine in underserved rural communities; (2) providing rural-focused training and experience; and (3) increasing the number of recent allopathic and osteopathic medical school graduates who practice in underserved rural communities.

Directs the Secretary, acting through the Administrator of HRSA, to award grants or enter into contracts with eligible entities to provide training to graduate medical residents in preventive medicine specialties.

Reauthorizes appropriations for public health workforce activities.

Revises provisions related to fulfillment of service obligations under the National Health Service Corps related to half-time clinical practice and teaching.

(Sec. 10502) Authorizes appropriations to HHS for debt service on, or direct construction or renovation of, a health care facility that provides research, inpatient tertiary care, or outpatient clinical services and that meets certain requirements, including that it is critical for the provision of greater access to health care within the state.

(Sec. 10503) Establishes a Community Health Center Fund to provide for expanded and sustained national investment in community health centers. Authorizes appropriations to such Fund.

(Sec. 10504) Requires the Secretary, acting through the Administrator of HRSA, to establish a demonstration project to provide access to comprehensive health care services to the uninsured at reduced fees.

Subtitle F: Provisions Relating to Title VI - (Sec. 10601) Revises provisions of Subtitles A through E of Title IV of this Act (as reflected in the summary of those provisions).

(Sec. 10606) Directs the U.S. Sentencing Commission to amend the Federal Sentencing Guidelines to provide two-level, three-level, and four-level increases in the offense level for any defendant convicted of a federal health care offense relating to a government health care program of a loss between $1 million and $7 million, between $7 million and $20 million, and at least $20 million, respectively.

Provides that a person need not have actual knowledge of the prohibition against health care fraud nor specific intent to violate it in order to commit health care fraud.

Expands the scope of violations constituting a federal health care offense.

Amends the Civil Rights of Institutionalized Persons Act to authorize the Attorney General to require access to an institution by subpoena to investigate conditions depriving residents of specified constitutional or federal rights.

(Sec. 10607) Authorizes the Secretary to award demonstration grants to states for the development, implementation, and evaluation of alternatives to current tort litigation for resolving disputes over injuries allegedly caused by health care providers or health care organizations.

(Sec. 10608) Amends the Public Health Service Act to extend medical malpractice coverage to free clinics by deeming their officers, employees, board members, and contractors to be employees of the Public Health Service.

(Sec. 10609) Amends the Federal Food, Drug, and Cosmetic Act to set forth circumstances under which a generic drug may be approved with a label different from the listed drug.

Subtitle G: Provisions Relating to Title VIII - (Sec. 10801) Revises provisions of or related to Title VIII of this Act (as reflected in the summary of those provisions).

Subtitle H: Provisions Relating to Title IX: (Sec. 10901) Revises provisions of or related to Title IX of this Act (as reflected in the summary of those provisions).

(Sec. 10907) Amends the Internal Revenue Code to impose a 10% excise tax on any amount paid for indoor tanning services on or after July 1, 2010. Exempts phototherapy

services performed by a licensed medical professional from the definition of "indoor tanning services."

(Sec. 10908) Excludes from gross income any payments under the National Health Service Corps Loan Repayment Program and any other state loan repayment or forgiveness programs intended to increase the availability of health care services in underserved or health professional shortage areas.

(Sec. 10909) Increases from $10,000 to $13,170 the dollar limitation on: (1) the tax credit for adoption expenses; and (2) the tax exclusion for employer-provided adoption assistance. Allows an inflation adjustment to such limitation after 2010. Makes such credit refundable. Extends through 2011 the general terminating date of the Economic Growth and Tax Relief Reconciliation Act of 2001 with respect to such credit and exclusion.

Impacts and Implications of Healthcare Reforms
An Historical Perspective

Perceptive writers have waxed poetic about the failings of healthcare financing for centuries. Moliere, an articulate French playwright wrote about his own healthcare system faults eloquently in the 1600s. Arguably his most famous play, The Imaginary Invalid, describes how a hypochondriacal gentleman plots to marry his daughter off to a physician for the resulting free medical care. Fee-for-service medical costs, it appears, were too expensive even for the wealthy in the 1600s.

Perceptive writers like Moliere have entertained audiences with gallows humor about their shared tribulations for some 400 years.

More recently George Bernard Shaw wrote The Doctor's Dilemma in 1909 to skewer the private, fee-based healthcare financing system of the time. His analysis of the then-healthcare system mirrored Moliere's from 3 centuries earlier, showing that, unfortunately, some things never change. Shaw's Preface, reproduced below, 'is an extensive tirade against the … medical profession, as being excessively given to protestations of the public good and the actual pursuit of private interest' according to the Wikipedia summary. Shaw saw physicians as professionals who claimed to do well for themselves by doing good for others, but in the end, always did well for themselves and only sometimes did good for others.

Since Shaw is far more articulate than me, I decided to include his Preface to the Doctor's Dilemma here. As you read this, consider how Shaw's complaints about his healthcare system in 1909 mirror many of our own today and ask yourself how much has changed over the past 113 years. (If you really want to depress yourself, read Moliere's Imaginary Invalid and ask yourself the same questions.) Then ask yourself how much – if at all – our healthcare reforms since 2003 have changed the incentive structure and underlying operation of the system. Yes, I understand that technology has improved. But I wonder if the system itself has.

We'll now hear from George Bernard Shaw himself.

The Doctor’s Dilemma
Preface
On Doctors, 1909

It is not the fault of our doctors that the medical service of the community, as at present provided for, is a murderous absurdity.

That any sane nation, having observed that you could provide for the supply of bread by giving bakers a pecuniary interest in baking for you, should go on to give a surgeon a pecuniary interest in cutting off your leg, is enough to make one despair of political humanity.

But that is precisely what we have done. And the more appalling the mutilation, the more the mutilator is paid. He who corrects the ingrowing toe-nail receives a few shillings: he who cuts your inside out receives hundreds of guineas, except when he does it to a poor person for practice.

Scandalized voices murmur that these operations are necessary. They may be. It may also be necessary to hang a man or pull down a house. But we take good care not to make the hangman and the housebreaker the judges of that. If we did, no man's neck would be safe and no man's house stable. But we do make the doctor the judge, and fine him anything from sixpence to several hundred guineas if he decides in our favor.

I cannot knock my shins severely without forcing on some surgeon the difficult question, "Could I not make a better use of a pocketful of guineas than this man is making of his leg? Could he not write as well—or even better—on one leg than on two? And the guineas would make all the difference in the world to me just now. My wife—my pretty ones—the leg may mortify—it is always safer to operate—he will be well in a fortnight—artificial legs are now so well made that they are really better than natural ones—evolution is towards motors and leglessness, etc., etc., etc."

Now there is no calculation that an engineer can make as to the behavior of a girder under a strain, or an astronomer as to the recurrence of a comet, more certain than the calculation that under such circumstances we shall be dismembered unnecessarily in all directions by surgeons who believe the operations to be necessary solely because they want to perform them. The process metaphorically called bleeding the rich man is performed not only metaphorically but literally every day by surgeons who are quite as honest as most of us. After all, what harm is there in it? The surgeon need not take off the rich man's (or woman's) leg or arm: he can remove the appendix or the uvula, and leave the patient none the worse after a fortnight or so in bed, whilst the nurse, the general practitioner, the apothecary, and the surgeon will be the better.

DOUBTFUL CHARACTER BORNE BY THE MEDICAL PROFESSION

Again I hear the voices indignantly muttering old phrases about the high character of a noble profession and the honor and conscience of its members. I must reply that the medical profession has not a high character: it has an infamous character. I do not know a single thoughtful and well-informed person who does not feel that the tragedy of illness at present is that it delivers you helplessly into the hands of a profession which you deeply mistrust, because it not only advocates and practices the most revolting cruelties in the pursuit of knowledge, and justifies them on grounds which would equally justify practicing the same cruelties on yourself or your children, or burning down London to test a patent fire extinguisher, but, when it has shocked the public, tries to reassure it with lies of breath-bereaving brazenness. That is the character the medical profession has got just now. It may be deserved or it may not: there it is at all events, and the doctors who have not realized this are living in a fool's paradise.

As to the humor and conscience of doctors, they have as much as any other class of men, no more and no less.

And what other men dare pretend to be impartial where they have a strong pecuniary interest on one side? Nobody supposes that doctors are less virtuous than judges; but a judge whose salary and reputation depended on whether the verdict was for plaintiff or defendant, prosecutor or prisoner, would be as little trusted as a general in the pay of the enemy.

To offer me a doctor as my judge, and then weight his decision with a bribe of a large sum of money and a virtual guarantee that if he makes a mistake it can never be proved against him, is to go wildly beyond the ascertained strain which human nature will bear. It is simply unscientific to allege or believe that doctors do not under existing circumstances perform unnecessary operations and manufacture and prolong lucrative illnesses.

The only ones who can claim to be above suspicion are those who are so much sought after that their cured patients are immediately replaced by fresh ones. And there is this curious psychological fact to be remembered: a serious illness or a death advertizes the doctor exactly as a hanging advertizes the barrister who defended the person hanged.

Suppose, for example, a royal personage gets something wrong with his throat, or has a pain in his inside. If a doctor effects some trumpery cure with a wet compress or a peppermint lozenge nobody takes the least notice of him. But if he operates on the throat and kills the patient, or extirpates an internal organ and keeps the whole nation palpitating for days whilst the patient hovers in pain and fever between life and death, his fortune is made: every rich man who omits to call him in when the same symptoms appear in his household is held not to have done his utmost duty to the patient. The wonder is that there is a king or queen left alive in Europe.

DOCTOR'S CONSCIENCES

There is another difficulty in trusting to the honor and conscience of a doctor. Doctors are just like other Englishmen: most of them have no honor and no conscience: what they commonly mistake for these is sentimentality and an intense dread of doing anything that everybody else does not do, or omitting to do anything that everybody else does. This of course does amount to a sort of working or rule-of-thumb conscience; but it means that you will do anything, good or bad, provided you get enough people to keep you in countenance by doing it also. It is the sort of conscience that makes it possible to keep order on a pirate ship, or in a troop of brigands. It may be said that in the last analysis there is no other sort of honor or conscience in existence—that the assent of the majority is the only sanction known to ethics. No doubt this holds good in political practice. If mankind knew the facts, and agreed with the doctors, then the doctors would be in the right; and any person who thought otherwise would be a lunatic. But mankind does not agree, and does not know the facts. All that can be said for medical popularity is that until there is a practicable alternative to blind trust in the doctor, the truth about the doctor is so terrible that we dare not face it. Moliere saw through the doctors; but he had to call them in just the same. Napoleon had no illusions about them; but he had to die under their treatment just as much as the most credulous ignoramus that ever paid sixpence for a bottle of strong medicine. In this predicament most people, to save themselves from unbearable mistrust and misery, or from being driven by their conscience into actual conflict with the law, fall back on the old rule that if you cannot have what you believe in you must believe in what you have. When your child is ill or your wife dying, and you happen to be very fond of them, or even when, if you are not fond of them, you are human enough to forget every personal grudge before the spectacle of a fellow creature in pain or peril, what you want is comfort, reassurance, something to clutch at, were it but a straw. This the doctor brings you. You have a wildly urgent feeling that something must be done; and the doctor does something. Sometimes what he does kills the patient; but you do not know that; and the doctor assures you that all that human skill could do has been done. And nobody has the brutality to say to the newly bereft father, mother, husband, wife, brother, or sister, "You have killed your lost darling by your credulity."

THE PECULIAR PEOPLE

Besides, the calling in of the doctor is now compulsory except in cases where the patient is an adult—and not too ill to decide the steps to be taken. We are subject to prosecution for manslaughter or for criminal neglect if the patient dies without the consolations of the medical profession. This menace is kept before the public by the Peculiar People. The Peculiars, as they are called, have gained their name by believing that the Bible is infallible, and taking their belief quite seriously. The Bible is very clear as to the treatment of illness. The Epistle of James; chapter v., contains the following explicit directions:

14. Is any sick among you? let him call for the elders of the Church; and let them pray over him, anointing him with oil in the name of the Lord:

15. And the prayer of faith shall save the sick, and the Lord shall raise him up; and if he have committed sins, they shall be forgiven him.

The Peculiars obey these instructions and dispense with doctors. They are therefore prosecuted for manslaughter when their children die.

When I was a young man, the Peculiars were usually acquitted. The prosecution broke down when the doctor in the witness box was asked whether, if the child had had medical attendance, it would have lived. It was, of course, impossible for any man of sense and honor to assume divine omniscience by answering this in the affirmative, or indeed pretending to be able to answer it at all. And on this the judge had to instruct the jury that they must acquit the prisoner. Thus a judge with a keen sense of law (a very rare phenomenon on the Bench, by the way) was spared the possibility of leaving to sentence one prisoner (under the Blasphemy laws) for questioning the authority of Scripture, and another for ignorantly and superstitiously accepting it as a guide to conduct. To-day all this is changed. The doctor never hesitates to claim divine omniscience, nor to clamor for laws to punish any scepticism on the part of laymen. A modern doctor thinks nothing of signing the death certificate of one of his own diphtheria patients, and then going into the witness box and swearing a peculiar into prison for six months by assuring the jury, on oath, that if the prisoner's child, dead of diphtheria, had been placed under his treatment instead of that of St. James, it would not have lived. And he does so not only with impunity, but with public applause, though the logical course would be to prosecute him either for the murder of his own patient or for perjury in the case of St. James. Yet no barrister, apparently, dreams of asking for the statistics of the relative case-mortality in diphtheria among the Peculiars and among the believers in doctors, on which alone any valid opinion could be founded. The barrister is as superstitious as the doctor is infatuated; and the Peculiar goes unpitied to his cell, though nothing whatever has been proved except that his child does without the interference of a doctor as effectually as any of the hundreds of children who die every day of the same diseases in the doctor's care.

RECOIL OF THE DOGMA OF MEDICAL INFALLIBILITY ON THE DOCTOR

On the other hand, when the doctor is in the dock, or is the defendant in an action for malpractice, he has to struggle against the inevitable result of his former pretences to infinite knowledge and unerring skill. He has taught the jury and the judge, and even his own counsel, to believe that every doctor can, with a glance at the tongue, a touch on the pulse, and a reading of the clinical thermometer, diagnose with absolute certainty a patient's complaint, also that on dissecting a dead body he can infallibly put his finger on the cause of death, and, in cases where poisoning is suspected, the nature of the poison used. Now all this supposed exactness and infallibility is imaginary; and to treat a doctor as if his mistakes were necessarily malicious or corrupt malpractices (an inevitable deduction from the postulate that the doctor, being omniscient, cannot make

mistakes) is as unjust as to blame the nearest apothecary for not being prepared to supply you with sixpenny-worth of the elixir of life, or the nearest motor garage for not having perpetual motion on sale in gallon tins. But if apothecaries and motor car makers habitually advertized elixir of life and perpetual motion, and succeeded in creating a strong general belief that they could supply it, they would find themselves in an awkward position if they were indicted for allowing a customer to die, or for burning a chauffeur by putting petrol into his car. That is the predicament the doctor finds himself in when he has to defend himself against a charge of malpractice by a plea of ignorance and fallibility. His plea is received with flat credulity; and he gets little sympathy, even from laymen who know, because he has brought the incredulity on himself. If he escapes, he can only do so by opening the eyes of the jury to the facts that medical science is as yet very imperfectly differentiated from common curemongering witchcraft; that diagnosis, though it means in many instances (including even the identification of pathogenic bacilli under the microscope) only a choice among terms so loose that they would not be accepted as definitions in any really exact science, is, even at that, an uncertain and difficult matter on which doctors often differ; and that the very best medical opinion and treatment varies widely from doctor to doctor, one practitioner prescribing six or seven scheduled poisons for so familiar a disease as enteric fever where another will not tolerate drugs at all; one starving a patient whom another would stuff; one urging an operation which another would regard as unnecessary and dangerous; one giving alcohol and meat which another would sternly forbid, etc., etc., etc.: all these discrepancies arising not between the opinion of good doctors and bad ones (the medical contention is, of course, that a bad doctor is an impossibility), but between practitioners of equal eminence and authority. Usually it is impossible to persuade the jury that these facts are facts. Juries seldom notice facts; and they have been taught to regard any doubts of the omniscience and omnipotence of doctors as blasphemy. Even the fact that doctors themselves die of the very diseases they profess to cure passes unnoticed. We do not shoot out our lips and shake our heads, saying, "They save others: themselves they cannot save": their reputation stands, like an African king's palace, on a foundation of dead bodies; and the result is that the verdict goes against the defendant when the defendant is a doctor accused of malpractice.

Fortunately for the doctors, they very seldom find themselves in this position, because it is so difficult to prove anything against them. The only evidence that can decide a case of malpractice is expert evidence: that is, the evidence of other doctors; and every doctor will allow a colleague to decimate a whole countryside sooner than violate the bond of professional etiquet by giving him away. It is the nurse who gives the doctor away in private, because every nurse has some particular doctor whom she likes; and she usually assures her patients that all the others are disastrous noodles, and soothes the tedium of the sick-bed by gossip about their blunders. She will even give a doctor away for the sake of making the patient believe that she knows more than the doctor. But she dare not, for her livelihood, give the doctor away in public. And the doctors stand by one another at all costs. Now and then some doctor in an unassailable

position, like the late Sir William Gull, will go into the witness box and say what he really thinks about the way a patient has been treated; but such behavior is considered little short of infamous by his colleagues.

WHY DOCTORS DO NOT DIFFER

The truth is, there would never be any public agreement among doctors if they did not agree to agree on the main point of the doctor being always in the right. Yet the two guinea man never thinks that the five shilling man is right: if he did, he would be understood as confessing to an overcharge of one pound seventeen shillings; and on the same ground the five shilling man cannot encourage the notion that the owner of the sixpenny surgery round the corner is quite up to his mark. Thus even the layman has to be taught that infallibility is not quite infallible, because there are two qualities of it to be had at two prices.

But there is no agreement even in the same rank at the same price. During the first great epidemic of influenza towards the end of the nineteenth century a London evening paper sent round a journalist-patient to all the great consultants of that day, and published their advice and prescriptions; a proceeding passionately denounced by the medical papers as a breach of confidence of these eminent physicians. The case was the same; but the prescriptions were different, and so was the advice. Now a doctor cannot think his own treatment right and at the same time think his colleague right in prescribing a different treatment when the patient is the same. Anyone who has ever known doctors well enough to hear medical shop talked without reserve knows that they are full of stories about each other's blunders and errors, and that the theory of their omniscience and omnipotence no more holds good among themselves than it did with Moliere and Napoleon. But for this very reason no doctor dare accuse another of malpractice. He is not sure enough of his own opinion to ruin another man by it. He knows that if such conduct were tolerated in his profession no doctor's livelihood or reputation would be worth a year's purchase. I do not blame him: I would do the same myself. But the effect of this state of things is to make the medical profession a conspiracy to hide its own shortcomings. No doubt the same may be said of all professions. They are all conspiracies against the laity; and I do not suggest that the medical conspiracy is either better or worse than the military conspiracy, the legal conspiracy, the sacerdotal conspiracy, the pedagogic conspiracy, the royal and aristocratic conspiracy, the literary and artistic conspiracy, and the innumerable industrial, commercial, and financial conspiracies, from the trade unions to the great exchanges, which make up the huge conflict which we call society. But it is less suspected. The Radicals who used to advocate, as an indispensable preliminary to social reform, the strangling of the last king with the entrails of the last priest, substituted compulsory vaccination for compulsory baptism without a murmur.

THE CRAZE FOR OPERATIONS

Thus everything is on the side of the doctor. When men die of disease they are said to die from natural causes. When they recover (and they mostly do) the doctor gets the credit of curing them. In surgery all operations are recorded as successful if the patient can be got out of the hospital or nursing home alive, though the subsequent history of the case may be such as would make an honest surgeon vow never to recommend or perform the operation again.

The large range of operations which consist of amputating limbs and extirpating organs admits of no direct verification of their necessity. There is a fashion in operations as there is in sleeves and skirts: the triumph of some surgeon who has at last found out how to make a once desperate operation fairly safe is usually followed by a rage for that operation not only among the doctors, but actually among their patients. There are men and women whom the operating table seems to fascinate; half-alive people who through vanity, or hypochondria, or a craving to be the constant objects of anxious attention or what not, lose such feeble sense as they ever had of the value of their own organs and limbs. They seem to care as little for mutilation as lobsters or lizards, which at least have the excuse that they grow new claws and new tails if they lose the old ones. Whilst this book was being prepared for the press a case was tried in the Courts, of a man who sued a railway company for damages because a train had run over him and amputated both his legs. He lost his case because it was proved that he had deliberately contrived the occurrence himself for the sake of getting an idler's pension at the expense of the railway company, being too dull to realize how much more he had to lose than to gain by the bargain even if he had won his case and received damages above his utmost hopes.

Thus amazing case makes it possible to say, with some prospect of being believed, that there is in the classes who can afford to pay for fashionable operations a sprinkling of persons so incapable of appreciating the relative importance of preserving their bodily integrity, (including the capacity for parentage) and the pleasure of talking about themselves and hearing themselves talked about as the heroes and heroines of sensational operations, that they tempt surgeons to operate on them not only with large fees, but with personal solicitation. Now it cannot be too often repeated that when an operation is once performed, nobody can ever prove that it was unnecessary. If I refuse to allow my leg to be amputated, its mortification and my death may prove that I was wrong; but if I let the leg go, nobody can ever prove that it would not have mortified had I been obstinate. Operation is therefore the safe side for the surgeon as well as the lucrative side. The result is that we hear of "conservative surgeons" as a distinct class of practitioners who make it a rule not to operate if they can possibly help it, and who are sought after by the people who have vitality enough to regard an operation as a last resort. But no surgeon is bound to take the conservative view. If he believes that an organ is at best a useless survival, and that if he extirpates it the patient will be well and none the worse in a fortnight, whereas to await the natural cure would mean a month's illness, then he is clearly justified in recommending the operation even if the cure without operation is as certain as anything of the kind ever can be. Thus the

conservative surgeon and the radical or extirpatory surgeon may both be right as far as the ultimate cure is concerned; so that their consciences do not help them out of their differences.

CREDULITY AND CHLOROFORM

There is no harder scientific fact in the world than the fact that belief can be produced in practically unlimited quantity and intensity, without observation or reasoning, and even in defiance of both, by the simple desire to believe founded on a strong interest in believing. Everybody recognizes this in the case of the amatory infatuations of the adolescents who see angels and heroes in obviously (to others) commonplace and even objectionable maidens and youths. But it holds good over the entire field of human activity. The hardest-headed materialist will become a consulter of table-rappers and slate-writers if he loses a child or a wife so beloved that the desire to revive and communicate with them becomes irresistible. The cobbler believes that there is nothing like leather. The Imperialist who regards the conquest of England by a foreign power as the worst of political misfortunes believes that the conquest of a foreign power by England would be a boon to the conquered. Doctors are no more proof against such illusions than other men. Can anyone then doubt that under existing conditions a great deal of unnecessary and mischievous operating is bound to go on, and that patients are encouraged to imagine that modern surgery and anesthesia have made operations much less serious matters than they really are? When doctors write or speak to the public about operations, they imply, and often say in so many words, that chloroform has made surgery painless. People who have been operated on know better. The patient does not feel the knife, and the operation is therefore enormously facilitated for the surgeon; but the patient pays for the anesthesia with hours of wretched sickness; and when that is over there is the pain of the wound made by the surgeon, which has to heal like any other wound. This is why operating surgeons, who are usually out of the house with their fee in their pockets before the patient has recovered consciousness, and who therefore see nothing of the suffering witnessed by the general practitioner and the nurse, occasionally talk of operations very much as the hangman in Barnaby Rudge talked of executions, as if being operated on were a luxury in sensation as well as in price.

MEDICAL POVERTY

To make matters worse, doctors are hideously poor. The Irish gentleman doctor of my boyhood, who took nothing less than a guinea, though he might pay you four visits for it, seems to have no equivalent nowadays in English society. Better be a railway porter than an ordinary English general practitioner. A railway porter has from eighteen to twenty-three shillings a week from the Company merely as a retainer; and his additional fees from the public, if we leave the third-class twopenny tip out of account (and I am by no means sure that even this reservation need be made), are equivalent to doctor's fees in the case of second-class passengers, and double doctor's fees in the case of first.

Any class of educated men thus treated tends to become a brigand class, and doctors are no exception to the rule. They are offered disgraceful prices for advice and medicine. Their patients are for the most part so poor and so ignorant that good advice would be resented as impracticable and wounding. When you are so poor that you cannot afford to refuse eighteenpence from a man who is too poor to pay you any more, it is useless to tell him that what he or his sick child needs is not medicine, but more leisure, better clothes, better food, and a better drained and ventilated house.

It is kinder to give him a bottle of something almost as cheap as water, and tell him to come again with another eighteenpence if it does not cure him. When you have done that over and over again every day for a week, how much scientific conscience have you left? If you are weak-minded enough to cling desperately to your eighteenpence as denoting a certain social superiority to the sixpenny doctor, you will be miserably poor all your life; whilst the sixpenny doctor, with his low prices and quick turnover of patients, visibly makes much more than you do and kills no more people.

A doctor's character can no more stand out against such conditions than the lungs of his patients can stand out against bad ventilation. The only way in which he can preserve his self-respect is by forgetting all he ever learnt of science, and clinging to such help as he can give without cost merely by being less ignorant and more accustomed to sick-beds than his patients. Finally, he acquires a certain skill at nursing cases under poverty-stricken domestic conditions, just as women who have been trained as domestic servants in some huge institution with lifts, vacuum cleaners, electric lighting, steam heating, and machinery that turns the kitchen into a laboratory and engine house combined, manage, when they are sent out into the world to drudge as general servants, to pick up their business in a new way, learning the slatternly habits and wretched makeshifts of homes where even bundles of kindling wood are luxuries to be anxiously economized.

THE SUCCESSFUL DOCTOR

The doctor whose success blinds public opinion to medical poverty is almost as completely demoralized. His promotion means that his practice becomes more and more confined to the idle rich. The proper advice for most of their ailments is typified in Abernethy's "Live on sixpence a day and earn it." But here, as at the other end of the scale, the right advice is neither agreeable nor practicable. And every hypochondriacal rich lady or gentleman who can be persuaded that he or she is a lifelong invalid means anything from fifty to five hundred pounds a year for the doctor. Operations enable a surgeon to earn similar sums in a couple of hours; and if the surgeon also keeps a nursing home, he may make considerable profits at the same time by running what is the most expensive kind of hotel. These gains are so great that they undo much of the moral advantage which the absence of grinding pecuniary anxiety gives the rich doctor over the poor one. It is true that the temptation to prescribe a sham treatment because the real treatment is too dear for either patient or doctor does not exist for the rich

doctor. He always has plenty of genuine cases which can afford genuine treatment; and these provide him with enough sincere scientific professional work to save him from the ignorance, obsolescence, and atrophy of scientific conscience into which his poorer colleagues sink. But on the other hand his expenses are enormous. Even as a bachelor, he must, at London west end rates, make over a thousand a year before he can afford even to insure his life. His house, his servants, and his equipage (or autopage) must be on the scale to which his patients are accustomed, though a couple of rooms with a camp bed in one of them might satisfy his own requirements. Above all, the income which provides for these outgoings stops the moment he himself stops working. Unlike the man of business, whose managers, clerks, warehousemen and laborers keep his business going whilst he is in bed or in his club, the doctor cannot earn a farthing by deputy. Though he is exceptionally exposed to infection, and has to face all weathers at all hours of the night and day, often not enjoying a complete night's rest for a week, the money stops coming in the moment he stops going out; and therefore illness has special terrors for him, and success no certain permanence. He dare not stop making hay while the sun shines; for it may set at any time. Men do not resist pressure of this intensity. When they come under it as doctors they pay unnecessary visits; they write prescriptions that are as absurd as the rub of chalk with which an Irish tailor once charmed away a wart from my father's finger; they conspire with surgeons to promote operations; they nurse the delusions of the malade imaginaire (who is always really ill because, as there is no such thing as perfect health, nobody is ever really well); they exploit human folly, vanity, and fear of death as ruthlessly as their own health, strength, and patience are exploited by selfish hypochondriacs. They must do all these things or else run pecuniary risks that no man can fairly be asked to run. And the healthier the world becomes, the more they are compelled to live by imposture and the less by that really helpful activity of which all doctors get enough to preserve them from utter corruption. For even the most hardened humbug who ever prescribed ether tonics to ladies whose need for tonics is of precisely the same character as the need of poorer women for a glass of gin, has to help a mother through child-bearing often enough to feel that he is not living wholly in vain.

THE PSYCHOLOGY OF SELF-RESPECT IN SURGEONS

The surgeon, though often more unscrupulous than the general practitioner, retains his self-respect more easily. The human conscience can subsist on very questionable food. No man who is occupied in doing a very difficult thing, and doing it very well, ever loses his self-respect. The shirk, the duffer, the malingerer, the coward, the weakling, may be put out of countenance by his own failures and frauds; but the man who does evil skilfully, energetically, masterfully, grows prouder and bolder at every crime. The common man may have to found his self-respect on sobriety, honesty and industry; but a Napoleon needs no such props for his sense of dignity. If Nelson's conscience whispered to him at all in the silent watches of the night, you may depend on it it whispered about the Baltic and the Nile and Cape St. Vincent, and not about his unfaithfulness to his wife. A man who robs little children when no one is looking can

hardly have much self-respect or even self-esteem; but an accomplished burglar must be proud of himself. In the play to which I am at present preluding I have represented an artist who is so entirely satisfied with his artistic conscience, even to the point of dying like a saint with its support, that he is utterly selfish and unscrupulous in every other relation without feeling at the smallest disadvantage. The same thing may be observed in women who have a genius for personal attractiveness: they expend more thought, labor, skill, inventiveness, taste and endurance on making themselves lovely than would suffice to keep a dozen ugly women honest; and this enables them to maintain a high opinion of themselves, and an angry contempt for unattractive and personally careless women, whilst they lie and cheat and slander and sell themselves without a blush. The truth is, hardly any of us have ethical energy enough for more than one really inflexible point of honor. Andrea del Sarto, like Louis Dubedat in my play, must have expended on the attainment of his great mastery of design and his originality in fresco painting more conscientiousness and industry than go to the making of the reputations of a dozen ordinary mayors and churchwardens; but (if Vasari is to be believed) when the King of France entrusted him with money to buy pictures for him, he stole it to spend on his wife. Such cases are not confined to eminent artists. Unsuccessful, unskilful men are often much more scrupulous than successful ones. In the ranks of ordinary skilled labor many men are to be found who earn good wages and are never out of a job because they are strong, indefatigable, and skilful, and who therefore are bold in a high opinion of themselves; but they are selfish and tyrannical, gluttonous and drunken, as their wives and children know to their cost.

Not only do these talented energetic people retain their self-respect through shameful misconduct: they do not even lose the respect of others, because their talents benefit and interest everybody, whilst their vices affect only a few. An actor, a painter, a composer, an author, may be as selfish as he likes without reproach from the public if only his art is superb; and he cannot fulfil his condition without sufficient effort and sacrifice to make him feel noble and martyred in spite of his selfishness. It may even happen that the selfishness of an artist may be a benefit to the public by enabling him to concentrate himself on their gratification with a recklessness of every other consideration that makes him highly dangerous to those about him. In sacrificing others to himself he is sacrificing them to the public he gratifies; and the public is quite content with that arrangement. The public actually has an interest in the artist's vices.

It has no such interest in the surgeon's vices. The surgeon's art is exercised at its expense, not for its gratification. We do not go to the operating table as we go to the theatre, to the picture gallery, to the concert room, to be entertained and delighted: we go to be tormented and maimed, lest a worse thing should befall us. It is of the most extreme importance to us that the experts on whose assurance we face this horror and suffer this mutilation should leave no interests but our own to think of; should judge our cases scientifically; and should feel about them kindly. Let us see what guarantees we have: first for the science, and then for the kindness.

ARE DOCTORS MEN OF SCIENCE?

I presume nobody will question the existence of widely spread popular delusion that every doctor is a titan of science. It is escaped only in the very small class which understands by science something more than conjuring with retorts and spirit lamps, magnets and microscopes, and discovering magical cures for disease. To a sufficiently ignorant man every captain of a trading schooner is a Galileo, every organ-grinder a Beethoven, every piano-tuner a Hemholtz, every Old Bailey barrister a Solon, every Seven Dials pigeon dealer a Darwin, every scrivener a Shakespear, every locomotive engine a miracle, and its driver no less wonderful than George Stephenson. As a matter of fact, the rank and file of doctors are no more scientific than their tailors; or, if you prefer to put it the reverse way, their tailors are no less scientific than they. Doctoring is an art, not a science: any layman who is interested in science sufficiently to take in one of the scientific journals and follow the literature of the scientific movement, knows more about it than those doctors (probably a large majority) who are not interested in it, and practise only to earn their bread. Doctoring is not even the art of keeping people in health (no doctor seems able to advise you what to eat any better than his grandmother or the nearest quack): it is the art of curing illnesses.

It does happen exceptionally that a practising doctor makes a contribution to science (my play describes a very notable one); but it happens much oftener that he draws disastrous conclusions from his clinical experience because he has no conception of scientific method, and believes, like any rustic, that the handling of evidence and statistics needs no expertness. The distinction between a quack doctor and a qualified one is mainly that only the qualified one is authorized to sign death certificates, for which both sorts seem to have about equal occasion. Unqualified practitioners now make large incomes as hygienists, and are resorted to as frequently by cultivated amateur scientists who understand quite well what they are doing as by ignorant people who are simply dupes. Bone-setters make fortunes under the very noses of our greatest surgeons from educated and wealthy patients; and some of the most successful doctors on the register use quite heretical methods of treating disease, and have qualified themselves solely for convenience. Leaving out of account the village witches who prescribe spells and sell charms, the humblest professional healers in this country are the herbalists. These men wander through the fields on Sunday seeking for herbs with magic properties of curing disease, preventing childbirth, and the like. Each of them believes that he is on the verge of a great discovery, in which Virginia Snake Root will be an ingredient, heaven knows why! Virginia Snake Root fascinates the imagination of the herbalist as mercury used to fascinate the alchemists. On week days he keeps a shop in which he sells packets of pennyroyal, dandelion, etc., labelled with little lists of the diseases they are supposed to cure, and apparently do cure to the satisfaction of the people who keep on buying them. I have never been able to perceive any distinction between the science of the herbalist and that of the duly registered doctor. A relative of mine recently consulted a doctor about some of the ordinary symptoms which indicate the need for a holiday and a change. The doctor satisfied himself that the patient's heart

was a little depressed. Digitalis being a drug labelled as a heart specific by the profession, he promptly administered a stiff dose. Fortunately the patient was a hardy old lady who was not easily killed. She recovered with no worse result than her conversion to Christian Science, which owes its vogue quite as much to public despair of doctors as to superstition. I am not, observe, here concerned with the question as to whether the dose of digitalis was judicious or not; the point is, that a farm laborer consulting a herbalist would have been treated in exactly the same way.

BACTERIOLOGY AS A SUPERSTITION

The smattering of science that all—even doctors—pick up from the ordinary newspapers nowadays only makes the doctor more dangerous than he used to be. Wise men used to take care to consult doctors qualified before 1860, who were usually contemptuous of or indifferent to the germ theory and bacteriological therapeutics; but now that these veterans have mostly retired or died, we are left in the hands of the generations which, having heard of microbes much as St. Thomas Aquinas heard of angels, suddenly concluded that the whole art of healing could be summed up in the formula: Find the microbe and kill it. And even that they did not know how to do. The simplest way to kill most microbes is to throw them into an open street or river and let the sun shine on them, which explains the fact that when great cities have recklessly thrown all their sewage into the open river the water has sometimes been cleaner twenty miles below the city than thirty miles above it. But doctors instinctively avoid all facts that are reassuring, and eagerly swallow those that make it a marvel that anyone could possibly survive three days in an atmosphere consisting mainly of countless pathogenic germs. They conceive microbes as immortal until slain by a germicide administered by a duly qualified medical man. All through Europe people are adjured, by public notices and even under legal penalties, not to throw their microbes into the sunshine, but to collect them carefully in a handkerchief; shield the handkerchief from the sun in the darkness and warmth of the pocket; and send it to a laundry to be mixed up with everybody else's handkerchiefs, with results only too familiar to local health authorities.

In the first frenzy of microbe killing, surgical instruments were dipped in carbolic oil, which was a great improvement on not dipping them in anything at all and simply using them dirty; but as microbes are so fond of carbolic oil that they swarm in it, it was not a success from the anti-microbe point of view. Formalin was squirted into the circulation of consumptives until it was discovered that formalin nourishes the tubercle bacillus handsomely and kills men. The popular theory of disease is the common medical theory: namely, that every disease had its microbe duly created in the garden of Eden, and has been steadily propagating itself and producing widening circles of malignant disease ever since. It was plain from the first that if this had been even approximately true, the whole human race would have been wiped out by the plague long ago, and that every epidemic, instead of fading out as mysteriously as it rushed in, would spread over the whole world. It was also evident that the characteristic microbe of a disease

might be a symptom instead of a cause. An unpunctual man is always in a hurry; but it does not follow that hurry is the cause of unpunctuality: on the contrary, what is the matter with the patient is sloth. When Florence Nightingale said bluntly that if you overcrowded your soldiers in dirty quarters there would be an outbreak of smallpox among them, she was snubbed as an ignorant female who did not know that smallpox can be produced only by the importation of its specific microbe.

If this was the line taken about smallpox, the microbe of which has never yet been run down and exposed under the microscope by the bacteriologist, what must have been the ardor of conviction as to tuberculosis, tetanus, enteric fever, Maltese fever, diphtheria, and the rest of the diseases in which the characteristic bacillus had been identified! When there was no bacillus it was assumed that, since no disease could exist without a bacillus, it was simply eluding observation. When the bacillus was found, as it frequently was, in persons who were not suffering from the disease, the theory was saved by simply calling the bacillus an impostor, or pseudobacillus. The same boundless credulity which the public exhibit as to a doctor's power of diagnosis was shown by the doctors themselves as to the analytic microbe hunters. These witch finders would give you a certificate of the ultimate constitution of anything from a sample of the water from your well to a scrap of your lungs, for seven-and-sixpense. I do not suggest that the analysts were dishonest. No doubt they carried the analysis as far as they could afford to carry it for the money. No doubt also they could afford to carry it far enough to be of some use. But the fact remains that just as doctors perform for half-a-crown, without the least misgiving, operations which could not be thoroughly and safely performed with due scientific rigor and the requisite apparatus by an unaided private practitioner for less than some thousands of pounds, so did they proceed on the assumption that they could get the last word of science as to the constituents of their pathological samples for a two hours cab fare.

ECONOMIC DIFFICULTIES OF IMMUNIZATION

I have heard doctors affirm and deny almost every possible proposition as to disease and treatment. I can remember the time when doctors no more dreamt of consumption and pneumonia being infectious than they now dream of sea-sickness being infectious, or than so great a clinical observer as Sydenham dreamt of smallpox being infectious. I have heard doctors deny that there is such a thing as infection. I have heard them deny the existence of hydrophobia as a specific disease differing from tetanus. I have heard them defend prophylactic measures and prophylactic legislation as the sole and certain salvation of mankind from zymotic disease; and I have heard them denounce both as malignant spreaders of cancer and lunacy. But the one objection I have never heard from a doctor is the objection that prophylaxis by the inoculatory methods most in vogue is an economic impossibility under our private practice system. They buy some stuff from somebody for a shilling, and inject a pennyworth of it under their patient's skin for half-a-crown, concluding that, since this primitive rite pays the somebody and pays them, the problem of prophylaxis has been satisfactorily solved. The results are

sometimes no worse than the ordinary results of dirt getting into cuts; but neither the doctor nor the patient is quite satisfied unless the inoculation "takes"; that is, unless it produces perceptible illness and disablement. Sometimes both doctor and patient get more value in this direction than they bargain for. The results of ordinary private-practice-inoculation at their worst are bad enough to be indistinguishable from those of the most discreditable and dreaded disease known; and doctors, to save the credit of the inoculation, have been driven to accuse their patient or their patient's parents of having contracted this disease independently of the inoculation, an excuse which naturally does not make the family any more resigned, and leads to public recriminations in which the doctors, forgetting everything but the immediate quarrel, naively excuse themselves by admitting, and even claiming as a point in their favor, that it is often impossible to distinguish the disease produced by their inoculation and the disease they have accused the patient of contracting. And both parties assume that what is at issue is the scientific soundness of the prophylaxis. It never occurs to them that the particular pathogenic germ which they intended to introduce into the patient's system may be quite innocent of the catastrophe, and that the casual dirt introduced with it may be at fault. When, as in the case of smallpox or cowpox, the germ has not yet been detected, what you inoculate is simply undefined matter that has been scraped off an anything but chemically clean calf suffering from the disease in question. You take your chance of the germ being in the scrapings, and, lest you should kill it, you take no precautions against other germs being in it as well. Anything may happen as the result of such an inoculation. Yet this is the only stuff of the kind which is prepared and supplied even in State establishments: that is, in the only establishments free from the commercial temptation to adulterate materials and scamp precautionary processes.

Even if the germ were identified, complete precautions would hardly pay. It is true that microbe farming is not expensive. The cost of breeding and housing two head of cattle would provide for the breeding and housing of enough microbes to inoculate the entire population of the globe since human life first appeared on it. But the precautions necessary to insure that the inoculation shall consist of nothing else but the required germ in the proper state of attenuation are a very different matter from the precautions necessary in the distribution and consumption of beefsteaks. Yet people expect to find vaccines and antitoxins and the like retailed at "popular prices" in private enterprise shops just as they expect to find ounces of tobacco and papers of pins.

THE PERILS OF INOCULATION

The trouble does not end with the matter to be inoculated. There is the question of the condition of the patient. The discoveries of Sir Almroth Wright have shown that the appalling results which led to the hasty dropping in 1894 of Koch's tuberculin were not accidents, but perfectly orderly and inevitable phenomena following the injection of dangerously strong "vaccines" at the wrong moment, and reinforcing the disease instead of stimulating the resistance to it. To ascertain the right moment a laboratory and a staff of experts are needed. The general practitioner, having no such laboratory

and no such experience, has always chanced it, and insisted, when he was unlucky, that the results were not due to the inoculation, but to some other cause: a favorite and not very tactful one being the drunkenness or licentiousness of the patient. But though a few doctors have now learnt the danger of inoculating without any reference to the patient's "opsonic index" at the moment of inoculation, and though those other doctors who are denouncing the danger as imaginary and opsonin as a craze or a fad, obviously do so because it involves an operation which they have neither the means nor the knowledge to perform, there is still no grasp of the economic change in the situation. They have never been warned that the practicability of any method of extirpating disease depends not only on its efficacy, but on its cost. For example, just at present the world has run raving mad on the subject of radium, which has excited our credulity precisely as the apparitions at Lourdes excited the credulity of Roman Catholics. Suppose it were ascertained that every child in the world could be rendered absolutely immune from all disease during its entire life by taking half an ounce of radium to every pint of its milk. The world would be none the healthier, because not even a Crown Prince—no, not even the son of a Chicago Meat King, could afford the treatment. Yet it is doubtful whether doctors would refrain from prescribing it on that ground. The recklessness with which they now recommend wintering in Egypt or at Davos to people who cannot afford to go to Cornwall, and the orders given for champagne jelly and old port in households where such luxuries must obviously be acquired at the cost of stinting necessaries, often make one wonder whether it is possible for a man to go through a medical training and retain a spark of common sense. This sort of inconsiderateness gets cured only in the classes where poverty, pretentious as it is even at its worst, cannot pitch its pretences high enough to make it possible for the doctor (himself often no better off than the patient) to assume that the average income of an English family is about 2,000 pounds a year, and that it is quite easy to break up a home, sell an old family seat at a sacrifice, and retire into a foreign sanatorium devoted to some "treatment" that did not exist two years ago and probably will not exist (except as a pretext for keeping an ordinary hotel) two years hence. In a poor practice the doctor must find cheap treatments for cheap people, or humiliate and lose his patients either by prescribing beyond their means or sending them to the public hospitals. When it comes to prophylactic inoculation, the alternative lies between the complete scientific process, which can only be brought down to a reasonable cost by being very highly organized as a public service in a public institution, and such cheap, nasty, dangerous and scientifically spurious imitations as ordinary vaccination, which seems not unlikely to be ended, like its equally vaunted forerunner, XVIII. century inoculation, by a purely reactionary law making all sorts of vaccination, scientific or not, criminal offences. Naturally, the poor doctor (that is, the average doctor) defends ordinary vaccination frantically, as it means to him the bread of his children. To secure the vehement and practically unanimous support of the rank and file of the medical profession for any sort of treatment or operation, all that is necessary is that it can be easily practised by a rather shabbily dressed man in a surgically dirty room in a surgically dirty house without any assistance, and that the materials for it shall cost, say, a penny, and the charge for

it to a patient with 100 pounds a year be half-a-crown. And, on the other hand, a hygienic measure has only to be one of such refinement, difficulty, precision and costliness as to be quite beyond the resources of private practice, to be ignored or angrily denounced as a fad.

TRADE UNIONISM AND SCIENCE

Here we have the explanation of the savage rancor that so amazes people who imagine that the controversy concerning vaccination is a scientific one. It has really nothing to do with science. The medical profession, consisting for the most part of very poor men struggling to keep up appearances beyond their means, find themselves threatened with the extinction of a considerable part of their incomes: a part, too, that is easily and regularly earned, since it is independent of disease, and brings every person born into the nation, healthy or not, to the doctors. To boot, there is the occasional windfall of an epidemic, with its panic and rush for revaccination. Under such circumstances, vaccination would be defended desperately were it twice as dirty, dangerous, and unscientific in method as it actually is. The note of fury in the defence, the feeling that the anti-vaccinator is doing a cruel, ruinous, inconsiderate thing in a mood of indignant folly: all this, so puzzling to the observer who knows nothing of the economic side of the question, and only sees that the anti-vaccinator, having nothing whatever to gain and a good deal to lose by placing himself in opposition to the law and to the outcry that adds private persecution to legal penalties, can have no interest in the matter except the interest of a reformer in abolishing a corrupt and mischievous superstition, becomes intelligible the moment the tragedy of medical poverty and the lucrativeness of cheap vaccination is taken into account.

In the face of such economic pressure as this, it is silly to expect that medical teaching, any more than medical practice, can possibly be scientific. The test to which all methods of treatment are finally brought is whether they are lucrative to doctors or not. It would be difficult to cite any proposition less obnoxious to science, than that advanced by Hahnemann: to wit, that drugs which in large doses produce certain symptoms, counteract them in very small doses, just as in more modern practice it is found that a sufficiently small inoculation with typhoid rallies our powers to resist the disease instead of prostrating us with it. But Hahnemann and his followers were frantically persecuted for a century by generations of apothecary-doctors whose incomes depended on the quantity of drugs they could induce their patients to swallow. These two cases of ordinary vaccination and homeopathy are typical of all the rest. Just as the object of a trade union under existing conditions must finally be, not to improve the technical quality of the work done by its members, but to secure a living wage for them, so the object of the medical profession today is to secure an income for the private doctor; and to this consideration all concern for science and public health must give way when the two come into conflict. Fortunately they are not always in conflict. Up to a certain point doctors, like carpenters and masons, must earn their living by doing the work that the public wants from them; and as it is not in the nature of things possible that such public

want should be based on unmixed disutility, it may be admitted that doctors have their uses, real as well as imaginary. But just as the best carpenter or mason will resist the introduction of a machine that is likely to throw him out of work, or the public technical education of unskilled laborers' sons to compete with him, so the doctor will resist with all his powers of persecution every advance of science that threatens his income. And as the advance of scientific hygiene tends to make the private doctor's visits rarer, and the public inspector's frequenter, whilst the advance of scientific therapeutics is in the direction of treatments that involve highly organized laboratories, hospitals, and public institutions generally, it unluckily happens that the organization of private practitioners which we call the medical profession is coming more and more to represent, not science, but desperate and embittered antiscience: a statement of things which is likely to get worse until the average doctor either depends upon or hopes for an appointment in the public health service for his livelihood.

So much for our guarantees as to medical science. Let us now deal with the more painful subject of medical kindness.

DOCTORS AND VIVISECTION

The importance to our doctors of a reputation for the tenderest humanity is so obvious, and the quantity of benevolent work actually done by them for nothing (a great deal of it from sheer good nature) so large, that at first sight it seems unaccountable that they should not only throw all their credit away, but deliberately choose to band themselves publicly with outlaws and scoundrels by claiming that in the pursuit of their professional knowledge they should be free from the restraints of law, of honor, of pity, of remorse, of everything that distinguishes an orderly citizen from a South Sea buccaneer, or a philosopher from an inquisitor. For here we look in vain for either an economic or a sentimental motive. In every generation fools and blackguards have made this claim; and honest and reasonable men, led by the strongest contemporary minds, have repudiated it and exposed its crude rascality. From Shakespear and Dr. Johnson to Ruskin and Mark Twain, the natural abhorrence of sane mankind for the vivisector's cruelty, and the contempt of able thinkers for his imbecile casuistry, have been expressed by the most popular spokesmen of humanity. If the medical profession were to outdo the Anti-Vivisection Societies in a general professional protest against the practice and principles of the vivisectors, every doctor in the kingdom would gain substantially by the immense relief and reconciliation which would follow such a reassurance of the humanity of the doctor. Not one doctor in a thousand is a vivisector, or has any interest in vivisection, either pecuniary or intellectual, or would treat his dog cruelly or allow anyone else to do it. It is true that the doctor complies with the professional fashion of defending vivisection, and assuring you that people like Shakespear and Dr. Johnson and Ruskin and Mark Twain are ignorant sentimentalists, just as he complies with any other silly fashion: the mystery is, how it became the fashion in spite of its being so injurious to those who follow it. Making all possible allowance for the effect of the brazen lying of the few men who bring a rush of

despairing patients to their doors by professing in letters to the newspapers to have learnt from vivisection how to cure certain diseases, and the assurances of the sayers of smooth things that the practice is quite painless under the law, it is still difficult to find any civilized motive for an attitude by which the medical profession has everything to lose and nothing to gain.

THE PRIMITIVE SAVAGE MOTIVE

I say civilized motive advisedly; for primitive tribal motives are easy enough to find. Every savage chief who is not a Mahomet learns that if he wishes to strike the imagination of his tribe—and without doing that he can rule them—he must terrify or revolt them from time to time by acts of hideous cruelty or disgusting unnaturalness. We are far from being as superior to such tribes as we imagine. It is very doubtful indeed whether Peter the Great could have effected the changes he made in Russia if he had not fascinated and intimidated his people by his monstrous cruelties and grotesque escapades. Had he been a nineteenth-century king of England, he would have had to wait for some huge accidental calamity: a cholera epidemic, a war, or an insurrection, before waking us up sufficiently to get anything done. Vivisection helps the doctor to rule us as Peter ruled the Russians. The notion that the man who does dreadful things is superhuman, and that therefore he can also do wonderful things either as ruler, avenger, healer, or what not, is by no means confined to barbarians. Just as the manifold wickednesses and stupidities of our criminal code are supported, not by any general comprehension of law or study of jurisprudence, not even by simple vindictiveness, but by the superstition that a calamity of any sort must be expiated by a human sacrifice; so the wickednesses and stupidities of our medicine men are rooted in superstitions that have no more to do with science than the traditional ceremony of christening an ironclad has to do with the effectiveness of its armament. We have only to turn to Macaulay's description of the treatment of Charles II in his last illness to see how strongly his physicians felt that their only chance of cheating death was by outraging nature in tormenting and disgusting their unfortunate patient. True, this was more than two centuries ago; but I have heard my own nineteenth-century grandfather describe the cupping and firing and nauseous medicines of his time with perfect credulity as to their beneficial effects; and some more modern treatments appear to me quite as barbarous. It is in this way that vivisection pays the doctor. It appeals to the fear and credulity of the savage in us; and without fear and credulity half the private doctor's occupation and seven-eighths of his influence would be gone.

THE HIGHER MOTIVE. THE TREE OF KNOWLEDGE.

But the greatest force of all on the side of vivisection is the mighty and indeed divine force of curiosity. Here we have no decaying tribal instinct which men strive to root out of themselves as they strive to root out the tiger's lust for blood. On the contrary, the curiosity of the ape, or of the child who pulls out the legs and wings of a fly to see what it will do without them, or who, on being told that a cat dropped out of the window will

always fall on its legs, immediately tries the experiment on the nearest cat from the highest window in the house (I protest I did it myself from the first floor only), is as nothing compared to the thirst for knowledge of the philosopher, the poet, the biologist, and the naturalist. I have always despised Adam because he had to be tempted by the woman, as she was by the serpent, before he could be induced to pluck the apple from the tree of knowledge. I should have swallowed every apple on the tree the moment the owner's back was turned. When Gray said "Where ignorance is bliss, 'tis folly to be wise," he forgot that it is godlike to be wise; and since nobody wants bliss particularly, or could stand more than a very brief taste of it if it were attainable, and since everybody, by the deepest law of the Life Force, desires to be godlike, it is stupid, and indeed blasphemous and despairing, to hope that the thirst for knowledge will either diminish or consent to be subordinated to any other end whatsoever. We shall see later on that the claim that has arisen in this way for the unconditioned pursuit of knowledge is as idle as all dreams of unconditioned activity; but none the less the right to knowledge must be regarded as a fundamental human right. The fact that men of science have had to fight so hard to secure its recognition, and are still so vigorously persecuted when they discover anything that is not quite palatable to vulgar people, makes them sorely jealous for that right; and when they hear a popular outcry for the suppression of a method of research which has an air of being scientific, their first instinct is to rally to the defence of that method without further consideration, with the result that they sometimes, as in the case of vivisection, presently find themselves fighting on a false issue.

THE FLAW IN THE ARGUMENT

I may as well pause here to explain their error. The right to know is like the right to live. It is fundamental and unconditional in its assumption that knowledge, like life, is a desirable thing, though any fool can prove that ignorance is bliss, and that "a little knowledge is a dangerous thing" (a little being the most that any of us can attain), as easily as that the pains of life are more numerous and constant than its pleasures, and that therefore we should all be better dead. The logic is unimpeachable; but its only effect is to make us say that if these are the conclusions logic leads to, so much the worse for logic, after which curt dismissal of Folly, we continue living and learning by instinct: that is, as of right. We legislate on the assumption that no man may be killed on the strength of a demonstration that he would be happier in his grave, not even if he is dying slowly of cancer and begs the doctor to despatch him quickly and mercifully. To get killed lawfully he must violate somebody else's right to live by committing murder. But he is by no means free to live unconditionally. In society he can exercise his right to live only under very stiff conditions. In countries where there is compulsory military service he may even have to throw away his individual life to save the life of the community.

It is just so in the case of the right to knowledge. It is a right that is as yet very imperfectly recognized in practice. But in theory it is admitted that an adult person in

pursuit of knowledge must not be refused it on the ground that he would be better or happier without it. Parents and priests may forbid knowledge to those who accept their authority; and social taboo may be made effective by acts of legal persecution under cover of repressing blasphemy, obscenity, and sedition; but no government now openly forbids its subjects to pursue knowledge on the ground that knowledge is in itself a bad thing, or that it is possible for any of us to have too much of it.

LIMITATIONS OF THE RIGHT TO KNOWLEDGE

But neither does any government exempt the pursuit of knowledge, any more than the pursuit of life, liberty, and happiness (as the American Constitution puts it), from all social conditions. No man is allowed to put his mother into the stove because he desires to know how long an adult woman will survive at a temperature of 500 degrees Fahrenheit, no matter how important or interesting that particular addition to the store of human knowledge may be. A man who did so would have short work made not only of his right to knowledge, but of his right to live and all his other rights at the same time. The right to knowledge is not the only right; and its exercise must be limited by respect for other rights, and for its own exercise by others. When a man says to Society, "May I torture my mother in pursuit of knowledge?" Society replies, "No." If he pleads, "What! Not even if I have a chance of finding out how to cure cancer by doing it?" Society still says, "Not even then." If the scientist, making the best of his disappointment, goes on to ask may he torture a dog, the stupid and callous people who do not realize that a dog is a fellow-creature and sometimes a good friend, may say Yes, though Shakespear, Dr. Johnson and their like may say No. But even those who say "You may torture A dog" never say "You may torture MY dog." And nobody says, "Yes, because in the pursuit of knowledge you may do as you please." Just as even the stupidest people say, in effect, "If you cannot attain to knowledge without burning your mother you must do without knowledge," so the wisest people say, "If you cannot attain to knowledge without torturing a dog, you must do without knowledge."

A FALSE ALTERNATIVE

But in practice you cannot persuade any wise man that this alternative can ever be forced on anyone but a fool, or that a fool can be trusted to learn anything from any experiment, cruel or humane. The Chinaman who burnt down his house to roast his pig was no doubt honestly unable to conceive any less disastrous way of cooking his dinner; and the roast must have been spoiled after all (a perfect type of the average vivisectionist experiment); but this did not prove that the Chinaman was right: it only proved that the Chinaman was an incapable cook and, fundamentally, a fool.

Take another celebrated experiment: one in sanitary reform. In the days of Nero Rome was in the same predicament as London to-day. If some one would burn down London, and it were rebuilt, as it would now have to be, subject to the sanitary by-laws and Building Act provisions enforced by the London County Council, it would be enormously improved; and the average lifetime of Londoners would be considerably prolonged.

Nero argued in the same way about Rome. He employed incendiaries to set it on fire; and he played the harp in scientific raptures whilst it was burning. I am so far of Nero's way of thinking that I have often said, when consulted by despairing sanitary reformers, that what London needs to make her healthy is an earthquake. Why, then, it may be asked, do not I, as a public-spirited man, employ incendiaries to set it on fire, with a heroic disregard of the consequences to myself and others? Any vivisector would, if he had the courage of his opinions. The reasonable answer is that London can be made healthy without burning her down; and that as we have not enough civic virtue to make her healthy in a humane and economical way, we should not have enough to rebuild her in that way. In the old Hebrew legend, God lost patience with the world as Nero did with Rome, and drowned everybody except a single family. But the result was that the progeny of that family reproduced all the vices of their predecessors so exactly that the misery caused by the flood might just as well have been spared: things went on just as they did before. In the same way, the lists of diseases which vivisection claims to have cured is long; but the returns of the Registrar-General show that people still persist in dying of them as if vivisection had never been heard of. Any fool can burn down a city or cut an animal open; and an exceptionally foolish fool is quite likely to promise enormous benefits to the race as the result of such activities. But when the constructive, benevolent part of the business comes to be done, the same want of imagination, the same stupidity and cruelty, the same laziness and want of perseverance that prevented Nero or the vivisector from devising or pushing through humane methods, prevents him from bringing order out of the chaos and happiness out of the misery he has made. At one time it seemed reasonable enough to declare that it was impossible to find whether or not there was a stone inside a man's body except by exploring it with a knife, or to find out what the sun is made of without visiting it in a balloon. Both these impossibilities have been achieved, but not by vivisectors. The Rontgen rays need not hurt the patient; and spectrum analysis involves no destruction. After such triumphs of humane experiment and reasoning, it is useless to assure us that there is no other key to knowledge except cruelty. When the vivisector offers us that assurance, we reply simply and contemptuously, "You mean that you are not clever or humane or energetic enough to find one."

CRUELTY FOR ITS OWN SAKE

It will now, I hope, be clear why the attack on vivisection is not an attack on the right to knowledge: why, indeed, those who have the deepest conviction of the sacredness of that right are the leaders of the attack. No knowledge is finally impossible of human attainment; for even though it may be beyond our present capacity, the needed capacity is not unattainable. Consequently no method of investigation is the only method; and no law forbidding any particular method can cut us off from the knowledge we hope to gain by it. The only knowledge we lose by forbidding cruelty is knowledge at first hand of cruelty itself, which is precisely the knowledge humane people wish to be spared.

But the question remains: Do we all really wish to be spared that knowledge? Are humane methods really to be preferred to cruel ones? Even if the experiments come to nothing, may not their cruelty be enjoyed for its own sake, as a sensational luxury? Let us face these questions boldly, not shrinking from the fact that cruelty is one of the primitive pleasures of mankind, and that the detection of its Protean disguises as law, education, medicine, discipline, sport and so forth, is one of the most difficult of the unending tasks of the legislator.

OUR OWN CRUELTIES

At first blush it may seem not only unnecessary, but even indecent, to discuss such a proposition as the elevation of cruelty to the rank of a human right. Unnecessary, because no vivisector confesses to a love of cruelty for its own sake or claims any general fundamental right to be cruel. Indecent, because there is an accepted convention to repudiate cruelty; and vivisection is only tolerated by the law on condition that, like judicial torture, it shall be done as mercifully as the nature of the practice allows. But the moment the controversy becomes embittered, the recriminations bandied between the opposed parties bring us face-to-face with some very ugly truths. On one occasion I was invited to speak at a large Anti-Vivisection meeting in the Queen's Hall in London. I found myself on the platform with fox hunters, tame stag hunters, men and women whose calendar was divided, not by pay days and quarter days, but by seasons for killing animals for sport: the fox, the hare, the otter, the partridge and the rest having each its appointed date for slaughter. The ladies among us wore hats and cloaks and head-dresses obtained by wholesale massacres, ruthless trappings, callous extermination of our fellow creatures. We insisted on our butchers supplying us with white veal, and were large and constant consumers of pate de foie gras; both comestibles being obtained by revolting methods. We sent our sons to public schools where indecent flogging is a recognized method of taming the young human animal. Yet we were all in hysterics of indignation at the cruelties of the vivisectors. These, if any were present, must have smiled sardonically at such inhuman humanitarians, whose daily habits and fashionable amusements cause more suffering in England in a week than all the vivisectors of Europe do in a year. I made a very effective speech, not exclusively against vivisection, but against cruelty; and I have never been asked to speak since by that Society, nor do I expect to be, as I should probably give such offence to its most affluent subscribers that its attempts to suppress vivisection would be seriously hindered. But that does not prevent the vivisectors from freely using the "youre another" retort, and using it with justice.

We must therefore give ourselves no airs of superiority when denouncing the cruelties of vivisection. We all do just as horrible things, with even less excuse. But in making that admission we are also making short work of the virtuous airs with which we are sometimes referred to the humanity of the medical profession as a guarantee that vivisection is not abused—much as if our burglars should assure us that they arc too

honest to abuse the practice of burgling. We are, as a matter of fact, a cruel nation; and our habit of disguising our vices by giving polite names to the offences we are determined to commit does not, unfortunately for my own comfort, impose on me. Vivisectors can hardly pretend to be better than the classes from which they are drawn, or those above them; and if these classes are capable of sacrificing animals in various cruel ways under cover of sport, fashion, education, discipline, and even, when the cruel sacrifices are human sacrifices, of political economy, it is idle for the vivisector to pretend that he is incapable of practising cruelty for pleasure or profit or both under the cloak of science. We are all tarred with the same brush; and the vivisectors are not slow to remind us of it, and to protest vehemently against being branded as exceptionally cruel and its devisors of horrible instruments of torture by people whose main notion of enjoyment is cruel sport, and whose requirements in the way of villainously cruel traps occupy pages of the catalogue of the Army and Navy Stores.

THE SCIENTIFIC INVESTIGATION OF CRUELTY

There is in man a specific lust for cruelty which infects even his passion of pity and makes it savage. Simple disgust at cruelty is very rare. The people who turn sick and faint and those who gloat are often alike in the pains they take to witness executions, floggings, operations or any other exhibitions of suffering, especially those involving bloodshed, blows, and laceration. A craze for cruelty can be developed just as a craze for drink can; and nobody who attempts to ignore cruelty as a possible factor in the attraction of vivisection and even of antivivisection, or in the credulity with which we accept its excuses, can be regarded as a scientific investigator of it. Those who accuse vivisectors of indulging the well-known passion of cruelty under the cloak of research are therefore putting forward a strictly scientific psychological hypothesis, which is also simple, human, obvious, and probable. It may be as wounding to the personal vanity of the vivisector as Darwin's Origin of Species was to the people who could not bear to think that they were cousins to the monkeys (remember Goldsmith's anger when he was told that he could not move his upper jaw); but science has to consider only the truth of the hypothesis, and not whether conceited people will like it or not. In vain do the sentimental champions of vivisection declare themselves the most humane of men, inflicting suffering only to relieve it, scrupulous in the use of anesthetics, and void of all passion except the passion of pity for a disease-ridden world. The really scientific investigator answers that the question cannot be settled by hysterical protestations, and that if the vivisectionist rejects deductive reasoning, he had better clear his character by his own favorite method of experiment.

SUGGESTED LABORATORY TESTS OF THE VIVISECTOR'S EMOTIONS

Take the hackneyed case of the Italian who tortured mice, ostensibly to find out about the effects of pain rather less than the nearest dentist could have told him, and who boasted of the ecstatic sensations (he actually used the word love) with which he carried out his experiments. Or the gentleman who starved sixty dogs to death to

establish the fact that a dog deprived of food gets progressively lighter and weaker, becoming remarkably emaciated, and finally dying: an undoubted truth, but ascertainable without laboratory experiments by a simple enquiry addressed to the nearest policeman, or, failing him, to any sane person in Europe. The Italian is diagnosed as a cruel voluptuary: the dog-starver is passed over as such a hopeless fool that it is impossible to take any interest in him. Why not test the diagnosis scientifically? Why not perform a careful series of experiments on persons under the influence of voluptuous ecstasy, so as to ascertain its physiological symptoms? Then perform a second series on persons engaged in mathematical work or machine designing, so as to ascertain the symptoms of cold scientific activity? Then note the symptoms of a vivisector performing a cruel experiment; and compare them with the voluptuary symptoms and the mathematical symptoms? Such experiments would be quite as interesting and important as any yet undertaken by the vivisectors. They might open a line of investigation which would finally make, for instance, the ascertainment of the guilt or innocence of an accused person a much exacter process than the very fallible methods of our criminal courts. But instead of proposing such an investigation, our vivisectors offer us all the pious protestations and all the huffy recriminations that any common unscientific mortal offers when he is accused of unworthy conduct.

ROUTINE

Yet most vivisectors would probably come triumphant out of such a series of experiments, because vivisection is now a routine, like butchering or hanging or flogging; and many of the men who practise it do so only because it has been established as part of the profession they have adopted. Far from enjoying it, they have simply overcome their natural repugnance and become indifferent to it, as men inevitably become indifferent to anything they do often enough. It is this dangerous power of custom that makes it so difficult to convince the common sense of mankind that any established commercial or professional practice has its root in passion. Let a routine once spring from passion, and you will presently find thousands of routineers following it passionlessly for a livelihood. Thus it always seems strained to speak of the religious convictions of a clergyman, because nine out of ten clergymen have no religions convictions: they are ordinary officials carrying on a routine of baptizing, marrying, and churching; praying, reciting, and preaching; and, like solicitors or doctors, getting away from their duties with relief to hunt, to garden, to keep bees, to go into society, and the like. In the same way many people do cruel and vile things without being in the least cruel or vile, because the routine to which they have been brought up is superstitiously cruel and vile. To say that every man who beats his children and every schoolmaster who flogs a pupil is a conscious debauchee is absurd: thousands of dull, conscientious people beat their children conscientiously, because they were beaten themselves and think children ought to be beaten. The ill-tempered vulgarity that instinctively strikes at and hurts a thing that annoys it (and all children are annoying), and the simple stupidity that requires from a child perfection beyond the reach of the wisest and best adults (perfect truthfulness coupled with perfect obedience is quite a

common condition of leaving a child unwhipped), produce a good deal of flagellation among people who not only do not lust after it, but who hit the harder because they are angry at having to perform an uncomfortable duty. These people will beat merely to assert their authority, or to carry out what they conceive to be a divine order on the strength of the precept of Solomon recorded in the Bible, which carefully adds that Solomon completely spoilt his own son and turned away from the god of his fathers to the sensuous idolatry in which he ended his days.

In the same way we find men and women practising vivisection as senselessly as a humane butcher, who adores his fox terrier, will cut a calf's throat and hang it up by its heels to bleed slowly to death because it is the custom to eat veal and insist on its being white; or as a German purveyor nails a goose to a board and stuffs it with food because fashionable people eat pate de foie gras; or as the crew of a whaler breaks in on a colony of seals and clubs them to death in wholesale massacre because ladies want sealskin jackets; or as fanciers blind singing birds with hot needles, and mutilate the ears and tails of dogs and horses. Let cruelty or kindness or anything else once become customary and it will be practised by people to whom it is not at all natural, but whose rule of life is simply to do only what everybody else does, and who would lose their employment and starve if they indulged in any peculiarity. A respectable man will lie daily, in speech and in print, about the qualities of the article he lives by selling, because it is customary to do so. He will flog his boy for telling a lie, because it is customary to do so. He will also flog him for not telling a lie if the boy tells inconvenient or disrespectful truths, because it is customary to do so. He will give the same boy a present on his birthday, and buy him a spade and bucket at the seaside, because it is customary to do so, being all the time neither particularly mendacious, nor particularly cruel, nor particularly generous, but simply incapable of ethical judgment or independent action.

Just so do we find a crowd of petty vivisectionists daily committing atrocities and stupidities, because it is the custom to do so. Vivisection is customary as part of the routine of preparing lectures in medical schools. For instance, there are two ways of making the action of the heart visible to students. One, a barbarous, ignorant, and thoughtless way, is to stick little flags into a rabbit's heart and let the students see the flags jump. The other, an elegant, ingenious, well-informed, and instructive way, is to put a sphygmograph on the student's wrist and let him see a record of his heart's action traced by a needle on a slip of smoked paper. But it has become the custom for lecturers to teach from the rabbit; and the lecturers are not original enough to get out of their groove. Then there are the demonstrations which are made by cutting up frogs with scissors. The most humane man, however repugnant the operation may be to him at first, cannot do it at lecture after lecture for months without finally—and that very soon—feeling no more for the frog than if he were cutting up pieces of paper. Such clumsy and lazy ways of teaching are based on the cheapness of frogs and rabbits. If machines were as cheap as frogs, engineers would not only be taught the anatomy of machines and the functions of their parts: they would also have machines misused and

wrecked before them so that they might learn as much as possible by using their eyes, and as little as possible by using their brains and imaginations. Thus we have, as part of the routine of teaching, a routine of vivisection which soon produces complete indifference to it on the part even of those who are naturally humane. If they pass on from the routine of lecture preparation, not into general practice, but into research work, they carry this acquired indifference with them into the laboratory, where any atrocity is possible, because all atrocities satisfy curiosity. The routine man is in the majority in his profession always: consequently the moment his practice is tracked down to its source in human passion there is a great and quite sincere poohpoohing from himself, from the mass of the profession, and from the mass of the public, which sees that the average doctor is much too commonplace and decent a person to be capable of passionate wickedness of any kind.

Here then, we have in vivisection, as in all the other tolerated and instituted cruelties, this anti-climax: that only a negligible percentage of those who practise and consequently defend it get any satisfaction out of it. As in Mr. Galsworthy's play Justice the useless and detestable torture of solitary imprisonment is shown at its worst without the introduction of a single cruel person into the drama, so it would be possible to represent all the torments of vivisection dramatically without introducing a single vivisector who had not felt sick at his first experience in the laboratory. Not that this can exonerate any vivisector from suspicion of enjoying his work (or her work: a good deal of the vivisection in medical schools is done by women). In every autobiography which records a real experience of school or prison life, we find that here and there among the routineers there is to be found the genuine amateur, the orgiastic flogging schoolmaster or the nagging warder, who has sought out a cruel profession for the sake of its cruelty. But it is the genuine routineer who is the bulwark of the practice, because, though you can excite public fury against a Sade, a Bluebeard, or a Nero, you cannot rouse any feeling against dull Mr. Smith doing his duty: that is, doing the usual thing. He is so obviously no better and no worse than anyone else that it is difficult to conceive that the things he does are abominable. If you would see public dislike surging up in a moment against an individual, you must watch one who does something unusual, no matter how sensible it may be. The name of Jonas Hanway lives as that of a brave man because he was the first who dared to appear in the streets of this rainy island with an umbrella.

THE OLD LINE BETWEEN MAN AND BEAST

But there is still a distinction to be clung to by those who dare not tell themselves the truth about the medical profession because they are so helplessly dependent on it when death threatens the household. That distinction is the line that separates the brute from the man in the old classification. Granted, they will plead, that we are all cruel; yet the tame-stag-hunter does not hunt men; and the sportsman who lets a leash of greyhounds loose on a hare would be horrified at the thought of letting them loose on a human child. The lady who gets her cloak by flaying a sable does not flay a negro; nor

does it ever occur to her that her veal cutlet might be improved on by a slice of tender baby.

Now there was a time when some trust could be placed in this distinction. The Roman Catholic Church still maintains, with what it must permit me to call a stupid obstinacy, and in spite of St. Francis and St. Anthony, that animals have no souls and no rights; so that you cannot sin against an animal, or against God by anything you may choose to do to an animal. Resisting the temptation to enter on an argument as to whether you may not sin against your own soul if you are unjust or cruel to the least of those whom St. Francis called his little brothers, I have only to point out here that nothing could be more despicably superstitious in the opinion of a vivisector than the notion that science recognizes any such step in evolution as the step from a physical organism to an immortal soul. That conceit has been taken out of all our men of science, and out of all our doctors, by the evolutionists; and when it is considered how completely obsessed biological science has become in our days, not by the full scope of evolution, but by that particular method of it which has neither sense nor purpose nor life nor anything human, much less godlike, in it: by the method, that is, of so-called Natural Selection (meaning no selection at all, but mere dead accident and luck), the folly of trusting to vivisectors to hold the human animal any more sacred than the other animals becomes so clear that it would be waste of time to insist further on it. As a matter of fact the man who once concedes to the vivisector the right to put a dog outside the laws of honor and fellowship, concedes to him also the right to put himself outside them; for he is nothing to the vivisector but a more highly developed, and consequently more interesting-to-experiment-on vertebrate than the dog.

VIVISECTING THE HUMAN SUBJECT

I have in my hand a printed and published account by a doctor of how he tested his remedy for pulmonary tuberculosis, which was to inject a powerful germicide directly into the circulation by stabbing a vein with a syringe. He was one of those doctors who are able to command public sympathy by saying, quite truly, that when they discovered that the proposed treatment was dangerous, they experimented thenceforth on themselves. In this case the doctor was devoted enough to carry his experiments to the point of running serious risks, and actually making himself very uncomfortable. But he did not begin with himself. His first experiment was on two hospital patients. On receiving a message from the hospital to the effect that these two martyrs to therapeutic science had all but expired in convulsions, he experimented on a rabbit, which instantly dropped dead. It was then, and not until then, that he began to experiment on himself, with the germicide modified in the direction indicated by the experiments made on the two patients and the rabbit. As a good many people countenance vivisection because they fear that if the experiments are not made on rabbits they will be made on themselves, it is worth noting that in this case, where both rabbits and men were equally available, the men, being, of course, enormously more instructive, and costing nothing, were experimented on first. Once grant the ethics of the vivisectionists and you not only

sanction the experiment on the human subject, but make it the first duty of the vivisector. If a guinea pig may be sacrificed for the sake of the very little that can be learnt from it, shall not a man be sacrificed for the sake of the great deal that can be learnt from him? At all events, he is sacrificed, as this typical case shows. I may add (not that it touches the argument) that the doctor, the patients, and the rabbit all suffered in vain, as far as the hoped-for rescue of the race from pulmonary consumption is concerned.

"THE LIE IS A EUROPEAN POWER"

Now at the very time when the lectures describing these experiments were being circulated in print and discussed eagerly by the medical profession, the customary denials that patients are experimented on were as loud, as indignant, as high-minded as ever, in spite of the few intelligent doctors who point out rightly that all treatments are experiments on the patient. And this brings us to an obvious but mostly overlooked weakness in the vivisector's position: that is, his inevitable forfeiture of all claim to have his word believed. It is hardly to be expected that a man who does not hesitate to vivisect for the sake of science will hesitate to lie about it afterwards to protect it from what he deems the ignorant sentimentality of the laity. When the public conscience stirs uneasily and threatens suppression, there is never wanting some doctor of eminent position and high character who will sacrifice himself devotedly to the cause of science by coming forward to assure the public on his honor that all experiments on animals are completely painless; although he must know that the very experiments which first provoked the antivivisection movement by their atrocity were experiments to ascertain the physiological effects of the sensation of extreme pain (the much more interesting physiology of pleasure remains uninvestigated) and that all experiments in which sensation is a factor are voided by its suppression. Besides, vivisection may be painless in cases where the experiments are very cruel. If a person scratches me with a poisoned dagger so gently that I do not feel the scratch, he has achieved a painless vivisection; but if I presently die in torment I am not likely to consider that his humility is amply vindicated by his gentleness. A cobra's bite hurts so little that the creature is almost, legally speaking, a vivisector who inflicts no pain. By giving his victims chloroform before biting them he could comply with the law completely.

Here, then, is a pretty deadlock. Public support of vivisection is founded almost wholly on the assurances of the vivisectors that great public benefits may be expected from the practice. Not for a moment do I suggest that such a defence would be valid even if proved. But when the witnesses begin by alleging that in the cause of science all the customary ethical obligations (which include the obligation to tell the truth) are suspended, what weight can any reasonable person give to their testimony? I would rather swear fifty lies than take an animal which had licked my hand in good fellowship and torture it. If I did torture the dog, I should certainly not have the face to turn round and ask how any person there suspect an honorable man like myself of telling lies. Most sensible and humane people would, I hope, reply flatly that honorable men do not

behave dishonorably, even to dogs. The murderer who, when asked by the chaplain whether he had any other crimes to confess, replied indignantly, "What do you take me for?" reminds us very strongly of the vivisectors who are so deeply hurt when their evidence is set aside as worthless.

AN ARGUMENT WHICH WOULD DEFEND ANY CRIME

The Achilles heel of vivisection, however, is not to be found in the pain it causes, but in the line of argument by which it is justified. The medical code regarding it is simply criminal anarchism at its very worst. Indeed no criminal has yet had the impudence to argue as every vivisector argues. No burglar contends that as it is admittedly important to have money to spend, and as the object of burglary is to provide the burglar with money to spend, and as in many instances it has achieved this object, therefore the burglar is a public benefactor and the police are ignorant sentimentalists. No highway robber has yet harrowed us with denunciations of the puling moralist who allows his child to suffer all the evils of poverty because certain faddists think it dishonest to garotte an alderman. Thieves and assassins understand quite well that there are paths of acquisition, even of the best things, that are barred to all men of honor. Again, has the silliest burglar ever pretended that to put a stop to burglary is to put a stop to industry? All the vivisections that have been performed since the world began have produced nothing so important as the innocent and honorable discovery of radiography; and one of the reasons why radiography was not discovered sooner was that the men whose business it was to discover new clinical methods were coarsening and stupefying themselves with the sensual villanies and cutthroat's casuistries of vivisection. The law of the conservation of energy holds good in physiology as in other things: every vivisector is a deserter from the army of honorable investigators. But the vivisector does not see this. He not only calls his methods scientific: he contends that there are no other scientific methods. When you express your natural loathing for his cruelty and your natural contempt for his stupidity, he imagines that you are attacking science. Yet he has no inkling of the method and temper of science. The point at issue being plainly whether he is a rascal or not, he not only insists that the real point is whether some hotheaded antivivisectionist is a liar (which he proves by ridiculously unscientific assumptions as to the degree of accuracy attainable in human statement), but never dreams of offering any scientific evidence by his own methods.

There are many paths to knowledge already discovered; and no enlightened man doubts that there are many more waiting to be discovered. Indeed, all paths lead to knowledge; because even the vilest and stupidest action teaches us something about vileness and stupidity, and may accidentally teach us a good deal more: for instance, a cutthroat learns (and perhaps teaches) the anatomy of the carotid artery and jugular vein; and there can be no question that the burning of St. Joan of Arc must have been a most instructive and interesting experiment to a good observer, and could have been made more so if it had been carried out by skilled physiologists under laboratory conditions. The earthquake in San Francisco proved invaluable as an experiment in the

stability of giant steel buildings; and the ramming of the Victoria by the Camperdown settled doubtful points of the greatest importance in naval warfare. According to vivisectionist logic our builders would be justified in producing artificial earthquakes with dynamite, and our admirals in contriving catastrophes at naval manoeuvres, in order to follow up the line of research thus accidentally discovered.

The truth is, if the acquisition of knowledge justifies every sort of conduct, it justifies any sort of conduct, from the illumination of Nero's feasts by burning human beings alive (another interesting experiment) to the simplest act of kindness. And in the light of that truth it is clear that the exemption of the pursuit of knowledge from the laws of honor is the most hideous conceivable enlargement of anarchy; worse, by far, than an exemption of the pursuit of money or political power, since there can hardly be attained without some regard for at least the appearances of human welfare, whereas a curious devil might destroy the whole race in torment, acquiring knowledge all the time from his highly interesting experiment. There is more danger in one respectable scientist countenancing such a monstrous claim than in fifty assassins or dynamitards. The man who makes it is ethically imbecile; and whoever imagines that it is a scientific claim has not the faintest conception of what science means. The paths to knowledge are countless. One of these paths is a path through darkness, secrecy, and cruelty. When a man deliberately turns from all other paths and goes down that one, it is scientific to infer that what attracts him is not knowledge, since there are other paths to that, but cruelty. With so strong and scientific a case against him, it is childish for him to stand on his honor and reputation and high character and the credit of a noble profession and so forth: he must clear himself either by reason or by experiment, unless he boldly contends that evolution has retained a passion of cruelty in man just because it is indispensable to the fulness of his knowledge.

THOU ART THE MAN

I shall not be at all surprised if what I have written above has induced in sympathetic readers a transport of virtuous indignation at the expense of the medical profession. I shall not damp so creditable and salutary a sentiment; but I must point out that the guilt is shared by all of us. It is not in his capacity of healer and man of science that the doctor vivisects or defends vivisection, but in his entirely vulgar lay capacity. He is made of the same clay as the ignorant, shallow, credulous, half-miseducated, pecuniarily anxious people who call him in when they have tried in vain every bottle and every pill the advertizing druggist can persuade them to buy. The real remedy for vivisection is the remedy for all the mischief that the medical profession and all the other professions are doing: namely, more knowledge. The juries which send the poor Peculiars to prison, and give vivisectionists heavy damages against humane persons who accuse them of cruelty; the editors and councillors and student-led mobs who are striving to make Vivisection one of the watchwords of our civilization, are not doctors: they are the British public, all so afraid to die that they will cling frantically to any idol which promises to cure all their diseases, and crucify anyone who tells them that they must not only die when

their time comes, but die like gentlemen. In their paroxysms of cowardice and selfishness they force the doctors to humor their folly and ignorance. How complete and inconsiderate their ignorance is can only be realized by those who have some knowledge of vital statistics, and of the illusions which beset Public Health legislation.

WHAT THE PUBLIC WANTS AND WILL NOT GET

The demands of this poor public are not reasonable, but they are quite simple. It dreads disease and desires to be protected against it. But it is poor and wants to be protected cheaply. Scientific measures are too hard to understand, too costly, too clearly tending towards a rise in the rates and more public interference with the insanitary, because insufficiently financed, private house. What the public wants, therefore, is a cheap magic charm to prevent, and a cheap pill or potion to cure, all disease. It forces all such charms on the doctors.

THE VACCINATION CRAZE

Thus it was really the public and not the medical profession that took up vaccination with irresistible faith, sweeping the invention out of Jenner's hand and establishing it in a form which he himself repudiated. Jenner was not a man of science; but he was not a fool; and when he found that people who had suffered from cowpox either by contagion in the milking shed or by vaccination, were not, as he had supposed, immune from smallpox, he ascribed the cases of immunity which had formerly misled him to a disease of the horse, which, perhaps because we do not drink its milk and eat its flesh, is kept at a greater distance in our imagination than our foster mother the cow. At all events, the public, which had been boundlessly credulous about the cow, would not have the horse on any terms; and to this day the law which prescribes Jennerian vaccination is carried out with an anti-Jennerian inoculation because the public would have it so in spite of Jenner. All the grossest lies and superstitions which have disgraced the vaccination craze were taught to the doctors by the public. It was not the doctors who first began to declare that all our old men remember the time when almost every face they saw in the street was horribly pitted with smallpox, and that all this disfigurement has vanished since the introduction of vaccination. Jenner himself alluded to this imaginary phenomenon before the introduction of vaccination, and attributed it to the older practice of smallpox inoculation, by which Voltaire, Catherine II. and Lady Mary Wortley Montagu so confidently expected to see the disease made harmless. It was not Jenner who set people declaring that smallpox, if not abolished by vaccination, had at least been made much milder: on the contrary, he recorded a pre-vaccination epidemic in which none of the persons attacked went to bed or considered themselves as seriously ill. Neither Jenner, nor any other doctor ever, as far as I know, inculcated the popular notion that everybody got smallpox as a matter of course before vaccination was invented. That doctors get infected with these delusions, and are in their unprofessional capacity as members of the public subject to them like other men, is

true; but if we had to decide whether vaccination was first forced on the public by the doctors or on the doctors by the public, we should have to decide against the public.

STATISTICAL ILLUSIONS

Public ignorance of the laws of evidence and of statistics can hardly be exaggerated. There may be a doctor here and there who in dealing with the statistics of disease has taken at least the first step towards sanity by grasping the fact that as an attack of even the commonest disease is an exceptional event, apparently over-whelming statistical evidence in favor of any prophylactic can be produced by persuading the public that everybody caught the disease formerly. Thus if a disease is one which normally attacks fifteen per cent of the population, and if the effect of a prophylactic is actually to increase the proportion to twenty per cent, the publication of this figure of twenty per cent will convince the public that the prophylactic has reduced the percentage by eighty per cent instead of increasing it by five, because the public, left to itself and to the old gentlemen who are always ready to remember, on every possible subject, that things used to be much worse than they are now (such old gentlemen greatly outnumber the laudatores tempori acti), will assume that the former percentage was about 100. The vogue of the Pasteur treatment of hydrophobia, for instance, was due to the assumption by the public that every person bitten by a rabid dog necessarily got hydrophobia. I myself heard hydrophobia discussed in my youth by doctors in Dublin before a Pasteur Institute existed, the subject having been brought forward there by the scepticism of an eminent surgeon as to whether hydrophobia is really a specific disease or only ordinary tetanus induced (as tetanus was then supposed to be induced) by a lacerated wound. There were no statistics available as to the proportion of dog bites that ended in hydrophobia; but nobody ever guessed that the cases could be more than two or three per cent of the bites. On me, therefore, the results published by the Pasteur Institute produced no such effect as they did on the ordinary man who thinks that the bite of a mad dog means certain hydrophobia. It seemed to me that the proportion of deaths among the cases treated at the Institute was rather higher, if anything, than might have been expected had there been no Institute in existence. But to the public every Pasteur patient who did not die was miraculously saved from an agonizing death by the beneficent white magic of that most trusty of all wizards, the man of science.

Even trained statisticians often fail to appreciate the extent to which statistics are vitiated by the unrecorded assumptions of their interpreters. Their attention is too much occupied with the cruder tricks of those who make a corrupt use of statistics for advertizing purposes. There is, for example, the percentage dodge. In some hamlet, barely large enough to have a name, two people are attacked during a smallpox epidemic. One dies: the other recovers. One has vaccination marks: the other has none. Immediately either the vaccinists or the antivaccinists publish the triumphant news that at such and such a place not a single vaccinated person died of smallpox whilst 100 per cent of the unvaccinated perished miserably; or, as the case may be, that 100 per cent of the unvaccinated recovered whilst the vaccinated succumbed to the last man. Or, to

take another common instance, comparisons which are really comparisons between two social classes with different standards of nutrition and education are palmed off as comparisons between the results of a certain medical treatment and its neglect. Thus it is easy to prove that the wearing of tall hats and the carrying of umbrellas enlarges the chest, prolongs life, and confers comparative immunity from disease; for the statistics show that the classes which use these articles are bigger, healthier, and live longer than the class which never dreams of possessing such things. It does not take much perspicacity to see that what really makes this difference is not the tall hat and the umbrella, but the wealth and nourishment of which they are evidence, and that a gold watch or membership of a club in Pall Mall might be proved in the same way to have the like sovereign virtues. A university degree, a daily bath, the owning of thirty pairs of trousers, a knowledge of Wagner's music, a pew in church, anything, in short, that implies more means and better nurture than the mass of laborers enjoy, can be statistically palmed off as a magic-spell conferring all sorts of privileges.

In the case of a prophylactic enforced by law, this illusion is intensified grotesquely, because only vagrants can evade it. Now vagrants have little power of resisting any disease: their death rate and their case-mortality rate is always high relatively to that of respectable folk. Nothing is easier, therefore, than to prove that compliance with any public regulation produces the most gratifying results. It would be equally easy even if the regulation actually raised the death-rate, provided it did not raise it sufficiently to make the average householder, who cannot evade regulations, die as early as the average vagrant who can.

THE SURPRISES OF ATTENTION AND NEGLECT

There is another statistical illusion which is independent of class differences. A common complaint of houseowners is that the Public Health Authorities frequently compel them to instal costly sanitary appliances which are condemned a few years later as dangerous to health, and forbidden under penalties. Yet these discarded mistakes are always made in the first instance on the strength of a demonstration that their introduction has reduced the death-rate. The explanation is simple. Suppose a law were made that every child in the nation should be compelled to drink a pint of brandy per month, but that the brandy must be administered only when the child was in good health, with its digestion and so forth working normally, and its teeth either naturally or artificially sound. Probably the result would be an immediate and startling reduction in child mortality, leading to further legislation increasing the quantity of brandy to a gallon. Not until the brandy craze had been carried to a point at which the direct harm done by it would outweigh the incidental good, would an anti-brandy party be listened to. That incidental good would be the substitution of attention to the general health of children for the neglect which is now the rule so long as the child is not actually too sick to run about and play as usual. Even if this attention were confined to the children's teeth, there would be an improvement which it would take a good deal of brandy to cancel.

This imaginary case explains the actual case of the sanitary appliances which our local sanitary authorities prescribe today and condemn tomorrow. No sanitary contrivance which the mind of even the very worst plumber can devize could be as disastrous as that total neglect for long periods which gets avenged by pestilences that sweep through whole continents, like the black death and the cholera. If it were proposed at this time of day to discharge all the sewage of London crude and untreated into the Thames, instead of carrying it, after elaborate treatment, far out into the North Sea, there would be a shriek of horror from all our experts. Yet if Cromwell had done that instead of doing nothing, there would probably have been no Great Plague of London. When the Local Health Authority forces every householder to have his sanitary arrangements thought about and attended to by somebody whose special business it is to attend to such things, then it matters not how erroneous or even directly mischievous may be the specific measures taken: the net result at first is sure to be an improvement. Not until attention has been effectually substituted for neglect as the general rule, will the statistics begin to show the merits of the particular methods of attention adopted. And as we are far from having arrived at this stage, being as to health legislation only at the beginning of things, we have practically no evidence yet as to the value of methods. Simple and obvious as this is, nobody seems as yet to discount the effect of substituting attention for neglect in drawing conclusions from health statistics. Everything is put to the credit of the particular method employed, although it may quite possibly be raising the death rate by five per thousand whilst the attention incidental to it is reducing the death rate fifteen per thousand. The net gain of ten per thousand is credited to the method, and made the excuse for enforcing more of it.

STEALING CREDIT FROM CIVILIZATION

There is yet another way in which specifics which have no merits at all, either direct or incidental, may be brought into high repute by statistics. For a century past civilization has been cleaning away the conditions which favor bacterial fevers. Typhus, once rife, has vanished: plague and cholera have been stopped at our frontiers by a sanitary blockade. We still have epidemics of smallpox and typhoid; and diphtheria and scarlet fever are endemic in the slums. Measles, which in my childhood was not regarded as a dangerous disease, has now become so mortal that notices are posted publicly urging parents to take it seriously. But even in these cases the contrast between the death and recovery rates in the rich districts and in the poor ones has led to the general conviction among experts that bacterial diseases are preventable; and they already are to a large extent prevented. The dangers of infection and the way to avoid it are better understood than they used to be. It is barely twenty years since people exposed themselves recklessly to the infection of consumption and pneumonia in the belief that these diseases were not "catching." Nowadays the troubles of consumptive patients are greatly increased by the growing disposition to treat them as lepers. No doubt there is a good deal of ignorant exaggeration and cowardly refusal to face a human and necessary share of the risk. That has always been the case. We now know that the medieval horror of leprosy was out of all proportion to the danger of infection, and was

accompanied by apparent blindness to the infectiousness of smallpox, which has since been worked up by our disease terrorists into the position formerly held by leprosy. But the scare of infection, though it sets even doctors talking as if the only really scientific thing to do with a fever patient is to throw him into the nearest ditch and pump carbolic acid on him from a safe distance until he is ready to be cremated on the spot, has led to much greater care and cleanliness. And the net result has been a series of victories over disease.

Now let us suppose that in the early nineteenth century somebody had come forward with a theory that typhus fever always begins in the top joint of the little finger; and that if this joint be amputated immediately after birth, typhus fever will disappear. Had such a suggestion been adopted, the theory would have been triumphantly confirmed; for as a matter of fact, typhus fever has disappeared. On the other hand cancer and madness have increased (statistically) to an appalling extent. The opponents of the little finger theory would therefore be pretty sure to allege that the amputations were spreading cancer and lunacy. The vaccination controversy is full of such contentions. So is the controversy as to the docking of horses' tails and the cropping of dogs' ears. So is the less widely known controversy as to circumcision and the declaring certain kinds of flesh unclean by the Jews. To advertize any remedy or operation, you have only to pick out all the most reassuring advances made by civilization, and boldly present the two in the relation of cause and effect: the public will swallow the fallacy without a wry face. It has no idea of the need for what is called a control experiment. In Shakespear's time and for long after it, mummy was a favorite medicament. You took a pinch of the dust of a dead Egyptian in a pint of the hottest water you could bear to drink; and it did you a great deal of good. This, you thought, proved what a sovereign healer mummy was. But if you had tried the control experiment of taking the hot water without the mummy, you might have found the effect exactly the same, and that any hot drink would have done as well.

BIOMETRIKA

Another difficulty about statistics is the technical difficulty of calculation. Before you can even make a mistake in drawing your conclusion from the correlations established by your statistics you must ascertain the correlations. When I turn over the pages of Biometrika, a quarterly journal in which is recorded the work done in the field of biological statistics by Professor Karl Pearson and his colleagues, I am out of my depth at the first line, because mathematics are to me only a concept: I never used a logarithm in my life, and could not undertake to extract the square root of four without misgiving. I am therefore unable to deny that the statistical ascertainment of the correlations between one thing and another must be a very complicated and difficult technical business, not to be tackled successfully except by high mathematicians; and I cannot resist Professor Karl Pearson's immense contempt for, and indignant sense of grave social danger in, the unskilled guesses of the ordinary sociologist.

Now the man in the street knows nothing of Biometrika: all he knows is that "you can prove anything by figures," though he forgets this the moment figures are used to prove anything he wants to believe. If he did take in Biometrika he would probably become abjectly credulous as to all the conclusions drawn in it from the correlations so learnedly worked out; though the mathematician whose correlations would fill a Newton with admiration may, in collecting and accepting data and drawing conclusions from them, fall into quite crude errors by just such popular oversights as I have been describing.

PATIENT-MADE THERAPEUTICS

To all these blunders and ignorances doctors are no less subject than the rest of us. They are not trained in the use of evidence, nor in biometrics, nor in the psychology of human credulity, nor in the incidence of economic pressure. Further, they must believe, on the whole, what their patients believe, just as they must wear the sort of hat their patients wear. The doctor may lay down the law despotically enough to the patient at points where the patient's mind is simply blank; but when the patient has a prejudice the doctor must either keep it in countenance or lose his patient. If people are persuaded that night air is dangerous to health and that fresh air makes them catch cold it will not be possible for a doctor to make his living in private practice if he prescribes ventilation. We have to go back no further than the days of The Pickwick Papers to find ourselves in a world where people slept in four-post beds with curtains drawn closely round to exclude as much air as possible. Had Mr. Pickwick's doctor told him that he would be much healthier if he slept on a camp bed by an open window, Mr. Pickwick would have regarded him as a crank and called in another doctor. Had he gone on to forbid Mr. Pickwick to drink brandy and water whenever he felt chilly, and assured him that if he were deprived of meat or salt for a whole year, he would not only not die, but would be none the worse, Mr. Pickwick would have fled from his presence as from that of a dangerous madman. And in these matters the doctor cannot cheat his patient. If he has no faith in drugs or vaccination, and the patient has, he can cheat him with colored water and pass his lancet through the flame of a spirit lamp before scratching his arm. But he cannot make him change his daily habits without knowing it.

THE REFORMS ALSO COME FROM THE LAITY

In the main, then, the doctor learns that if he gets ahead of the superstitions of his patients he is a ruined man; and the result is that he instinctively takes care not to get ahead of them. That is why all the changes come from the laity. It was not until an agitation had been conducted for many years by laymen, including quacks and faddists of all kinds, that the public was sufficiently impressed to make it possible for the doctors to open their minds and their mouths on the subject of fresh air, cold water, temperance, and the rest of the new fashions in hygiene. At present the tables have been turned on many old prejudices. Plenty of our most popular elderly doctors believe that cold tubs in the morning are unnatural, exhausting, and rheumatic; that fresh air is a fad and that everybody is the better for a glass or two of port wine every day; but they no longer dare

say as much until they know exactly where they are; for many very desirable patients in country houses have lately been persuaded that their first duty is to get up at six in the morning and begin the day by taking a walk barefoot through the dewy grass. He who shows the least scepticism as to this practice is at once suspected of being "an old-fashioned doctor," and dismissed to make room for a younger man.

In short, private medical practice is governed not by science but by supply and demand; and however scientific a treatment may be, it cannot hold its place in the market if there is no demand for it; nor can the grossest quackery be kept off the market if there is a demand for it.

FASHIONS AND EPIDEMICS

A demand, however, can be inculcated. This is thoroughly understood by fashionable tradesmen, who find no difficulty in persuading their customers to renew articles that are not worn out and to buy things they do not want. By making doctors tradesmen, we compel them to learn the tricks of trade; consequently we find that the fashions of the year include treatments, operations, and particular drugs, as well as hats, sleeves, ballads, and games. Tonsils, vermiform appendices, uvulas, even ovaries are sacrificed because it is the fashion to get them cut out, and because the operations are highly profitable. The psychology of fashion becomes a pathology; for the cases have every air of being genuine: fashions, after all, are only induced epidemics, proving that epidemics can be induced by tradesmen, and therefore by doctors.

THE DOCTOR'S VIRTUES

It will be admitted that this is a pretty bad state of things. And the melodramatic instinct of the public, always demanding; that every wrong shall have, not its remedy, but its villain to be hissed, will blame, not its own apathy, superstition, and ignorance, but the depravity of the doctors. Nothing could be more unjust or mischievous. Doctors, if no better than other men, are certainly no worse. I was reproached during the performances of The Doctor's Dilemma at the Court Theatre in 1907 because I made the artist a rascal, the journalist an illiterate incapable, and all the doctors "angels." But I did not go beyond the warrant of my own experience. It has been my luck to have doctors among my friends for nearly forty years past (all perfectly aware of my freedom from the usual credulity as to the miraculous powers and knowledge attributed to them); and though I know that there are medical blackguards as well as military, legal, and clerical blackguards (one soon finds that out when one is privileged to hear doctors talking shop among themselves), the fact that I was no more at a loss for private medical advice and attendance when I had not a penny in my pocket than I was later on when I could afford fees on the highest scale, has made it impossible for me to share that hostility to the doctor as a man which exists and is growing as an inevitable result of the present condition of medical practice. Not that the interest in disease and aberrations which turns some men and women to medicine and surgery is not sometimes as morbid as the interest in misery and vice which turns some others to

philanthropy and "rescue work." But the true doctor is inspired by a hatred of ill-health, and a divine impatience of any waste of vital forces. Unless a man is led to medicine or surgery through a very exceptional technical aptitude, or because doctoring is a family tradition, or because he regards it unintelligently as a lucrative and gentlemanly profession, his motives in choosing the career of a healer are clearly generous. However actual practice may disillusion and corrupt him, his selection in the first instance is not a selection of a base character.

THE DOCTOR'S HARDSHIPS

A review of the counts in the indictment I have brought against private medical practice will show that they arise out of the doctor's position as a competitive private tradesman: that is, out of his poverty and dependence. And it should be borne in mind that doctors are expected to treat other people specially well whilst themselves submitting to specially inconsiderate treatment. The butcher and baker are not expected to feed the hungry unless the hungry can pay; but a doctor who allows a fellow-creature to suffer or perish without aid is regarded as a monster. Even if we must dismiss hospital service as really venal, the fact remains that most doctors do a good deal of gratuitous work in private practice all through their careers. And in his paid work the doctor is on a different footing to the tradesman. Although the articles he sells, advice and treatment, are the same for all classes, his fees have to be graduated like the income tax. The successful fashionable doctor may weed his poorer patients out from time to time, and finally use the College of Physicians to place it out of his own power to accept low fees; but the ordinary general practitioner never makes out his bills without considering the taxable capacity of his patients.

Then there is the disregard of his own health and comfort which results from the fact that he is, by the nature of his work, an emergency man. We are polite and considerate to the doctor when there is nothing the matter, and we meet him as a friend or entertain him as a guest; but when the baby is suffering from croup, or its mother has a temperature of 104 degrees, or its grandfather has broken his leg, nobody thinks of the doctor except as a healer and saviour. He may be hungry, weary, sleepy, run down by several successive nights disturbed by that instrument of torture, the night bell; but who ever thinks of this in the face of sudden sickness or accident? We think no more of the condition of a doctor attending a case than of the condition of a fireman at a fire. In other occupations night-work is specially recognized and provided for. The worker sleeps all day; has his breakfast in the evening; his lunch or dinner at midnight; his dinner or supper before going to bed in the morning; and he changes to day-work if he cannot stand night-work. But a doctor is expected to work day and night. In practices which consist largely of workmen's clubs, and in which the patients are therefore taken on wholesale terms and very numerous, the unfortunate assistant, or the principal if he has no assistant, often does not undress, knowing that he will be called up before he has snatched an hour's sleep. To the strain of such inhuman conditions must be added the constant risk of infection. One wonders why the impatient doctors do not become

savage and unmanageable, and the patient ones imbecile. Perhaps they do, to some extent. And the pay is wretched, and so uncertain that refusal to attend without payment in advance becomes often a necessary measure of self-defence, whilst the County Court has long ago put an end to the tradition that the doctor's fee is an honorarium. Even the most eminent physicians, as such biographies as those of Paget show, are sometimes miserably, inhumanly poor until they are past their prime. In short, the doctor needs our help for the moment much more than we often need his. The ridicule of Moliere, the death of a well-informed and clever writer like the late Harold Frederic in the hands of Christian Scientists (a sort of sealing with his blood of the contemptuous disbelief in and dislike of doctors he had bitterly expressed in his books), the scathing and quite justifiable exposure of medical practice in the novel by Mr. Maarten Maartens entitled The New Religion: all these trouble the doctor very little, and are in any case well set off by the popularity of Sir Luke Fildes' famous picture, and by the verdicts in which juries from time to time express their conviction that the doctor can do no wrong. The real woes of the doctor are the shabby coat, the wolf at the door, the tyranny of ignorant patients, the work-day of 24 hours, and the uselessness of honestly prescribing what most of the patients really need: that is, not medicine, but money.

THE PUBLIC DOCTOR

What then is to be done?

Fortunately we have not to begin absolutely from the beginning: we already have, in the Medical Officer of Health, a sort of doctor who is free from the worst hardships, and consequently from the worst vices, of the private practitioner. His position depends, not on the number of people who are ill, and whom he can keep ill, but on the number of people who are well. He is judged, as all doctors and treatments should be judged, by the vital statistics of his district. When the death rate goes up his credit goes down. As every increase in his salary depends on the issue of a public debate as to the health of the constituency under his charge, he has every inducement to strive towards the ideal of a clean bill of health. He has a safe, dignified, responsible, independent position based wholly on the public health; whereas the private practitioner has a precarious, shabby-genteel, irresponsible, servile position, based wholly on the prevalence of illness.

It is true, there are grave scandals in the public medical service. The public doctor may be also a private practitioner eking out his earnings by giving a little time to public work for a mean payment. There are cases in which the position is one which no successful practitioner will accept, and where, therefore, incapables or drunkards get automatically selected for the post, faute de mieux; but even in these cases the doctor is less disastrous in his public capacity than in his private one: besides, the conditions which produce these bad cases are doomed, as the evil is now recognized and understood. A popular but unstable remedy is to enable local authorities, when they are too small to require the undivided time of such men as the Medical Officers of our great

municipalities, to combine for public health purposes so that each may share the services of a highly paid official of the best class; but the right remedy is a larger area as the sanitary unit.

MEDICAL ORGANIZATION

Another advantage of public medical work is that it admits of organization, and consequently of the distribution of the work in such a manner as to avoid wasting the time of highly qualified experts on trivial jobs. The individualism of private practice leads to an appalling waste of time on trifles. Men whose dexterity as operators or almost divinatory skill in diagnosis are constantly needed for difficult cases, are poulticing whitlows, vaccinating, changing unimportant dressings, prescribing ether drams for ladies with timid leanings towards dipsomania, and generally wasting their time in the pursuit of private fees. In no other profession is the practitioner expected to do all the work involved in it from the first day of his professional career to the last as the doctor is. The judge passes sentence of death; but he is not expected to hang the criminal with his own hands, as he would be if the legal profession were as unorganized as the medical. The bishop is not expected to blow the organ or wash the baby he baptizes. The general is not asked to plan a campaign or conduct a battle at half-past twelve and to play the drum at half-past two. Even if they were, things would still not be as bad as in the medical profession; for in it not only is the first-class man set to do third-class work, but, what is much more terrifying, the third-class man is expected to do first-class work. Every general practitioner is supposed to be capable of the whole range of medical and surgical work at a moment's notice; and the country doctor, who has not a specialist nor a crack consultant at the end of his telephone, often has to tackle without hesitation cases which no sane practitioner in a town would take in hand without assistance. No doubt this develops the resourcefulness of the country doctor, and makes him a more capable man than his suburban colleague; but it cannot develop the second-class man into a first-class one. If the practice of law not only led to a judge having to hang, but the hangman to judge, or if in the army matters were so arranged that it would be possible for the drummer boy to be in command at Waterloo whilst the Duke of Wellington was playing the drum in Brussels, we should not be consoled by the reflection that our hangmen were thereby made a little more judicial-minded, and our drummers more responsible, than in foreign countries where the legal and military professions recognized the advantages of division of labor.

Under such conditions no statistics as to the graduation of professional ability among doctors are available. Assuming that doctors are normal men and not magicians (and it is unfortunately very hard to persuade people to admit so much and thereby destroy the romance of doctoring) we may guess that the medical profession, like the other professions, consists of a small percentage of highly gifted persons at one end, and a small percentage of altogether disastrous duffers at the other. Between these extremes comes the main body of doctors (also, of course, with a weak and a strong end) who can be trusted to work under regulations with more or less aid from above according to

the gravity of the case. Or, to put it in terms of the cases, there are cases that present no difficulties, and can be dealt with by a nurse or student at one end of the scale, and cases that require watching and handling by the very highest existing skill at the other; whilst between come the great mass of cases which need visits from the doctor of ordinary ability and from the chiefs of the profession in the proportion of, say, seven to none, seven to one, three to one, one to one, or, for a day or two, none to one. Such a service is organized at present only in hospitals; though in large towns the practice of calling in the consultant acts, to some extent, as a substitute for it. But in the latter case it is quite unregulated except by professional etiquet, which, as we have seen, has for its object, not the health of the patient or of the community at large, but the protection of the doctor's livelihood and the concealment of his errors. And as the consultant is an expensive luxury, he is a last resource rather, as he should be, than a matter of course, in all cases where the general practitioner is not equal to the occasion: a predicament in which a very capable man may find himself at any time through the cropping up of a case of which he has had no clinical experience.

THE SOCIAL SOLUTION OF THE MEDICAL PROBLEM

The social solution of the medical problem, then, depends on that large, slowly advancing, pettishly resisted integration of society called generally Socialism. Until the medical profession becomes a body of men trained and paid by the country to keep the country in health it will remain what it is at present: a conspiracy to exploit popular credulity and human suffering. Already our M.O.H.s (Medical Officers of Health) are in the new position: what is lacking is appreciation of the change, not only by the public but by the private doctors. For, as we have seen, when one of the first-rate posts becomes vacant in one of the great cities, and all the leading M.O.H.s compete for it, they must appeal to the good health of the cities of which they have been in charge, and not to the size of the incomes the local private doctors are making out of the ill-health of their patients. If a competitor can prove that he has utterly ruined every sort of medical private practice in a large city except obstetric practice and the surgery of accidents, his claims are irresistible; and this is the ideal at which every M.O.H. should aim. But the profession at large should none the less welcome him and set its house in order for the social change which will finally be its own salvation. For the M.O.H. as we know him is only the beginning of that army of Public Hygiene which will presently take the place in general interest and honor now occupied by our military and naval forces. It is silly that an Englishman should be more afraid of a German soldier than of a British disease germ, and should clamor for more barracks in the same newspapers that protest against more school clinics, and cry out that if the State fights disease for us it makes us paupers, though they never say that if the State fights the Germans for us it makes us cowards. Fortunately, when a habit of thought is silly it only needs steady treatment by ridicule from sensible and witty people to be put out of countenance and perish. Every year sees an increase in the number of persons employed in the Public Health Service, who would formerly have been mere adventurers in the Private Illness Service. To put it another way, a host of men and women who have now a strong incentive to be

mischievous and even murderous rogues will have a much stronger, because a much honester, incentive to be not only good citizens but active benefactors to the community. And they will have no anxiety whatever about their incomes.

THE FUTURE OF PRIVATE PRACTICE

It must not be hastily concluded that this involves the extinction of the private practitioner. What it will really mean for him is release from his present degrading and scientifically corrupting slavery to his patients. As I have already shown the doctor who has to live by pleasing his patients in competition with everybody who has walked the hospitals, scraped through the examinations, and bought a brass plate, soon finds himself prescribing water to teetotallers and brandy or champagne jelly to drunkards; beefsteaks and stout in one house, and "uric acid free" vegetarian diet over the way; shut windows, big fires, and heavy overcoats to old Colonels, and open air and as much nakedness as is compatible with decency to young faddists, never once daring to say either "I don't know," or "I don't agree." For the strength of the doctor's, as of every other man's position when the evolution of social organization at last reaches his profession, will be that he will always have open to him the alternative of public employment when the private employer becomes too tyrannous. And let no one suppose that the words doctor and patient can disguise from the parties the fact that they are employer and employee. No doubt doctors who are in great demand can be as high-handed and independent as employees are in all classes when a dearth in their labor market makes them indispensable; but the average doctor is not in this position: he is struggling for life in an overcrowded profession, and knows well that "a good bedside manner" will carry him to solvency through a morass of illness, whilst the least attempt at plain dealing with people who are eating too much, or drinking too much, or frowsting too much (to go no further in the list of intemperances that make up so much of family life) would soon land him in the Bankruptcy Court.

Private practice, thus protected, would itself protect individuals, as far as such protection is possible, against the errors and superstitions of State medicine, which are at worst no worse than the errors and superstitions of private practice, being, indeed, all derived from it. Such monstrosities as vaccination are, as we have seen, founded, not on science, but on half-crowns. If the Vaccination Acts, instead of being wholly repealed as they are already half repealed, were strengthened by compelling every parent to have his child vaccinated by a public officer whose salary was completely independent of the number of vaccinations performed by him, and for whom there was plenty of alternative public health work waiting, vaccination would be dead in two years, as the vaccinator would not only not gain by it, but would lose credit through the depressing effects on the vital statistics of his district of the illness and deaths it causes, whilst it would take from him all the credit of that freedom from smallpox which is the result of good sanitary administration and vigilant prevention of infection. Such absurd panic scandals as that of the last London epidemic, where a fee of half-a-crown per re-vaccination produced raids on houses during the absence of parents, and the forcible

seizure and re-vaccination of children left to answer the door, can be prevented simply by abolishing the half-crown and all similar follies, paying, not for this or that ceremony of witchcraft, but for immunity from disease, and paying, too, in a rational way. The officer with a fixed salary saves himself trouble by doing his business with the least possible interference with the private citizen. The man paid by the job loses money by not forcing his job on the public as often as possible without reference to its results.

THE TECHNICAL PROBLEM

As to any technical medical problem specially involved, there is none. If there were, I should not be competent to deal with it, as I am not a technical expert in medicine: I deal with the subject as an economist, a politician, and a citizen exercising my common sense. Everything that I have said applies equally to all the medical techniques, and will hold good whether public hygiene be based on the poetic fancies of Christian Science, the tribal superstitions of the druggist and the vivisector, or the best we can make of our real knowledge. But I may remind those who confusedly imagine that the medical problem is also the scientific problem, that all problems are finally scientific problems. The notion that therapeutics or hygiene or surgery is any more or less scientific than making or cleaning boots is entertained only by people to whom a man of science is still a magician who can cure diseases, transmute metals, and enable us to live for ever. It may still be necessary for some time to come to practise on popular credulity, popular love and dread of the marvellous, and popular idolatry, to induce the poor to comply with the sanitary regulations they are too ignorant to understand. As I have elsewhere confessed, I have myself been responsible for ridiculous incantations with burning sulphur, experimentally proved to be quite useless, because poor people are convinced, by the mystical air of the burning and the horrible smell, that it exorcises the demons of smallpox and scarlet fever and makes it safe for them to return to their houses. To assure them that the real secret is sunshine and soap is only to convince them that you do not care whether they live or die, and wish to save money at their expense. So you perform the incantation; and back they go to their houses, satisfied. A religious ceremony—a poetic blessing of the threshold, for instance—would be much better; but unfortunately our religion is weak on the sanitary side. One of the worst misfortunes of Christendom was that reaction against the voluptuous bathing of the imperial Romans which made dirty habits a part of Christian piety, and in some unlucky places (the Sandwich Islands for example) made the introduction of Christianity also the introduction of disease, because the formulators of the superseded native religion, like Mahomet, had been enlightened enough to introduce as religious duties such sanitary measures as ablution and the most careful and reverent treatment of everything cast off by the human body, even to nail clippings and hairs; and our missionaries thoughtlessly discredited this godly doctrine without supplying its place, which was promptly taken by laziness and neglect. If the priests of Ireland could only be persuaded to teach their flocks that it is a deadly insult to the Blessed Virgin to place her image in a cottage that is not kept up to that high standard of Sunday cleanliness to which all her worshippers must believe she is accustomed, and to represent her as being especially particular

about stables because her son was born in one, they might do more in one year than all the Sanitary Inspectors in Ireland could do in twenty; and they could hardly doubt that Our Lady would be delighted. Perhaps they do nowadays; for Ireland is certainly a transfigured country since my youth as far as clean faces and pinafores can transfigure it. In England, where so many of the inhabitants are too gross to believe in poetic faiths, too respectable to tolerate the notion that the stable at Bethany was a common peasant farmer's stable instead of a first-rate racing one, and too savage to believe that anything can really cast out the devil of disease unless it be some terrifying hoodoo of tortures and stinks, the M.O.H. will no doubt for a long time to come have to preach to fools according to their folly, promising miracles, and threatening hideous personal consequences of neglect of by-laws and the like; therefore it will be important that every M.O.H. shall have, with his (or her) other qualifications, a sense of humor, lest (he or she) should come at last to believe all the nonsense that must needs be talked. But he must, in his capacity of an expert advising the authorities, keep the government itself free of superstition. If Italian peasants are so ignorant that the Church can get no hold of them except by miracles, why, miracles there must be. The blood of St. Januarius must liquefy whether the Saint is in the humor or not. To trick a heathen into being a dutiful Christian is no worse than to trick a whitewasher into trusting himself in a room where a smallpox patient has lain, by pretending to exorcise the disease with burning sulphur. But woe to the Church if in deceiving the peasant it also deceives itself; for then the Church is lost, and the peasant too, unless he revolt against it. Unless the Church works the pretended miracle painfully against the grain, and is continually urged by its dislike of the imposture to strive to make the peasant susceptible to the true reasons for behaving well, the Church will become an instrument of his corruption and an exploiter of his ignorance, and will find itself launched upon that persecution of scientific truth of which all priesthoods are accused and none with more justice than the scientific priesthood.

And here we come to the danger that terrifies so many of us: the danger of having a hygienic orthodoxy imposed on us. But we must face that: in such crowded and poverty ridden civilizations as ours any orthodoxy is better than laisser-faire. If our population ever comes to consist exclusively of well-to-do, highly cultivated, and thoroughly instructed free persons in a position to take care of themselves, no doubt they will make short work of a good deal of official regulation that is now of life-and-death necessity to us; but under existing circumstances, I repeat, almost any sort of attention that democracy will stand is better than neglect. Attention and activity lead to mistakes as well as to successes; but a life spent in making mistakes is not only more honorable but more useful than a life spent doing nothing. The one lesson that comes out of all our theorizing and experimenting is that there is only one really scientific progressive method; and that is the method of trial and error. If you come to that, what is laisser-faire but an orthodoxy? the most tyrannous and disastrous of all the orthodoxies, since it forbids you even to learn.

THE LATEST THEORIES

Medical theories are so much a matter of fashion, and the most fertile of them are modified so rapidly by medical practice and biological research, which are international activities, that the play which furnishes the pretext for this preface is already slightly outmoded, though I believe it may be taken as a faithful record for the year (1906) in which it was begun. I must not expose any professional man to ruin by connecting his name with the entire freedom of criticism which I, as a layman, enjoy; but it will be evident to all experts that my play could not have been written but for the work done by Sir Almroth Wright in the theory and practice of securing immunization from bacterial diseases by the inoculation of "vaccines" made of their own bacteria: a practice incorrectly called vaccinetherapy (there is nothing vaccine about it) apparently because it is what vaccination ought to be and is not. Until Sir Almroth Wright, following up one of Metchnikoff's most suggestive biological romances, discovered that the white corpuscles or phagocytes which attack and devour disease germs for us do their work only when we butter the disease germs appetizingly for them with a natural sauce which Sir Almroth named opsonin, and that our production of this condiment continually rises and falls rhythmically from negligibility to the highest efficiency, nobody had been able even to conjecture why the various serums that were from time to time introduced as having effected marvellous cures, presently made such direful havoc of some unfortunate patient that they had to be dropped hastily. The quantity of sturdy lying that was necessary to save the credit of inoculation in those days was prodigious; and had it not been for the devotion shown by the military authorities throughout Europe, who would order the entire disappearance of some disease from their armies, and bring it about by the simple plan of changing the name under which the cases were reported, or for our own Metropolitan Asylums Board, which carefully suppressed all the medical reports that revealed the sometimes quite appalling effects of epidemics of revaccination, there is no saying what popular reaction might not have taken place against the whole immunization movement in therapeutics.

The situation was saved when Sir Almroth Wright pointed out that if you inoculated a patient with pathogenic germs at a moment when his powers of cooking them for consumption by the phagocytes was receding to its lowest point, you would certainly make him a good deal worse and perhaps kill him, whereas if you made precisely the same inoculation when the cooking power was rising to one of its periodical climaxes, you would stimulate it to still further exertions and produce just the opposite result. And he invented a technique for ascertaining in which phase the patient happened to be at any given moment. The dramatic possibilities of this discovery and invention will be found in my play. But it is one thing to invent a technique: it is quite another to persuade the medical profession to acquire it. Our general practitioners, I gather, simply declined to acquire it, being mostly unable to afford either the acquisition or the practice of it when acquired. Something simple, cheap, and ready at all times for all comers, is, as I have shown, the only thing that is economically possible in general practice, whatever may be the case in Sir Almroth's famous laboratory in St. Mary's Hospital. It would have become necessary to denounce opsonin in the trade papers as a fad and Sir Almroth as

a dangerous man if his practice in the laboratory had not led him to the conclusion that the customary inoculations were very much too powerful, and that a comparatively infinitesimal dose would not precipitate a negative phase of cooking activity, and might induce a positive one. And thus it happens that the refusal of our general practitioners to acquire the new technique is no longer quite so dangerous in practice as it was when The Doctor's Dilemma was written: nay, that Sir Ralph Bloomfield Boningtons way of administering inoculations as if they were spoonfuls of squills may sometimes work fairly well. For all that, I find Sir Almroth Wright, on the 23rd May, 1910, warning the Royal Society of Medicine that "the clinician has not yet been prevailed upon to reconsider his position," which means that the general practitioner ("the doctor," as he is called in our homes) is going on just as he did before, and could not afford to learn or practice a new technique even if he had ever heard of it. To the patient who does not know about it he will say nothing. To the patient who does, he will ridicule it, and disparage Sir Almroth. What else can he do, except confess his ignorance and starve?

But now please observe how "the whirligig of time brings its revenges." This latest discovery of the remedial virtue of a very, very tiny hair of the dog that bit you reminds us, not only of Arndt's law of protoplasmic reaction to stimuli, according to which weak and strong stimuli provoke opposite reactions, but of Hahnemann's homeopathy, which was founded on the fact alleged by Hahnemann that drugs which produce certain symptoms when taken in ordinary perceptible quantities, will, when taken in infinitesimally small quantities, provoke just the opposite symptoms; so that the drug that gives you a headache will also cure a headache if you take little enough of it. I have already explained that the savage opposition which homeopathy encountered from the medical profession was not a scientific opposition; for nobody seems to deny that some drugs act in the alleged manner. It was opposed simply because doctors and apothecaries lived by selling bottles and boxes of doctor's stuff to be taken in spoonfuls or in pellets as large as peas; and people would not pay as much for drops and globules no bigger than pins' heads. Nowadays, however, the more cultivated folk are beginning to be so suspicious of drugs, and the incorrigibly superstitious people so profusely supplied with patent medicines (the medical advice to take them being wrapped round the bottle and thrown in for nothing) that homeopathy has become a way of rehabilitating the trade of prescription compounding, and is consequently coming into professional credit. At which point the theory of opsonins comes very opportunely to shake hands with it.

Add to the newly triumphant homeopathist and the opsonist that other remarkable innovator, the Swedish masseur, who does not theorize about you, but probes you all over with his powerful thumbs until he finds out your sore spots and rubs them away, besides cheating you into a little wholesome exercise; and you have nearly everything in medical practice to-day that is not flat witchcraft or pure commercial exploitation of human credulity and fear of death. Add to them a good deal of vegetarian and teetotal controversy raging round a clamor for scientific eating and drinking, and resulting in little so far except calling digestion Metabolism and dividing the public between the eminent

doctor who tells us that we do not eat enough fish, and his equally eminent colleague who warns us that a fish diet must end in leprosy, and you have all that opposes with any sort of countenance the rise of Christian Science with its cathedrals and congregations and zealots and miracles and cures: all very silly, no doubt, but sane and sensible, poetic and hopeful, compared to the pseudo science of the commercial general practitioner, who foolishly clamors for the prosecution and even the execution of the Christian Scientists when their patients die, forgetting the long death roll of his own patients.

By the time this preface is in print the kaleidoscope may have had another shake; and opsonin may have gone the way of phlogiston at the hands of its own restless discoverer. I will not say that Hahnemann may have gone the way of Diafoirus; for Diafoirus we have always with us. But we shall still pick up all our knowledge in pursuit of some Will o' the Wisp or other. What is called science has always pursued the Elixir of Life and the Philosopher's Stone, and is just as busy after them to-day as ever it was in the days of Paracelsus. We call them by different names: Immunization or Radiology or what not; but the dreams which lure us into the adventures from which we learn are always at bottom the same. Science becomes dangerous only when it imagines that it has reached its goal. What is wrong with priests and popes is that instead of being apostles and saints, they are nothing but empirics who say "I know" instead of "I am learning," and pray for credulity and inertia as wise men pray for scepticism and activity. Such abominations as the Inquisition and the Vaccination Acts are possible only in the famine years of the soul, when the great vital dogmas of honor, liberty, courage, the kinship of all life, faith that the unknown is greater than the known and is only the As Yet Unknown, and resolution to find a manly highway to it, have been forgotten in a paroxysm of littleness and terror in which nothing is active except concupiscence and the fear of death, playing on which any trader can filch a fortune, any blackguard gratify his cruelty, and any tyrant make us his slaves.

Lest this should seem too rhetorical a conclusion for our professional men of science, who are mostly trained not to believe anything unless it is worded in the jargon of those writers who, because they never really understand what they are trying to say, cannot find familiar words for it, and are therefore compelled to invent a new language of nonsense for every book they write, let me sum up my conclusions as dryly as is consistent with accurate thought and live conviction.

1. Nothing is more dangerous than a poor doctor: not even a poor employer or a poor landlord.

2. Of all the anti-social vested interests the worst is the vested interest in ill-health.

3. Remember that an illness is a misdemeanor; and treat the doctor as an accessory unless he notifies every case to the Public Health authority.

4. Treat every death as a possible and under our present system a probable murder, by making it the subject of a reasonably conducted inquest; and execute the doctor, if necessary, as a doctor, by striking him off the register.

5. Make up your mind how many doctors the community needs to keep it well. Do not register more or less than this number; and let registration constitute the doctor a civil servant with a dignified living wage paid out of public funds.

6. Municipalize Harley Street.

7. Treat the private operator exactly as you would treat a private executioner.

8. Treat persons who profess to be able to cure disease as you treat fortune tellers.

9. Keep the public carefully informed, by special statistics and announcements of individual cases, of all illnesses of doctors or in their families.

10. Make it compulsory for a doctor using a brass plate to have inscribed on it, in addition to the letters indicating his qualifications, the words "Remember that I too am mortal."

11. In legislation and social organization, proceed on the principle that invalids, meaning persons who cannot keep themselves alive by their own activities, cannot, beyond reason, expect to be kept alive by the activity of others. There is a point at which the most energetic policeman or doctor, when called upon to deal with an apparently drowned person, gives up artificial respiration, although it is never possible to declare with certainty, at any point short of decomposition, that another five minutes of the exercise would not effect resuscitation. The theory that every individual alive is of infinite value is legislatively impracticable. No doubt the higher the life we secure to the individual by wise social organization, the greater his value is to the community, and the more pains we shall take to pull him through any temporary danger or disablement. But the man who costs more than he is worth is doomed by sound hygiene as inexorably as by sound economics.

12. Do not try to live for ever. You will not succeed.

13. Use your health, even to the point of wearing it out. That is what it is for. Spend all you have before you die; and do not outlive yourself.

14. Take the utmost care to get well born and well brought up. This means that your mother must have a good doctor. Be careful to go to a school where there is what they call a school clinic, where your nutrition and teeth and eyesight and other matters of importance to you will be attended to. Be particularly careful to have all this done at the expense of the nation, as otherwise it will not be done at all, the chances being about forty to one against your being able to pay for it directly yourself, even if you know how to set about it. Otherwise you will be what most people are at present: an unsound citizen of an unsound nation, without sense enough to be ashamed or unhappy about it.

Some Current Health Insurance Risks

The US Surgeon General occasionally issues Advisories on key health issues affecting Americans. We will present two here; one on Loneliness and Isolation and a second on Social Media and Youth Mental Health. Both were issued in 2023. Consider these as examples of the research and information available from public sources; it is truly extensive.

Consider also as you read these, how licensed brokers and the larger insurance industry can respond.[222]

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Our Epidemic of Loneliness and Isolation: The U.S. Surgeon General's Advisory on the Healing Effects of Social Connection and Community

Our relationships and interactions with family, friends, colleagues, and neighbors are just some of what create social connection. Our connection with others and our community is also informed by our neighborhoods, digital environments, schools, and workplaces. Social connection— the structure, function, and quality of our relationships with others—is a critical and underappreciated contributor to individual and population health, community safety, resilience, and prosperity. However, far too many Americans lack social connection in one or more ways, compromising these benefits and leading to poor health and other negative outcomes.

Introduction from Vivek H. Murthy, US Surgeon General, April 2023

When I first took office as Surgeon General in 2014, I didn't view loneliness as a public health concern. But that was before I embarked on a cross-country listening tour, where I heard stories from my fellow Americans that surprised me.

People began to tell me they felt isolated, invisible, and insignificant. Even when they couldn't put their finger on the word "lonely," time and time again, people of all ages and socioeconomic backgrounds, from every corner of the country, would tell me, "I have to shoulder all of life's burdens by myself," or "if I disappear tomorrow, no one will even notice."

In recent years, about one-in-two adults in America reported experiencing loneliness. And that was before the COVID-19 pandemic cut off so many of us from friends, loved ones, and support systems, exacerbating loneliness and isolation.

Loneliness is far more than just a bad feeling—it harms both individual and societal health. It is associated with a greater risk of cardiovascular disease, dementia, stroke, depression, anxiety, and premature death. The mortality impact of being socially

[222] Reference footnotes for this chapter are available on request. This material comes from the US Surgeon General and is reproduced under 17 U.S.C. § 105,

disconnected is similar to that caused by smoking up to 15 cigarettes a day, and even greater than that associated with obesity and physical inactivity. And the harmful consequences of a society that lacks social connection can be felt in our schools, workplaces, and civic organizations, where performance, productivity, and engagement are diminished.

Given the profound consequences of loneliness and isolation, we have an opportunity, and an obligation, to make the same investments in addressing social connection that we have made in addressing tobacco use, obesity, and the addiction crisis. This Surgeon General's Advisory shows us how to build more connected lives and a more connected society.

If we fail to do so, we will pay an ever-increasing price in the form of our individual and collective health and well-being. And we will continue to splinter and divide until we can no longer stand as a community or a country. Instead of coming together to take on the great challenges before us, we will further retreat to our corners—angry, sick, and alone.

We are called to build a movement to mend the social fabric of our nation. It will take all of us—individuals and families, schools and workplaces, health care and public health systems, technology companies, governments, faith organizations, and communities—working together to destigmatize loneliness and change our cultural and policy response to it. It will require reimagining the structures, policies, and programs that shape a community to best support the development of healthy relationships.

Each of us can start now, in our own lives, by strengthening our connections and relationships. Our individual relationships are an untapped resource—a source of healing hiding in plain sight. They can help us live healthier, more productive, and more fulfilled lives. Answer that phone call from a friend. Make time to share a meal. Listen without the distraction of your phone. Perform an act of service. Express yourself authentically. The keys to human connection are simple, but extraordinarily powerful.

Each of us can start now, in our own lives, by strengthening our connections and relationships.

Loneliness and isolation represent profound threats to our health and well-being. But we have the power to respond. By taking small steps every day to strengthen our relationships, and by supporting community efforts to rebuild social connection, we can rise to meet this moment together. We can build lives and communities that are healthier and happier. And we can ensure our country and the world are better poised than ever to take on the challenges that lay ahead.

Our future depends on what we do today.

Vivek H. Murthy, M.D., M.B.A.
19th and 21st Surgeon General of the United States
Vice Admiral, United States Public Health Service

Introduction: Why Social Connection Matters

People may lack social connection in a variety of ways, though it is often illustrated in scientific research by measuring loneliness and social isolation. Social isolation and loneliness are related, but they are not the same. Social isolation is objectively having few social relationships, social roles, group memberships, and infrequent social interaction. On the other hand, loneliness is a subjective internal state. It's the distressing experience that results from perceived isolation or unmet need between an individual's preferred and actual experience.

The lack of social connection poses a significant risk for individual health and longevity. Loneliness and social isolation increase the risk for premature death by 26% and 29% respectively. More broadly, lacking social connection can increase the risk for premature death as much as smoking up to 15 cigarettes a day. In addition, poor or insufficient social connection is associated with increased risk of disease, including a 29% increased risk of heart disease and a 32% increased risk of stroke. Furthermore, it is associated with increased risk for anxiety, depression, and dementia. Additionally, the lack of social connection may increase susceptibility to viruses and respiratory illness and cost employers an estimated $154 billion annually. The impact of social connection not only affects individuals, but also the communities they live in. Social connection is an important social determinant of health, and more broadly, of community well-being, including (but not limited to) population health, community resilience when natural hazards strike, community safety, economic prosperity, and representative government.

What drives these profound health and well-being outcomes? Social connection is a fundamental human need, as essential to survival as food, water, and shelter. Throughout history, our ability to rely on one another has been crucial to survival. Now, even in modern times, we human beings are biologically wired for social connection. Our brains have adapted to expect proximity to others. Our distant ancestors relied on others to help them meet their basic needs. Living in isolation, or outside the group, means having to fulfill the many difficult demands of survival on one's own. This requires far more effort and reduces one's chances of survival. Despite current advancements that now allow us to live without engaging with others (e.g., food delivery, automation, remote entertainment), our biological need to connect remains.

The health and societal impacts of social isolation and loneliness are a critical public health concern in light of mounting evidence that millions of Americans lack adequate social connection in one or more ways. A 2022 study found that when people were asked how close they felt to others emotionally, only 39% of adults in the U.S. said that they felt very connected to others. An important indicator of this declining social connection is an increase in the proportion of Americans experiencing loneliness.

Recent surveys have found that approximately half of U.S. adults report experiencing loneliness, with some of the highest rates among young adults. These estimates and multiple other studies indicate that loneliness and isolation are more widespread than many of the other major health issues of our day, including smoking (12.5% of U.S. adults), diabetes (14.7%), and obesity (41.9%), and with comparable levels of risk to health and premature death. Despite such high prevalence, less than 20% of individuals who often or always feel lonely or isolated recognize it as a major problem.

Together, this represents an urgent public health concern. Every level of increase in social connection corresponds with a risk reduction across many health conditions. Further, social connection can be a proactive approach to living a fulfilled and happy life, enhancing life satisfaction, educational attainment, and performance in the workplace, as well as contributing to more-connected communities that are healthier, safer, and more prosperous.

Unsurprisingly, social connection is generally not something we can do alone and not something that is accessible equitably. That is partially because we need others to connect with, but also because our society —including our schools, workplaces, neighborhoods, public policies, and digital environments—plays a role in either facilitating or hindering social connection. Moreover, it is critical to carefully consider equity in any approach to addressing social connection, as access and barriers to social opportunities are often not the same for everyone and often reinforce longstanding and historical inequities.

This advisory calls attention to the critical role that social connection plays in individual and societal health and well-being and offers a framework for how we can all contribute to advancing social connection.

What is Social Connection?

Social connection can encompass the interactions, relationships, roles, and sense of connection individuals, communities, or society may experience. An individual's level of social connection is not simply determined by the number of close relationships they have. There are many ways we can connect socially, and many ways we can lack social connection. These generally fall under one of three vital components of social connection: structure, function, and quality.

- **Structure**

The number of relationships, variety of relationships (e.g., co-worker, friend, family, neighbor), and the frequency of interactions with others.

- **Function**

The degree to which others can be relied upon for various needs.

- **Quality**

The degree to which relationships and interactions with others are positive, helpful, or satisfying (vs. negative, unhelpful, or unsatisfying).

These three vital components of social connection are each important for health, and may influence health in different ways.

It's also critical to understand other defining features of social connection.

First, it is a continuum. Too often, indicators of social connection or social disconnection are considered in dichotomous ways (e.g., someone is lonely or they're not), but the evidence points more to a gradient. Everyone falls somewhere on the continuum of social connection, with low social connection generally associated with poorer outcomes and higher social connection with better outcomes.

Second, social connection is dynamic. The amount and quality of social connection in our lives is not static. Social connectedness changes over time and can be improved or compromised for a myriad of reasons. Illness, moves, job transitions, and countless other life events, as well as changes in one's community and society, can all impact social connectedness in one direction or another. Further, how long we remain on one end of the continuum may matter. Transient feelings of loneliness may be less problematic, or even adaptive, because the distressing feeling motivates us to reconnect socially.[60] Similarly, temporary experiences of solitude may help us manage social demands.[61] However, chronic loneliness (even if someone is not isolated) and isolation (even if someone is not lonely) represent a significant health concern.

Third, much like the absence of disease does not equate to good health, the absence of social deficits (e.g., loneliness) does not necessarily equate to high levels of social connection. Although some measures of social connection represent the full continuum, others only focus on deficits, which do not capture the degree to which social assets may contribute to resilience, or even enable thriving. Consider two examples: first, an individual who is part of a large, highly-involved family, and second, an individual who has regular contact with colleagues through work but has little time for personal relationships outside of work. In each case, such an individual is not objectively isolated and may not feel subjectively lonely. However, in both cases key measures of isolation and loneliness may miss whether they are reaping the benefits of social connection in other ways, such as feeling adequately supported or having high-quality, close relationships.

Current Trends: Is Social Connection Declining?

Across many measures, Americans appear to be becoming less socially connected over time. This is not a new problem—certain declines have been occurring for decades. While precise estimates of the rates of social connection nationally can be challenging because studies vary based on which indicator is measured, when the same measure is used at multiple time points, we can identify trends.

Trends in Social Networks and Social Participation

Social networks are getting smaller, and levels of social participation are declining distinct from whether individuals report that they are lonely. For example, objective measures of social exposure obtained from 2003-2020 find that social isolation, measured by the average time spent alone, increased from 2003 (285-minutes/day, 142.5-hours/month) to 2019 (309-minutes/day, 154.5-hours/month) and continued to increase in 2020 (333-minutes/day, 166.5-hours/month). This represents an increase of 24 hours per month spent alone. At the same time, social participation across several types of relationships has steadily declined. For instance, the amount of time respondents engaged with friends socially in-person decreased from 2003 (60-minutes/day, 30-hours/month) to 2020 (20-minutes/day, 10-hours/month). This represents a decrease of 20 hours per month spent engaging with friends. This decline is starkest for young people ages 15 to 24. For this age group, time spent in-person with friends has reduced by nearly 70% over almost two decades, from roughly 150 minutes per day in 2003 to 40 minutes per day in 2020. The COVID-19 pandemic accelerated trends in declining social participation.

The number of close friendships has also declined over several decades. Among people not reporting loneliness or social isolation, nearly 90% have three or more confidants. Yet, almost half of Americans (49%) in 2021 reported having three or fewer close friends —only about a quarter (27%) reported the same in 1990. Social connection continued to decline during the COVID-19 pandemic, with one study finding a 16% decrease in network size from June 2019 to June 2020 among participants.

Demographic Trends

Societal trends, including demographic changes such as age, marital/partnership status, and household size, also provide clues to current trends. For example, family size and marriage rates have been in steady decline for decades. The percentage of Americans living alone has also increased decade-to-decade. In 1960, single-person households accounted for only 13% of all U.S. households. In 2022, that number more than doubled, to 29% of all households.

The reasons people choose to remain single or unmarried, have smaller families, and live alone over time are complex and encompass many factors. Yet at the same time, it is important to acknowledge the contribution these demographic changes have on social disconnection because of the significant health impacts identified in the scientific evidence. Moreover, awareness can help individuals consider these impacts and cultivate ways to foster sufficient social connection outside of chosen traditional means and structures.

The research in this section points to overall declines in some of the critical structural elements of social connection (e.g., marital status, household size), which helps to explain increases in reported loneliness and social isolation and contributes to the

overall crisis of connection we are experiencing. Finally, this suggests we have fewer informal supports to draw upon in times of need—all while the number of older individuals and those living with chronic conditions continues to increase.

Trends in Community Involvement

Although the concept of community has evolved over time, many traditional indicators of community involvement, including with religious groups, clubs, and labor unions, show declining trends in the United States since at least the 1970s. In 2018, only 16% of Americans reported that they felt very attached to their local community.

Membership in organizations that have been important pillars of community connection have declined significantly in this time. Take faith organizations, for example. Research produced by Gallup, Pew Research Center, and the National Opinion Research Center's General Social Survey demonstrates that since the 1970s, religious preference, affiliation, and participation among U.S. adults have declined. In 2020, only 47% of Americans said they belonged to a church, synagogue, or mosque. This is down from 70% in 1999 and represents a dip below 50% for the first time in the history of the survey question. Religious or faith-based groups can be a source for regular social contact, serve as a community of support, provide meaning and purpose, create a sense of belonging around shared values and beliefs, and are associated with reduced risk-taking behaviors. As a consequence of this decline in participation, individuals' health may be undermined in different ways.

What Leads Us to Be More or Less Socially Connected?

A wide variety of factors can influence an individual or community's level of social connection. One organizing tool that helps us better understand these factors is the social-ecological model. This model organizes the interrelated factors that affect health on the individual level, in our relationships, in our communities, and in society. Each of these levels—from the smallest to the broadest—contribute to social connection and its associated risks and protection for health.

Social connection is most often viewed as driven by the individual —one's genetics, health, socioeconomic status, race, gender, age, household living situation, and personality, among other factors. These can influence motivation, ability, or access to connect socially. As we've seen, the level of one's connection is also dependent on the structure, function, and quality of relationships. However, connectedness is influenced by more than simply personal or interpersonal factors. It is also shaped by the social infrastructure of the community (or communities) in which one is born, grows up, learns, plays, works, and ages.

Social infrastructure includes the physical assets of a community (such as libraries and parks), programs (such as volunteer organizations and member associations), and local policies (such as public transportation and housing) that support the development of social connection.

The social infrastructure of these communities is in turn influenced by broader social policies, cultural norms, the technology environment, the political environment, and macroeconomic factors. Moreover, individuals are simultaneously influenced by societal-level conditions such as cooperation, discrimination, inequality, and the collective social connectedness or disconnectedness of the community. All of these shape the availability of opportunities for social connection.

In sum, social connection is more than a personal issue. The structural and social characteristics of the community produce the settings in which people build, maintain, and grow their social networks. Because many contributors to social connection go beyond an individual's control, in order to promote health, change is needed across the full scope of the social-ecological model. While every factor can be important contributors to social connection, it's important to look across these levels. That gives us clues to barriers to connection and the types of interventions which could successfully increase social connection. This broader view can also help identify what places groups at highest risk for social isolation and loneliness, as well as factors that reinforce cycles of risk or resilience.

Anyone of any age or background can experience loneliness and isolation, but some groups are at higher risk than others. Not all individuals or groups experience the factors that facilitate or become barriers to social connection equally. Some people or groups are exposed to greater barriers. It's critical to examine and highlight the disproportionate risk they face and to target interventions to address their needs.

Although risk may differ across indicators of social disconnection, currently, studies find the highest prevalence for loneliness and isolation among people with poor physical or mental health, disabilities, financial insecurity, those who live alone, single parents, as well as younger and older populations. For example, while the highest rates of social isolation are found among older adults, young adults are almost twice as likely to report feeling lonely than those over 65. The rate of loneliness among young adults increased every year between 1976 and 2019. In addition, lower-income adults are more likely to be lonely than those with higher incomes. Sixty-three percent of adults who earn less than $50,000 per year are considered lonely, which is 10 percentage points higher than those who earn more than $50,000 per year. These data do not suggest that individual or demographic factors inherently generate loneliness or isolation. Rather, the data enable us to understand the different socioeconomic, political, and cultural mechanisms that may indicate higher risk for certain groups and lead to loneliness and isolation.

Additional at-risk groups may include individuals from ethnic and racial minority groups, LGBTQ+ individuals, rural residents, victims of domestic violence, and those who experience discrimination or marginalization. Further research is needed to fully understand the disproportionate impacts of social disconnection.

Impacts of Technology on Social Connection

There is more and more evidence pointing to the importance of our environments for health, and the same is true for digital environments and our social health. A variety of technologies have quickly and dramatically changed how we live, work, communicate, and socialize. These technologies include social media, smartphones, virtual reality, remote work, artificial intelligence, and assistive technologies, to name just a few.

These technologies are pervasive in our lives. Nearly all teens and adults under 65 (96-99%), and 75% of adults 65 and over, say that they use the internet. Americans spend an average of six hours per day on digital media. One-in-three U.S. adults 18 and over report that they are online “almost constantly,” and the percentage of teens ages 13 to 17 years who say they are online “almost constantly” has doubled since 2015. When looking at social media specifically, the percentage of U.S. adults 18 and over who reported using social media increased from 5% in 2005 to roughly 80% in 2019. Among teens ages 13 to 17 years, 95% report using social media as of 2022, with more than half reporting it would be hard to give up social media. Although tech adoption is relatively high among all groups, Americans with disabilities, adults with lower incomes, and Americans from rural areas[92] continue to experience a persistent, albeit shrinking, digital divide. They are relatively less likely to own a computer, smartphone, or tablet, or have broadband internet access.

Technology has evolved rapidly, and the evidence around its impact on our relationships has been complex. Each type of technology, the way in which it is used, and the characteristics of who is using it, needs to be considered when determining how it may contribute to greater or reduced risk for social disconnection. There are multiple meta-analyses and reviews examining this topic that identify both benefits and harms.

Several examples of benefits include technology that can foster connection by providing opportunities to stay in touch with friends and family, offering other routes for social participation for those with disabilities, and creating opportunities to find community, especially for those from marginalized groups. For example, online support groups allow individuals to share their personal experiences and to seek, receive, and provide social support—including information, advice, and emotional support.

Several examples of harms include technology that displaces in-person engagement, monopolizes our attention, reduces the quality of our interactions, and even diminishes our self-esteem. This can lead to greater loneliness, fear of missing out, conflict, and reduced social connection. For example, frequent phone use during face-to-face interactions between parents and children, and between family and friends, increased distraction, reduced conversation quality, and lowered self-reported enjoyment of time spent together in-person. In a U.S.-based study, participants who reported using social media for more than two hours a day had about double the odds of reporting increased perceptions of social isolation compared to those who used social media for less than 30 minutes per day. Additionally, targets of online harassment report feelings of increased loneliness, isolation, and relationship problems, as well as lower self-esteem

and trust in others. Evidence shows that even perpetrators of cyberbullying experience weakened emotional bonds with social contacts and deficits in perceived belongingness.

Understanding how technology can enhance or detract from social connection is complicated by ever-changing social media algorithms, complex differences in individual technology use, and balancing concerns over obtaining private user data. Advancing research in this area is essential. With that said, the existing evidence illustrates that we have reason to be concerned about the impact of some kinds of technology use on our relationships, our degree of social connection, and our health.

Risk and Resilience Can Be Reinforcing

The factors that facilitate, or become barriers to, social connection can also reinforce either a virtuous or vicious cycle. Economic status, health, and service are just a few illustrative examples—better social connection can lead to better health, whereas less social connection can lead to poorer health. However, each of these can be reinforcing. Being in poorer health can become a barrier to engaging socially, reducing social opportunities and support, and reinforcing a vicious cycle of poorer health and less connection. A similar kind of pattern could occur among those struggling financially. For example, financial insecurity may require someone to work multiple jobs, resulting in less leisure time and limiting opportunities for social participation and connection—which, in turn, could provide fewer resources and financial opportunities. While these cycles can be reinforcing, they are not always negative. There is, for instance, a virtuous cycle between social connection and volunteerism or service. Those who are more connected to their communities are more likely to engage in service, and those who are engaged in service are more likely to feel connected to their communities and the individuals in it. Interestingly, there is also evidence showing that the well-being benefits associated with volunteering are even greater for those with higher social connectedness than those with less. Because these cycles can be reinforcing, prioritizing social connection can not only disrupt vicious cycles but also reinforce virtuous ones.

Lessons from the COVID-19 Pandemic

While social connection had been declining for decades prior to the COVID-19 pandemic, the onset of the pandemic, with its lockdowns and stay-at-home orders, was a critical time during which the issue of connection came to the forefront of public consciousness, raising awareness about this critical and ongoing public health concern.

Many of us felt lonely or isolated in a way we had never experienced before. We postponed or canceled meaningful life moments and celebrations like birthdays, graduations, and marriages. Children’s education shifted online—and they missed out on the many benefits of interacting with their friends. Many people lost jobs and homes. We were unable to visit our children, siblings, parents, or grandparents. Many lost loved

ones. We experienced feelings of anxiety, stress, fear, sadness, grief, anger, and pain through the loss of these moments, rituals, celebrations, and relationships.

Although the COVID-19 pandemic was a collective experience, it impacted certain populations differently. Frontline workers had a different experience than those who could work from home. Parents managing their own work and their children's online school had a different experience than single young people unable to interact in-person with friends. And those at greater risk of severe COVID-19, including older individuals, those living in nursing homes, and people with underlying health conditions, faced unique challenges. Emerging data suggests that people with close and positive familial connections may have had a different experience than those without. A recent national survey showed that, by April 2021, 1 in 4 individuals reported feeling less close to family members compared to the beginning of the pandemic. Yet, at the same time, about 1 in 5 said they felt closer to family members,[122] perhaps indicating that the pandemic exacerbated existing family dynamics of connection or disconnection.

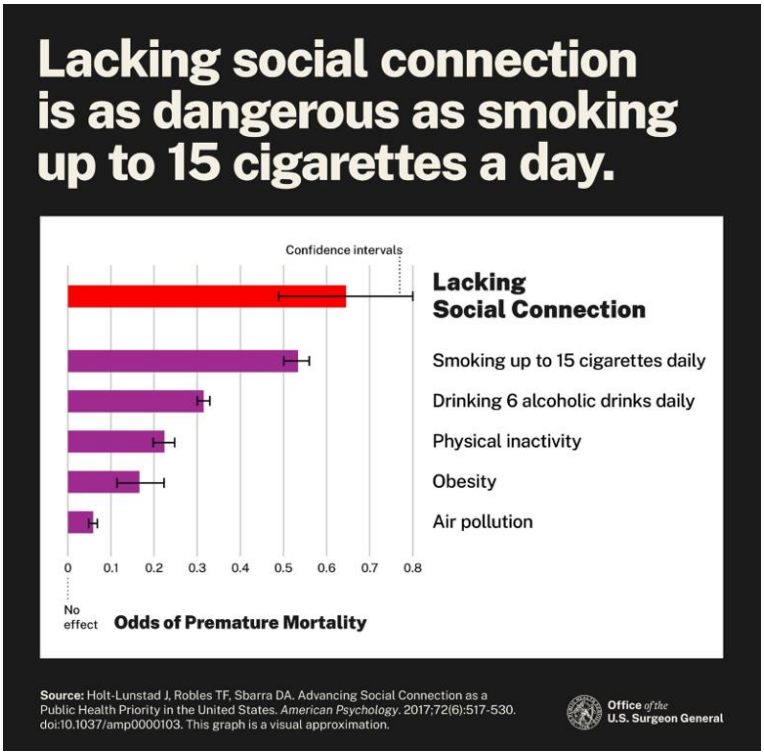
We also witnessed first responders, health care workers, community members, neighbors, and volunteers stepping up and offering their social support to one another. Service can be a powerful source of connection. From September 2020 to September 2021, the majority (51%) of U.S. individuals ages 16 and older reported informally helping others. This represents more than 120 million U.S. individuals helping informally, in addition to an estimated 60 million individuals formally volunteering through an organization during the same period. By engaging in service work, many were able to find and create pockets of connection for themselves and others during a public health crisis.

While profoundly disruptive in so many ways, the COVID-19 pandemic offers an opportunity to reflect more deeply on the state of social connection in our lives and in society. As we emerge from this era, rebuilding social connection and community offers us a promising and hopeful way forward.

How Social Connection Impacts Individual Health and Well-Being

Extensive scientific findings from a variety of disciplines, including epidemiology, neuroscience, medicine, psychology, and sociology, converge on the same conclusion: social connection is a significant predictor of longevity and better physical, cognitive, and mental health, while social isolation and loneliness are significant predictors of premature death and poor health. In fact, the benefits of social connection extend beyond health-related outcomes. They influence an individual's educational attainment, workplace satisfaction, economic prosperity, and overall feelings of well-being and life fulfillment. This chapter summarizes the rapidly growing body of evidence on the relationship between various indicators of social connection and these outcomes for individuals.

Evidence across scientific disciplines converges on the conclusion that socially connected people live longer. Large population studies have documented that, among initially healthy people tracked over time, those who are more socially connected live longer, while those environmental factors (e.g., air pollution), and clinical interventions (e.g., flu vaccine, high blood pressure medication, rehabilitation).



Over the years, the number of studies, the rigor of their methods, and the size of the samples have all increased substantially, providing stronger confidence in this evidence. These replicate the finding that social connection decreases the risk of premature death.

Taken together, this research establishes that the lack of social connection is an independent risk factor for deaths from all causes, including deaths caused by diseases.

The evidence linking social connection to physical health is strongest in heart disease and stroke outcomes. Dozens of studies have found that social isolation and loneliness significantly increase the risk of morbidities from these conditions. Among this evidence, a synthesis of data across 16 independent longitudinal studies shows poor social relationships (social isolation, poor social support, loneliness) were associated with a 29% increase in the risk of heart disease and a 32% increase in the risk of stroke. Interestingly, these effects can begin early in life and stretch over a lifetime. Research has also found that childhood social isolation is associated with increased cardiovascular risk factors such as obesity, high blood pressure, and blood glucose

levels in adulthood. Further, in a 2022 statement, the American Heart Association concluded that “social isolation and loneliness are common, yet underrecognized, determinants of cardiovascular health and brain health.”

Heart failure patients who reported high levels of loneliness had a 68% increased risk of hospitalization, a 57% higher risk of emergency department visits, and a 26% increased risk of outpatient visits, compared with patients reporting low levels of loneliness. Combining data from 13 studies on heart failure patients, researchers found that poor social connection is associated with a 55% greater risk of hospital readmission. This was consistent across both objective and perceived social isolation, including living alone, lack of social support, and poor social network. Furthermore, evidence suggests that people who are less socially connected, particularly those living alone, may be less likely to make it to the hospital, increasing their risk of dying from a cardiac event. Conversely, a heart attack is less likely to be fatal for people living with others or who have more social contacts, perhaps because of the immediate response and availability of help during the event.

Hypertension

High blood pressure (hypertension) is one of the leading causes of cardiovascular disease. Several studies demonstrate that the more social support one has, the greater the reduction in the possibility of developing high blood pressure, even in populations who are at higher risk for the condition, such as Black Americans. Greater social support in this group is associated with a 36% lower risk of high blood pressure in the long-term. Among older adults, the effect of social isolation on hypertension risk is even greater than that of other major clinical risk factors such as diabetes.

Since high blood pressure most often doesn’t have symptoms, it is possible for people to be unaware of even severe underlying cases. The disorder may remain undiagnosed for years, which can elevate the risk for a wide range of physiological complications. However, among older adults, people with higher perceived emotional support from family and friends, and with frequent exposure to health-related information within their social networks, are significantly less likely to have undiagnosed and uncontrolled hypertension.

The results of many research studies also reflect a strong correlation between social connection and high blood pressure control. Regular participation in two or more social or community-based groups; emotional and informational support from family, friends, professional contacts, community organizations, and peer groups; and frequent network interactions may improve hypertension management, including following treatment recommendations and long-term lifestyle adjustments. Findings from the National Social Life, Health, and Aging Project (NSHAP) suggest a “causal role of social connections in reducing hypertension,” particularly in adults over the age of 50.

Diabetes

Evidence gathered over the last 25 years has demonstrated that social context is important to the development and management of diabetes. Population-based studies show the impact of social connection on the development of type 2 diabetes and diabetic complications. For example, social disconnection (poor structural social support and living alone in men, low emotional support in women, and not having a current partner in women older than 70) has been linked to an increased risk for the development of type 2 diabetes. Furthermore, living alone increased the risk of developing type 2 diabetes among women with impaired glucose tolerance.

By contrast, social connection has been associated with better self-rated health and disease management among individuals with diabetes. The involvement and support of family members has also been repeatedly shown to improve disease management and the health of people with type 1 diabetes and type 2 diabetes. Whereas, smaller social network size has been associated with newly diagnosed type 2 diabetes and complications from diabetes. These associations between social connection and broader diabetic outcomes including diagnosed pre-diabetes and type 2 diabetes, macrovascular complications (e.g., heart attack, stroke) and microvascular complications (e.g., diabetic retinopathy, impaired sensitivity in the feet, and signs of kidney disease) were independent of blood sugar (glucose) control, quality of life, and other cardiac risk factors.

What explains this phenomenon? Diabetic outcomes may be better among people who are more socially connected due to better diabetic management behaviors and patient self-care such as medication adherence, physical activity, diet, and foot care. For example, in a meta-analysis of 28 studies, social support from family and friends was significantly associated with better self-care, particularly blood sugar monitoring. Finally, evidence from the National Health and Nutrition Examination Survey found that among older adults with diabetes, those with a large social support network size (at least six close friends) had a reduced risk of all-cause mortality.

Infectious Diseases

People who are less socially connected may have increased susceptibility and weaker immune responses when they are exposed to infectious diseases. In a series of studies examining factors that contribute to illness after exposure to viruses like the common cold and flu, loneliness and poor social support were found to significantly contribute to the development and severity of the illnesses. In one study where participants were exposed to a common cold virus, individuals with social ties to six or more diverse social roles (e.g., parent, spouse, friend, family, co-worker, group membership) had a four-fold lower risk of developing a cold when compared to people who had ties to fewer (1-3) diverse social roles. These effects cannot be explained by previous exposure, since those who are more socially connected have stronger immune responses independent of baseline antibody count—suggesting stronger immune responses even when exposed to new viruses. A study conducted on immune responses to the COVID-19

vaccine found that a lack of social connection with neighbors and resultant loneliness was associated with weaker antibody responses to the vaccine.

Cognitive Function

Substantial evidence also links social isolation and loneliness with accelerated cognitive decline and an increased risk of dementia in older adults,[1] including Alzheimer's disease. Chronic loneliness and social isolation can increase the risk of developing dementia by approximately 50% in older adults, even after controlling for demographics and health status. A study that followed older adults over 12 years found that cognitive abilities declined 20% faster among those who reported loneliness.

When taken together, this evidence consistently shows that wider social networks and more frequent social engagements with friends and family are associated with better cognitive function and may protect against the risk of dementia. This suggests that investments in social connection may be an important public health response to cognitive decline.

Depression and Anxiety

Depression and anxiety are often characterized by social withdrawal, which increases the risk for both social isolation and loneliness; however, social isolation and loneliness also predict increased risk for developing depression and anxiety and can worsen these conditions over time. A systematic review of multiple longitudinal studies found that the odds of developing depression in adults is more than double among people who report feeling lonely often, compared to those who rarely or never feel lonely. Furthermore, in older adults, both social isolation and loneliness have been shown to independently increase the likelihood of depression or anxiety. These findings are also consistent among younger people. A review of 63 studies concluded that loneliness and social isolation among children and adolescents increase the risk of depression and anxiety, and that this risk remained high even up to nine years later.

Importantly, social connection also seems to protect against depression even in people with a higher probability of developing the condition. For example, frequently confiding in others is associated with up to 15% reduced odds of developing depression among people who are already at higher risk due to their history of traumatic or otherwise adverse life experiences.

Suicidality and Self-Harm

While many factors may contribute to suicide, more than a century of research has demonstrated significant links between a lack of social connection and death by suicide. This research suggests that social connection may protect against suicide as a cause of death, especially for men.

One study found that among men, deaths due to suicide are associated with loneliness and more strongly with indicators of objective isolation such as living alone.[170] In this

study of over 500,000 middle-aged adults, the probability of dying by suicide more than doubled among men who lived alone. The same study showed that for women loneliness was significantly associated with hospitalization for self-harm. Further, when examining suicidality among nursing home and other long-term care facility residents, cancer patients, older adults, and adolescents, systematic reviews of studies on loneliness, social isolation, and low social support were associated with suicidal ideation. These links may result from a low sense of belonging and perceiving oneself as a burden to others.

Loneliness and low social support are also associated with increased risk of self-harm. In a review of 40 studies of more than 60,000 older adults, an increase in loneliness was reported to be among the primary motivations for self-harm.

Given the totality of the evidence, social connection may be one of the strongest protective factors against self-harm and suicide among people with and without serious underlying mental health challenges.

Social Connection Influences Health Through Multiple Pathways

While the effects of social connection on health are clear, research also helps explain how our level of social connection ultimately results in better or worse health. A key part of the explanation involves understanding how social connection influences behavioral, biological, and psychological processes, which in turn influence health outcomes. A large body of evidence has identified several plausible pathways.

Social Connection Influences Biological Processes

The role of social connection on biology emerges early in life and continues across the life course, contributing to risk and protection from disease. Several reviews document that social connection can influence health through specific biological pathways, including cardiovascular and neuroendocrine dysregulation, immunity, and gut-microbiome interactions. Because regulation of these systems is critical for good health, the documented influence between social connection and these biological pathways likely explains the impact on the risk of the development of disease.

Biological systems often do not operate independently. This means that increases in blood pressure, circulating stress hormones, and inflammation may occur simultaneously, potentially compounding risk across several biological systems.

One biological pathway of great interest is inflammation, given that it has been implicated as a factor in many chronic illnesses. Evidence shows that being objectively isolated, or even the perception of isolation, can increase inflammation to the same degree as physical inactivity. Similarly, lower social support is associated with higher inflammation. Chronic inflammation throughout the body has been linked to various chronic illnesses across the lifespan, such as cardiovascular disease, cancer, diabetes, depression, and Alzheimer’s disease, as well as a variety of mental, cognitive, and

physical health outcomes that increase the risk of premature mortality. Thus, inflammation may be a common pathway that explains the many diverse health outcomes associated with isolation and loneliness.

The protective, or positive, effects of social connection may operate on biological systems in a similar way, meaning that social connection may reduce the risk of disease by reducing biological system dysregulation. For example, increased levels of social connection can improve various biomarkers of cardiovascular functioning, including blood pressure, cardiovascular reactivity, and oxidative stress. In addition, social support and social bonding are associated with better regulation of the neuroendocrine system, including the role of oxytocin in both early life and adult attachment.

Social Connection Influences Behaviors

Social connection is also significantly associated with a number of health-related behaviors, including lifestyle behaviors (e.g., diet, exercise, sleep), and treatment adherence (e.g., taking medication as directed, engaging in recommended prevention measures) which ultimately influence our health and longevity. Social influence can be direct—loved ones encouraging one to get more sleep or reminding one to take their medication—or subtle, through social norms that communicate approval or disapproval of certain behaviors (like vaccination, smoking, exercise). In fact, evidence shows people are far more likely to be physically active if their peers and friends also exercise,[213,214] and they are more likely to stop smoking themselves if their social contacts do so as well. However, they are also less likely to stop smoking if they are in close connection to others who smoke, or even at risk for relapse if they had successfully quit smoking previously. Thus, it is clear that it is not just the presence of social connection and social support but the nature of the behaviors and norms in one's social network that influence health-related behaviors.

Individual Educational and Economic Benefits

The benefits of social connection extend beyond the well-being of individuals' health to quality of life, education, employment, and economic outcomes. Just as with health, those who lack sufficient social connection, whether because they are isolated, lonely, or in poor-quality relationships, seem to be at higher risk for poorer outcomes in these aspects of life as well.

Educational Benefits

Research shows that children and adolescents who enjoy positive relationships with their peers, parents, and teachers experience improved academic outcomes. For example, a review of youth mentoring programs found a positive association between mentoring programs intended to promote positive youth outcomes and improved school attendance, grades, and academic achievement test scores. Further, school and family connectedness during adolescent years may predict subsequent positive outcomes in

early adulthood, including a higher likelihood of graduating college and attaining a 4-year college degree.

In contrast, the lack of quality social connections inhibits student progression even in higher education settings. For example, among medical students, feeling socially isolated is associated with dropping out. The lack of social connection is cited as a prime reason for leaving a program.

Economic Benefits

Supportive and inclusive relationships at work are associated with employee job satisfaction, creativity, competence, and better job performance. Quality social support, social integration, and regular communication among co-workers of all levels are key in preventing chronic work stress and workplace burnout. These resources may even be linked to shorter recovery times and less missed work after work-related injuries or illnesses. Workplace connectedness is also associated with enhanced individual innovation, engagement, and quality of work, all of which can influence career advancements, income, and overall economic stability.

Social connection outside the workplace also plays an important role in an individual's economic situation. Diverse social networks that facilitate interaction and relationship-building among people of differing socioeconomic status (SES) may provide opportunities for individuals from lower SES backgrounds to gain stronger footing in the labor market and obtain higher-paying jobs. Such bridging, cross-class ties are among the most important predictors of upward economic mobility.

Additionally, activities that better connect individuals to one another, including immersion in local community-based activities or volunteering, can also equip individuals with desirable skills that make them more employable, and significantly increase the likelihood of unemployed individuals becoming employed.

How Social Connection Impacts Communities

Decades of research across disciplines such as political science, economics, sociology, behavioral science, and public health, among others, have examined the relationship between group social connection and population health and well-being. Though variation exists across studies and methodologies, the cumulative evidence generally points to the same conclusion: higher levels of social connectedness suggest better community outcomes, ranging from population health to community safety, resilience, prosperity, and representative government; while lower levels of social connectedness suggest worse outcomes in each of these areas. These studies establish that social connection is vital not only to our individual physical, mental, and emotional health, but also to the health and well-being of our communities.

This chapter explores what it means to be a socially connected community and examines the evidence that more connected communities benefit from higher levels of

well-being. The chapter also addresses the potential harms of negative social connection for community and societal well-being.

Socially Connected Communities

The scientific literature on social connection has defined “community” in many ways. Broadly, the term refers to a group of people with a characteristic in common. For the purpose of this advisory, however, the terms “community” and “communities” refer to a shared geographic location—neighborhoods, towns, cities. This chapter summarizes research that pertains to in-person social connection and the benefits that exist within place-based communities.

This does not diminish other types of communities (including those online) that can also provide support and other important elements of social connection. However, in-depth review of these types of communities is beyond the scope of this advisory and requires additional research.

Social capital is a key concept that researchers have identified as an important characteristic for understanding the social connectedness of communities. The definition and measurement of social capital varies by discipline, but broadly, social capital may be understood as “the resources to which individuals and groups have access through their social networks.” The term social capital is often used as an umbrella for both social support and social cohesion.

Social support refers to the perceived or actual availability of emotional, informational, or tangible resources from other individuals in one’s social network. **Social cohesion** refers to the sense of solidarity within groups, marked by strong social connections and high levels of social participation, that generates trust, norms of reciprocity, and a sense of belonging.

Trust is a critical component of socially connected communities and a subjective indicator frequently used to measure social capital. Again, the scientific literature defines trust in many ways, but, broadly, it refers to an individual’s expectation of positive intent and benevolence from the actions of others. Trust is an attitude that informs behavior towards unknown people (**generalized trust**), towards a known individual or group (**particularized trust**), or towards organizations and government (**institutional trust**).[29,234] It underlies communication and cooperation, both elements of social cohesion and social support. Higher levels of trust have been linked to improved population health, economic prosperity, and social functioning.

The **social infrastructure** of a community shapes its social capital. This refers to the programs (such as volunteer organizations, sports groups, religious groups, and member associations), policies (like public transportation, housing, and education), and physical elements of a community (such as libraries, parks, green spaces, and playgrounds) that facilitate bringing people together. Social infrastructure may help a community by providing opportunities to foster social connections among residents,

local leaders, and community-serving organizations. As social networks grow in size, diversity, and strength, this produces greater levels of social support and social cohesion and builds social capital for a community.

Because belonging to a group is generally adaptive and improves survival, people have a natural tendency to build and maintain relationships with those who are most like themselves (e.g., those with similar educational backgrounds, incomes, professions, or family status). This type of social connection, defined as **bonding social capital**, is important and can provide the support and resources needed not only to prevent or reduce loneliness and social isolation but also to contribute to fulfillment and well-being.

Research suggests that diversifying social relationships to include connections with people who are outside of your group (**bridging social capital**), as well as connections between people of differing power status in the community (**linking social capital**) are also associated with improved community health and well-being. Examples of these types of relationships include cultivating intergenerational friendships (bridging) or developing programs like a mentorship exchange between youth and local employers (linking).

Larger and more diverse social networks, with a mixture of types of relationships, can provide access to more varied types of social support and generate greater levels of social capital. Furthermore, interacting with people from diverse backgrounds can help to stimulate creative thinking and encourage the consideration of different perspectives, leading to better problem-solving and decision-making. Finally, social interactions with neighbors and other community members —like small gestures such as smiling at a passerby or brief conversations at the bank, post office, grocery store, or local coffee shop—can foster a sense of interpersonal trust and create and maintain norms of reciprocity. This can also increase **empathy**, one of the best documented sources of altruism, by enhancing understanding with one another, supporting the development of shared identities and affiliations, and facilitating cooperation and beneficial interactions across individuals and groups. This helps to generate more social capital for the broader community.

These community interactions can be associated with a positive reinforcing cycle. As this chapter illustrates, individuals who immerse themselves in community-based activities are more likely to experience stronger feelings of social belonging and develop trusting relationships with fellow community members. This can lead people to more readily contribute their time and resources back to their communities. When community-based participation becomes the norm, social networks grow and produce high levels of trust among themselves, which facilitates the efficient exchange of information and sharing of resources within a community.

The Benefits of More Connected Communities

Population Health

Communities with higher levels of social connection typically enjoy significantly better health outcomes than communities that have lower levels. Studies find that community-level social capital is positively associated with a reduced burden of disease and risk for all-cause mortality. A meta-analysis of several studies looking at the cumulative effects across multiple indicators of social capital on all-cause mortality and general health found that on average, a one-unit increase in social capital increases the likelihood of survival by 17% and of self-reporting good health by 29%. In a separate study using data from 39 states, the authors found a dose-response relationship between the extent of social capital within a community and age-adjusted mortality. A 10% increase (one standard deviation) in the proportion of residents in each state who felt that other people could be trusted was associated with an 8% decline in overall mortality. Another study found that those with very strong perceptions of community belonging—an indicator of social cohesion—reported very good or excellent health at a rate 2.6 times higher than those with very low perceptions of belongingness. This was true even after adjusting for demographic variables, health and health behaviors, and the built environment. Finally, communities with higher levels of social capital are also more likely to see decreased hospital readmission rates.

The positive effects of social capital on health are not only evident when added up across individuals. Synergistic effects among various aspects of social capital also exist and impact community-wide health outcomes. Connected individuals who leverage available social capital resources to improve their health-related behaviors or collectively reform their community culture can generate downstream improvements in overall population-level health.

For example, personal biases and fears about highly stigmatized diseases such as HIV create barriers to health care and social inclusion for individuals living with HIV. A review of multiple studies shows that high levels of social capital in high-risk populations can buffer against those harmful social barriers and significantly increase the likelihood of HIV prevention behaviors. In turn, members of highly connected communities are more likely to participate in health-protective efforts and seek care when needed, thereby decreasing the disease burden and risk of disease transmission among the whole population. Similarly, more connected communities have higher utilization of immunization services, and are more likely to adopt recommended health-protective behaviors— all of which benefit the broader community.

Evidence also shows that stronger social bonds and social capital in communities increase the likelihood that local community groups and health care institutions will build population health-focused partnerships. These partnerships rely on the existing mutual trust and reciprocity within community settings to increase engagement opportunities within the population and improve access to health care in low-resource populations.

On the other hand, several reports have found that lower community social connection is linked to poorer health outcomes. This was made clear when examining the spread of

the COVID-19 virus. One study in the United States compared changes in the county-level spread of COVID-19 against several measures of social capital. These included family structure and involvement, trust in community institutions, popularity of volunteerism, levels of participation in political discussions and voting efforts, and cohesion among community members. After controlling for potential alternative explanatory factors, the researchers found that lower levels of social capital were associated with a higher number of cases and deaths from COVID-19 infection. Further, counties with strong social ties experienced fewer deaths during the COVID-19 pandemic. Relatedly, an international study of COVID-19 infection and fatality rates across 177 countries also observed a statistically significant association between greater interpersonal and government trust and lower infection rates.

Natural Hazard Preparation and Resilience

A community's resilience to natural hazard events such as earthquakes, tsunamis, hurricanes, large-scale flooding, and fires depends upon the collective ability of individuals, households, and institutions to prepare for anticipated events, adapt to and withstand changing conditions, and recover rapidly following disruption.

Studies show that neighbors are often the first to respond in disaster situations, even before trained emergency professionals, because they are physically nearby. Growing evidence suggests that in neighborhoods and communities where people know one another and are connected to community institutions (like service organizations, religious groups, or community-based organizations) people prepare for, respond to, and recover more quickly from natural hazards than those with lower levels of social connection.

In such connected communities, it is more likely that people will share their knowledge and informal resources with neighbors, prepare for natural hazards, comply with emergency procedures including evacuation, and engage in coordination of emergency response efforts after natural hazard events.

Further, high levels of social connection reduce the exodus of people immediately following a natural hazard, preserve valuable social capital like social support and interpersonal trust, enable neighbors to provide aid to one another, and allow communities to overcome collective action problems such as coordinating recovery and rebuilding. Despite these benefits of connection within and for neighborhood communities, only 3 in 10 Americans report knowing all or most of their neighbors.

Community Safety

Not only do higher levels of social connection within a community correspond to better health and disaster outcomes, but they are also associated with lower levels of community violence.[271-274] One recent study on community violence showed that a one standard deviation increase in social connectedness was associated with a 21% reduction in murders and a 20% reduction in motor vehicle thefts. The Project on

Human Development in Chicago Neighborhoods longitudinal study that began in the late 1990s found that neighborhoods with higher perceptions of social cohesion and where residents felt a “willingness to act” on behalf of community members (**collective efficacy**) were more likely to have reduced levels of crime and residents were more likely to feel safer. Many subsequent analyses have confirmed the association between social connection, greater perceived collective efficacy, and community safety. Recent studies have found that greater perceived collective efficacy, trust, and social norms on violence as unacceptable behavior can be protective factors against community violence. Fostering social connection is not a singular solution to community violence; however, it does play an instrumental role in prevention and response.

Economic Prosperity

Economic prosperity, including economic development, employment, the sharing of economic opportunities or information, and overall economic connectedness, is a key measure of the value that exists within a given society. Evidence illustrates that connected communities generally experience higher levels of economic prosperity. For example, an analysis of economic factors across the U.S. found that communities with higher social capital levels experienced greater resilience against unemployment between 2006 and 2010 and were able to weather the recession more successfully. In addition, a three-year study of 26 cities in the U.S. found that those with the highest levels of resident attachment experienced the greatest growth in GDP during the study period.

Further, members of these connected communities are more likely to recommend job and educational opportunities to one another, collaborate on ideas for innovation, build partnerships for local businesses, and directly advance economic progress in their communities. In addition, longitudinal evidence shows that civic engagement, another form of community participation, in adolescence and early adulthood positively predicts educational attainment and income potential in adulthood. In this way, local community participation may also influence socioeconomic mobility of individuals across their lifespan and also reduce large-scale socioeconomic disparities.

In contrast to the clear benefits of community connectedness, the consequences of disconnection on community prosperity can be detrimental. Long-standing systemic disinvestment, inequitable zoning laws, underdeveloped transportation systems, and residential segregation can perpetuate chronic poverty and isolate entire neighborhoods or towns from more prosperous local economies. On the other hand, cross-class exposure could have positive impacts on economic mobility across generations. For example, if children of low socioeconomic backgrounds had the share of high socioeconomic friends comparable to that of the average child with a high socioeconomic background, these children would increase their incomes in adulthood by an average of 20%. Pro-connection policies and practices can promote economic

prosperity in communities harmed by structural barriers and eliminate such obstacles toward prosperity.

Civic Engagement and Representative Government

Higher levels of social connection are associated with increased levels of civic engagement (defined as “actions to address issues of public concern”) and more representative government. Emerging evidence has shown that civic engagement helps to develop “empathy, problem solving, [and] cooperation” among community members. One study showed that higher levels of family and community connection during adolescence predicted civic engagement outcomes in young adulthood including a greater likelihood of voting and involvement in social action and conversation groups. Further examples of civic engagement include registering to vote and voting, participating in advocacy groups or clubs, and connecting to information and current events. In addition, studies show that group membership and social networks strongly influence the decision to participate in the political process. Moreover, in a positive cycle, research suggests that greater civic engagement can lead to policies and programs that better reflect the will of a community’s residents, which in turn can promote continued and increased civic engagement.

The Potential Negative Side of Social Connection

Our fundamental human need for belonging is so strong that we may seek it out even in ways that may be unhealthy to ourselves or to our broader community. This can include participation in gangs and joining extremist or other harmful groups. Our natural tendency to associate with those most like us can be manipulated, with potentially negative consequences for individual and community well-being. When there are scarce resources, this can also lead to competition among various groups, leading to an “us” versus “them” mentality.

We tend to view our own group as more favorable and deserving than members of other groups.[290] This can result in distrust and rejection of outsiders.[291] In addition, among highly cohesive groups, there are also strong pressures to conform to the group norms[292]—often with high costs like rejection or ostracization if one doesn’t comply. While high cohesion and conformity to group norms can be healthy and productive in many cases, among some groups, these social pressures may justify, rationalize, or encourage unhealthy, unsafe, or unfair behaviors such as binge drinking, violence, and discrimination.

Societal Polarization

One consequence of the natural tendency for people to build and maintain relationships with those who are like themselves is the risk for exacerbating polarization in our discourse and in society—potentially leading to poorer outcomes for broader society.

“Core discussion networks,” are circles of people who have conversations on timely but difficult topics such as politics, finances, world events, religion, health, and more. The nature, size, and diversity of these discussion networks are important to how individuals form opinions, attitudes, and awareness of differing perspectives. They ultimately foster political tolerance. Generally, the size and diversity of core discussion networks have been shrinking substantially over the recent decades. One survey of 1,055 U.S. adults during the 2016 U.S. presidential election found that core discussion networks were smaller than in any other observed period and that the proportion of individuals with the same political preference within core discussion networks was higher than reported previously.

As discussion networks shrink and become more politically homogenous while society becomes more polarized, it is perhaps not surprising that almost 6 in 10 U.S. adults report that it is “stressful and frustrating” to talk about politics with people who hold different political opinions. A recent survey found that 64% of individuals believe that people are incapable of having constructive and civil debates about issues on which they disagree. Additionally, growing ideological divisions in the U.S. are fueling skepticism and even animosity between groups across the political divide —sentiments of enmity and disapproval between Democrats and Republicans more than doubled between 1994 and 2014. Polarization can lead to identity-based extremism and violence, pointing to the urgent need to foster social connection across group-based ideological differences through **bridging social capital**.

A National Strategy to Advance Social Connection

The world is just beginning to recognize the vital importance of social connection. While the evidence of the severe consequences of social isolation, loneliness, and overall social disconnection has been building for decades, a global pandemic crystallized and accelerated the urgency for the United States to establish a National Strategy to Advance Social Connection. Such a strategy not only recognizes the critical importance of advancing social connection, but also serves as a commitment to invest in and take actions establishing that our connection with others is a core value of this nation.

As this advisory has shown, fulfilling connections are a critical and often underappreciated contributor to individual and population health and longevity, safety, prosperity, and well-being. On the other hand, social disconnection contributes to many poor health outcomes, and even to premature death. Sadly, around 50% of adults in the U.S. reported being lonely in recent years[1-3]— and that was even before COVID-19 separated so many of us from our friends, loved ones, and support systems. Our bonds with others and our community are also part of this equation. Research has shown that more connected communities enjoy higher levels of well-being. The converse is also true. How do we put this important information to practical use in our society? What actionable steps can we take to enhance social connection so that we can all enjoy its benefits?

A National Strategy to Advance Social Connection is the critical next step to catalyze action essential to our nation's health, safety, and prosperity. The strategy includes six foundational pillars and a series of key recommendations, organized according to stakeholder group, to support a whole-of-society approach to advancing social connection. Individuals and organizations can use this framework to propel the critical work of reversing these worrisome trends and strengthening social connection and community.

Doing so won't always be easy. Fostering greater connection requires widespread individual and institutional action. It demands our sustained investment, effort, and focus. But it will be worth it, because when we each take these critical steps, we are choosing better lives, and to create a better world for all.

Such a world, where we recognize that relationships are just as essential to our well-being as the air we breathe and the food we eat, is a world where everyone is healthier, physically and mentally. It is a world where we respect and value one another, where we look out for one another, and where we create opportunities to uplift one another. A world where our highs are higher because we celebrate them together; where our lows are more manageable because we respond to them together; and where our recovery is faster because we grieve and rebuild together.

It is a world where we are strong enough to hold our differences, where we are more comfortable and motivated to engage civically, and where our leaders and institutions are more representative of the people they serve. It is a world where we trust one another, where we feel safe to challenge one another and change our minds, and where prosperity and progress are not the privilege of the few but accessible to all.

We can choose, in short, to take the core values that make us strong—love, kindness, respect, service, and commitment to one another—and reflect them in the world we build for ourselves and our children. This strategy shows us how to create the connected lives and the connected world we need.

Benefits of a National Strategy to Advance Social Connection

- **Cultivating individual health and well-being** across physical and mental health and educational and economic outcomes. This enables individuals to be happier, more prosperous, and to contribute more fully to society.
- **Strengthening community health, safety, and prosperity** by cultivating social cohesion and social capital within and across communities. This enables communities to overcome adversity and thrive.
- **Building resilience for the next set of challenges** such as natural hazards, pandemics, and safety threats. This enables society to withstand unanticipated crises through stronger recovery and resilience.

- **Advancing civic engagement and representative government** by fostering a more engaged citizenry. This enables policies and programs to better reflect the will of a community and its individuals.

Many factors that influence social connection are environmental. Decisions about the layout of our cities, from the usability and reach of public transportation to the design of housing and green spaces, have a direct effect on social interaction in a community.[302,303] This is why strengthening social infrastructure that promotes social connection is critical to advancing key aspects of community health, resilience, safety, and prosperity. Social infrastructure refers to the programs (such as volunteer organizations, sports groups, religious groups, and member associations), policies (like public transportation, housing, and education), and physical elements of a community (such as libraries, parks, green spaces, and playgrounds) that support the development of social connection.

Investing in local communities and in social infrastructure will fall short if access to the benefits is limited to only some groups. Equitable access to social infrastructure for all groups, including those most at-risk for social disconnection, is foundational to building a connected national and global community, and is essential to this pillar's success.

Moreover, community programs, such as those that connect us to our neighbors, those that help students establish social skills in schools, and those that generate opportunities for high-risk populations to create community, also have a powerful role in building relationships. For example, volunteering is a demonstrated and powerful way to advance connection to one's community and create diverse ties among community members. Finally, institutions that gather individuals for work, study, or prayer, such as workplaces, schools, and faith organizations, can function as sources of positive connection and thereby bolster the community's trust in those institutions and in fellow members. Investing in community connection will be important to repairing divisions and rebuilding trust in each other and our institutions, and is vital to achieving common societal goals.

National, state, local, and tribal governments play a critical role in strengthening social connection and community across all sectors. These institutions recognize the importance of social connection to the health of their communities. Policymakers understand that while the effects of social connection may be most evident for health, the drivers of connection and disconnection can be found in all types of policies, from transportation and zoning to nutrition and labor. A "Connection-in-All-Policies" approach recognizes that every sector of society is relevant to social connection, and that policy within each sector may potentially hinder or facilitate connection. Conversely, government has a responsibility to use its authority to monitor and mitigate the public health harm caused by policies, products, and services that drive social disconnection.

Prioritizing social connection in policy agendas and leveraging a "Connectionin-All-Policies" approach requires establishing cross-departmental leadership to develop and

oversee an overarching social connection strategy. Diversity, equity, inclusion, and accessibility are critical components of any such strategy. It must recognize that everyone is impacted by social connection, but that some groups may be more disproportionally impacted by some policies. Thus, policymakers must give focused attention to reducing disparities in risk and ensuring equal access to benefits.

Social connection is an independent protective factor, and social isolation and loneliness are independent risk factors for several major health conditions, including cardiovascular disease, dementia, depression, and premature mortality from all causes.[128] While all organizations have a role in addressing social connection, mobilizing the health sector—most notably health care delivery systems and the public health community—is a core pillar of the National Strategy.

It is critical that we invest in health care provider education on the physical and mental health benefits of social connection, as well as the risks associated with social disconnection. We must also create systems that enable and incentivize health care providers to educate patients as part of preventative care, assess for social disconnection, and respond to patients' health-relevant social needs. This can be accomplished both within the medical system and by linking individuals to community-based organizations that can provide necessary support and resources specifically designed to increase social connection.[10,285,304,305] Public health organizations can help track the community prevalence of social disconnection, promote individual best practices, and advance community solutions. By integrating social connection into primary-, secondary-, and tertiary-level prevention and care efforts, we can strive to prevent forms of social disconnection in healthy individuals, mitigate forms of social disconnection early on before they become severe, and provide adequate support for those who are experiencing severe forms of social disconnection.

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But these benefits come at a cost. Technology can also distract us and occupy our mental bandwidth, make us feel worse about ourselves or our relationships, and diminish our ability to connect deeply with others. Some technology fans the flames of marginalization and discrimination, bullying, and other forms of severe social negativity.

We must decide how technology is designed and how we use it. There are many ways to minimize harms. We must learn more by requiring data transparency from technology companies. This will enable us to understand their current and long-term effects on social connection, and implement and enforce safety standards (such as age-related protections for young people) that ensure products do not worsen social disconnection. In a positive vein, we should support the development of pro-connection technology to promote healthy social connection, create safe environments for discourse, and

safeguard the well-being of users. This should be coupled with the public's greater ability to avoid or limit their own uses.

Finally, we need to recognize the unique aspects of digital technology that may differ from other modes of connecting socially. The modality of delivery matters, and should be strategically and explicitly acknowledged and evaluated.

This Surgeon General's Advisory outlines a summary of the evidence about how social connection and disconnection impact individual and community health and overall well-being. The totality of this evidence illustrates that urgent action is needed, including additional research to further advance our understanding of the causes and consequences of social connection, trends, populations at risk, and the effectiveness of interventions and other efforts to advance connection.

As a next step, relevant stakeholders, including government, policymakers, practitioners, and researchers, should work together to establish a research agenda focused on addressing identified gaps in the evidence base, fund research at levels commensurate with the seriousness of the problem, and create a plan to increase research coordination. Deepening our knowledge of social connection and disconnection also requires us to further refine and expand our capacity to measure these states via agreed upon standardized metrics. As individuals, communities, institutions, and governments implement the pillars of the National Strategy, consistent measurement will be critical to better understanding the driving forces of connection and disconnection, and how we can be more effective and efficient in addressing these states.

Public understanding of the essential role of social connection in health and well-being is critical to this pillar. Social connection should be included as a key driver of health in formal health education, from elementary to professional school curricula. It is also imperative that we share this knowledge beyond health professionals. Public awareness and education of the drivers and solutions of connection and disconnection will be a critical foundation to support sustained policy and cultural change.

A culture of connection is vital to creating the changes needed in society. While formal programs and policies can be impactful, the informal practices of everyday life—the norms and culture of how we engage one another—significantly influence social connection. These shared beliefs and values drive our individual and collective behaviors that then shape programs and policies. We cannot be successful in the other pillars without this underlying culture of connection.

Such a culture of connection rests on core values of kindness, respect, service, and commitment to one another. Everyone contributes to the collective culture of social connection by regularly practicing these values. Advancing this culture requires individuals and leaders to seek opportunities to do so in public and private dialogue, schools, workplaces, and in the forces that shape our society like media and

entertainment, among others. Behaviors are both learned from and reinforced by the groups we participate in and the communities we are a part of. Thus, the more we observe others practicing these values, the more they will be reinforced in us.

All types of leaders and influencers (national, local, political, cultural, corporate, etc.) can use their voices to underscore these core values and model healthy social connection and dialogue. Media and entertainment shape our beliefs through the depiction of stories. These narratives can help individuals see themselves in stories and help to reduce stigma, thus enabling more connection. Further, our institutions should invest time, attention, and resources in ways that demonstrate these values.

Office *of the* U.S. Surgeon General

The Six Pillars to Advance Social Connection

1

Strengthen Social Infrastructure in Local Communities

Design the built environment to promote social connection

Establish and scale community connection programs

Invest in local institutions that bring people together

2

Enact Pro-Connection Public Policies

Adopt a "Connection-in-All-Policies" approach

Advance policies that minimize harm from disconnection

Establish cross-departmental leadership at all levels of government

3

Mobilize the Health Sector

Train health care providers

Assess and support patients

Expand public health surveillance and interventions

4

Reform Digital Environments

Require data transparency

Establish and implement safety standards

Support development of pro-connection technologies

5

Deepen Our Knowledge

Develop and coordinate a national research agenda

Accelerate research funding

Increase public awareness

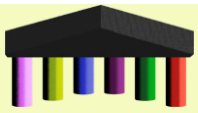
6

Build a Culture of Connection

Cultivate values of kindness, respect, service, and commitment to one another

Model connection values in positions of leadership and influence

Expand conversation on social connection in schools, workplaces, and communities



The Six Pillars to Advance Social Connection

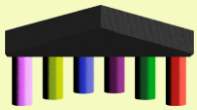
Pillar 1 Strengthen Social Infrastructure in Local Communities

- Design the built environment to promote social connection
- Establish and scale community connection programs
- Invest in local institutions that bring people together

Many factors that influence social connection are environmental. Decisions about the layout of our cities, from the usability and reach of public transportation to the design of housing and green spaces, have a direct effect on social interaction in a community.[302,303] This is why strengthening social infrastructure that promotes social connection is critical to advancing key aspects of community health, resilience, safety, and prosperity. Social infrastructure refers to the programs (such as volunteer organizations, sports groups, religious groups, and member associations), policies (like public transportation, housing, and education), and physical elements of a community (such as libraries, parks, green spaces, and playgrounds) that support the development of social connection.

Investing in local communities and in social infrastructure will fall short if access to the benefits is limited to only some groups. Equitable access to social infrastructure for all groups, including those most at-risk for social disconnection, is foundational to building a connected national and global community, and is essential to this pillar's success.

Moreover, community programs, such as those that connect us to our neighbors, those that help students establish social skills in schools, and those that generate opportunities for high-risk populations to create community, also have a powerful role in building relationships. For example, volunteering is a demonstrated and powerful way to advance connection to one's community and create diverse ties among community members. Finally, institutions that gather individuals for work, study, or prayer, such as workplaces, schools, and faith organizations, can function as sources of positive connection and thereby bolster the community's trust in those institutions and in fellow members. Investing in community connection will be important to repairing divisions and rebuilding trust in each other and our institutions, and is vital to achieving common societal goals.



The Six Pillars to Advance Social Connection

Pillar 2 Enact Pro-Connection Public Policies

- Adopt a "Connection-in-All-Policies" approach
- Advance policies that minimize harm from disconnection
- Establish cross-departmental leadership at all levels of government

National, state, local, and tribal governments play a critical role in strengthening social connection and community across all sectors. These institutions recognize the importance of social connection to the health of their communities. Policymakers understand that while the effects of social connection may be most evident for health, the drivers of connection and disconnection can be found in all types of policies, from transportation and zoning to nutrition and labor. A "Connection-in-All-Policies" approach recognizes that every sector of society is relevant to social connection, and that policy within each sector may potentially hinder or facilitate connection. Conversely, government has a responsibility to use its authority to monitor and mitigate the public health harm caused by policies, products, and services that drive social disconnection.

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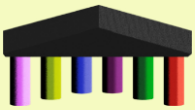

The Six Pillars to Advance Social Connection

Pillar 3 Mobilize the Health Sector

- Train health care providers
- Assess and support patients
- Expand public health surveillance and interventions

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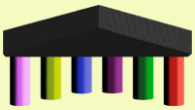

The Six Pillars to Advance Social Connection

Pillar 5 Deepen our Knowledge

- Develop and coordinate a national research agenda
- Accelerate research funding
- Increase public awareness

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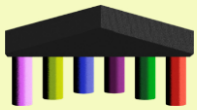

The Six Pillars to Advance Social Connection

Pillar 6 Cultivate a Culture of Connection

- Cultivate values of kindness, respect, service, and commitment to one another
- Model connection values in positions of leadership and influence
- Expand conversations on social connection in schools, workplaces, and communities

A culture of connection is vital to creating the changes needed in society. While formal programs and policies can be impactful, the informal practices of everyday life—the norms and culture of how we engage one another—significantly influence social connection. These shared beliefs and values drive our individual and collective behaviors that then shape programs and policies. We cannot be successful in the other pillars without this underlying culture of connection.

Such a culture of connection rests on core values of kindness, respect, service, and commitment to one another. Everyone contributes to the collective culture of social connection by regularly practicing these values. Advancing this culture requires individuals and leaders to seek opportunities to do so in public and private dialogue, schools, workplaces, and in the forces that shape our society like media and entertainment, among others. Behaviors are both learned from and reinforced by the groups we participate in and the communities we are a part of. Thus, the more we observe others practicing these values, the more they will be reinforced in us.

All types of leaders and influencers (national, local, political, cultural, corporate, etc.) can use their voices to underscore these core values and model healthy social connection and dialogue. Media and entertainment shape our beliefs through the depiction of stories. These narratives can help individuals see themselves in stories and help to reduce stigma, thus enabling more connection. Further, our institutions should invest time, attention, and resources in ways that demonstrate these values.

What National, Territory, State, Local, and Tribal Governments Can Do

- **Designate social connection a priority** by including it in public health and policy agendas, providing critical resources, and creating strategies to strengthen

social connection and community that include clear benchmarks, measurable outcomes, and periodic evaluation.

- **Establish a dedicated leadership position** to work across departments, convene stakeholders, and advance pro-connection policies.

- **Utilize a "Connection-in-All-Policies" Approach** that examines policies across sectors, including health, education, labor, housing, transportation, and the environment, and looks to identify and remedy policies that drive disconnection while advancing those that drive connection. Periodically, evaluate and revise existing policies and programs, and when appropriate, propose new policies to advance social connection. Examples of pro-connection policies include paid leave, which enables individuals to spend time with family during critical early life stages, and increased access to public transit, which allows individuals to physically connect more easily.

- **Monitor and regulate technology** by establishing transparency, accountability, safety, and consumer protections to ensure social health and safety (including for minors) and the ability for independent researchers to evaluate the impact of technology on our health and well-being.[306]

- **Create a standardized national measure or set of measures for social connection and standardized definitions for relevant terms**, in collaboration with the research community. Implement consistent, regular measurement of social connection metrics in current national health surveys, with the ability to capture the level of granularity needed to guide strategic decision-making, planning, and evaluation of strategies.

- **Prioritize research funding** such that research is supported at levels commensurate with the societal impact of loneliness, social isolation, and other forms of social disconnection, and enhance collaboration with researchers to improve research coordination.

- **Launch sustained and inclusive public education and awareness efforts**, including the development of national guidelines for social connection.[307]

- **Invest in social infrastructure at the local level**, including the programs, policies, and physical elements of a community that facilitate bringing people together.

- **Incentivize the assessment and integration of social connection** into health care delivery and public health, including through public insurance coverage and other government funding mechanisms.

- **Increase evaluation and oversight** of policy and programmatic outcomes from public institutions, programs, and services, and make the results available through public facing reports, databases, and other mechanisms. This will help improve existing policies and programs, demonstrate transparency, and increase public trust in institutions.

What Health Workers, Health Care Systems, and Insurers Can Do

- Explicitly **acknowledge social connection as a priority** for health.
- **Provide health professionals with formal training** and continuing education on the health and medical relevance of social connection and risks associated with social disconnection (e.g., isolation, loneliness, low social support, social negativity), as well as advanced training on prevention and interventions.

- Insurance companies should **provide adequate reimbursement** for time spent assessing and addressing concerns about social disconnection (e.g., isolation, loneliness, low social support, poor relationship quality), and incorporate these measurements into value-based payment models.
- **Facilitate inclusion of assessment results in electronic health records.**
- Providers and insurers can **educate and incentivize patients to understand the risks** of, and take action to address, inadequate social connection, with a particular focus on at-risk individuals, including but not limited to those with physical or mental health conditions or disabilities, financial insecurity, those who live alone, single parents, and both younger and aging populations.
- **Integrate social connection into patient care** in primary-, secondary-, and tertiary-level care settings by:

  ◦ Actively assessing patients' level of social connection to identify those who are at increased risk or already experiencing social disconnection and evaluate the level of necessary supports.[305]

  ◦ Educating patients about the benefits of social connection and the risk factors for social disconnection as part of primary prevention.

  ◦ Leveraging interventions that provide psychosocial support to patients, including involving family or other caregivers in treatment, group therapies, and other evidence-based options.[304]

- **Work with community organizations** to create partnerships that provide support for people who are at risk for, or are struggling with, loneliness, isolation, low social support, or poor-quality relationships.
- Create opportunities for clinicians to partner with researchers to **evaluate the application of evidence-based assessment tools and interventions within clinical settings,** including evaluating the efficacy of applications for specific populations.[10]

What Public Health Professionals and Public Health Departments Can Do

- **Establish social connection as a priority health indicator and social determinant of health** with the goal of improving health and well-being through programs, education, research, and promotion of healthy lifestyles across the lifespan.

- **Develop, lead, and support public education programs, awareness campaigns, and health professional training programs** focused on the health impacts of social disconnection. Integrate social connection as a key component of health promotion and wellness programs focused on related health issues (e.g., suicide, workplace burnout, substance use).
- **Study and support research on the causes of social disconnection.**

- **Evaluate, develop, and implement sustainable interventions and strategies** (e.g., programs, campaigns, tools, partnerships) across the social-ecological model to promote greater connection and prevent social disconnection.

Consistently and regularly track social connection using validated metrics (such as the Berkman-Syme Social Network Index, UCLA Loneliness Scale), and validate new measures to capture the full complexity of social connection to guide strategic decision-making, planning, and evaluation of strategies.

What Researchers and Research Institutions Can Do

- **Establish social connection as a research priority** and support researchers in this field with time, space, and funding.[32]

- **Develop a cross-disciplinary research agenda** including basic, translational, evaluation, and dissemination research that prioritizes systematically mapping outstanding evidence gaps to ensure adequate evidence across all levels of the social-ecological model, sectors of society, and the life course, with attention to inclusion, diversity, equity, access, and modality considerations. This research should include investigations into:

◦ The root causes of social disconnection, including how causal mechanisms vary across age, income, culture, race, ethnicity, gender identity, sexual orientation, and health status to advance equity in social well-being for all members of the community, and ensure research is inclusive of under-represented groups.[10,19]

◦ What social connection indicators may intersect or act independently, additively, or synergistically to influence risk and resilience for health and other societal outcomes.

◦ Fuller examinations of age, developmental, and cohort processes that may influence the onset and progression of disease and other adverse outcomes.

◦ Rigorous evaluation of technology's evolving impact on social connection.

◦ The effectiveness, efficiency, and acceptability of prevention, intervention, and dissemination approaches.

◦ Additional examinations of individual and societal effects of social connection within and beyond health outcomes, including indicators of well-being (e.g., wider community participation, quality of life), prosperity (e.g., educational attainment, employment, economic mobility), and public safety.

- **Develop and establish additional standardized national and local measures** that are regularly evaluated and can be used across basic research, clinical assessment, population surveillance, intervention evaluation, and other contexts.
- **Improve research coordination**, including the development of an accessible evidence database, a way to coordinate utilization of evidence among researchers, and a comprehensive way to track connection and community metrics over time.

What Philanthropy Can Do

- **Fund new programs and invest in existing successful programs** that advance social connection among individuals and within communities, including those that aim to prevent and treat social isolation and loneliness and those that reach populations at highest risk.
- Because social connection can be advanced through programs designed to support other outcomes (e.g., population health, community resilience, public safety, educational attainment, economic progress) funders should **evaluate cross-sector programs for their impact on social connection** by adding social connection and relationship-building as indicators of grantee success.
- **Provide support for adequate evaluation, reporting, and knowledge sharing** about the effectiveness of interventions designed to reduce loneliness and isolation and improve social connection.
- **Convene stakeholders** working to understand or strengthen social connection.
- **Invest in efforts to increase public awareness** and dissemination of findings.

What Schools and Education Departments Can Do

School administrators and leaders, boards of education, boards of trustees, teachers, parent teacher associations, state departments of education, and online learning platforms can all play a role.

- **Develop a strategic plan for school connectedness and social skills with benchmark tracking.** This could include providing regular opportunities and spaces for students to develop social skills and strengthen relationships, and the adoption of evidenced-based practices leveraging elements of the CDC Framework: Whole School, Whole Community, Whole Child.[310] Strategies to enhance connectedness may include promoting quality adult support from family and school staff, peer-led programs, and partnerships with key community groups.

- **Build social connection into health curricula,** including up-to-date, age-appropriate information on the consequences of social connection on physical and mental health, key risk and protective factors, and strategies for increasing social connection.

- **Implement socially based educational techniques** such as cooperative learning projects that can improve educational outcomes as well as peer relations.[311]

- **Create a supportive school environment** that fosters belonging through equitable classroom management, mentoring, and peer support groups that allow students to lean on one another and learn from each other's experiences.

What Workplaces Can Do

- **Make social connection a strategic priority in the workplace** at all levels (administration, management, and employees).[48]

- **Train, resource, and empower leaders and managers** to promote connection in the workplace and implement programs that foster connection. Assess program effectiveness, identify barriers to success, and facilitate continuous quality improvement.

- **Leverage existing leadership and employee training, orientation, and wellness resources** to educate the workforce about the importance of social connection for workplace well-being, health, productivity, performance, retention, and other markers of success.

- **Create practices and a workplace culture** that allow people to connect to one another as whole people, not just as skill sets, and that fosters inclusion and belonging.

- **Put in place policies that protect workers' ability to nurture their relationships outside work** including respecting boundaries between work and non-work time, supporting caregiving responsibilities, and creating a culture of norms and practices that support these policies.

- **Consider the opportunities and challenges posed by flexible work hours and arrangements** (including remote, hybrid, and in-person work), which may impact

workers' abilities to connect with others both within and outside of work. Evaluate how these policies can be applied equitably across the workforce.

What Community-Based Organizations Can Do

Community-based organizations include, but are not limited to, membership-based organizations, civic groups, arts and education groups, faith-based organizations, direct service providers, and youth-led organizations. Regardless of whether the mission of a community-based organization is focused on social connection, every organization can promote stronger social connection.

- **Create opportunities and spaces for inclusive social connection** and establish programs that foster positive and safe relationships, including among individuals of different ages, backgrounds, viewpoints, and life experiences.
- **Embed social connection** in internal policies, practices, programs, and evaluations.
- **Actively seek and build partnerships** with other community institutions (schools, health organizations, workplaces) to support those experiencing loneliness and social isolation, and to create a culture of connection in the broader community.
- **Advance public education and awareness efforts** to introduce and elevate the topic of social connection and disconnection among community members.
- **Create and provide education, resources, and support programs** for community members and key populations such as parents, youth, and at-risk populations. These could include community-wide social events, volunteering and community service activities, network-building professional development, and organizational opportunities for involvement by the community.
- **Foster a culture of connection in the broader community** by highlighting examples of healthy social connection and leading by example.

What Technology Companies Can Do

- **Be transparent with data** that illustrates both the positive and negative impacts of technology on social connection by sharing long-term and real-time data with independent researchers to enable a better understanding of technology's impact on individuals and communities, particularly those at higher risk of social disconnection.
- **Support the development and enforcement of industry-wide safety standards** with particular attention to social media, including age-appropriate protections and identity assurance mechanisms, to ensure safe digital environments that enable positive social connection, particularly for minors.

Intentionally design technology that fosters healthy dialogue and relationships, including across diverse communities and perspectives. The designs should prioritize

social health and safety as the first principle, from conception to launch to evaluation. This also means avoiding design features and algorithms that drive division, polarization, interpersonal conflict, and contribute to unhealthy perceptions of one's self and one's relationships.

What Media and Entertainment Industries Can Do

- **Create content that models and promotes positive social interactions**, healthy relationships, and reinforces the core values of connection: kindness, respect, service, and commitment to one another.
- **Utilize storylines and narratives** in film, television, and entertainment to provide messages that broaden public awareness of the health benefits of social connection and the risks of social disconnection.
- **Ensure that content related to social connection is scientifically accurate** in collaboration with the scientific community.
- **Avoid content and products that inadvertently increase disconnection or stigma around social disconnection**, recognizing the impact content can have on increasing societal distrust, polarization, and perpetuating harmful stereotypes.

What Parents and Caregivers Can Do

Parents and caregivers play an important role in shaping the experience of social connection. Although focused on parents of young children, many of these recommendations can apply more broadly to all types of caregivers.

- **Invest in your relationship with your child or loved one** by recognizing that strong, secure attachments are protective and a good foundation for other healthy relationships.
- **Model healthy social connection**, including constructive conflict resolution, spending time together, staying in regular contact with extended family, friends, and neighbors, setting time aside for socializing away from technology or social media, and participating in community events.
- **Help children and adolescents develop strong, safe, and stable relationships with supportive adults** like grandparents, teachers, coaches, counselors, and mentors.
- **Encourage healthy social connection with peers** by supporting individual friendships, as well as participation in structured activities such as volunteering, sports, community activities, and mentorship programs.
- **Be attentive to how young people spend their time online.** Delay the age at which children join social media platforms and monitor and decrease screen time in favor of positive, in-person, connection building activities.

- Identify and aim to **reduce behaviors and experiences that may increase the risk for social disconnection**, including bullying and excessive or harmful social media use.

- **Talk to your children about social connection regularly** to understand if they are struggling with loneliness or isolation, to destigmatize talking about these feelings, and to create space for children to share their perspective and needs.

◦ Look out for potential warning signs of loneliness and social isolation, such as increases in time spent alone, disproportionate online time, limited interactions with friends, or excessive attention-seeking behavior.[312,313]

◦ Connect youth to helpers like counselors, educators, and health care providers if they are struggling with loneliness, isolation, or unhealthy relationships.

What Individuals Can Do

- **Understand the power of social connection and the consequences of social disconnection** by learning how the vital components (structure, function, and quality) can impact your relationships, health, and well-being.

- **Invest time in nurturing your relationships** through consistent, frequent, and high-quality engagement with others. Take time each day to reach out to a friend or family member.

- **Minimize distraction during conversation** to increase the quality of the time you spend with others. For instance, don't check your phone during meals with friends, important conversations, and family time.

- **Seek out opportunities to serve and support others**, either by helping your family, co-workers, friends, or strangers in your community or by participating in community service.

- **Be responsive, supportive, and practice gratitude.**[314,315] As we practice these behaviors, others are more likely to reciprocate, strengthening our social bonds, improving relationship satisfaction, and building social capital.

- **Actively engage with people of different backgrounds and experiences** to expand your understanding of and relationships with others, given the benefits associated with diverse connections.

- **Participate in social and community groups** such as fitness, religious, hobby, professional, and community service organizations to foster a sense of belonging, meaning, and purpose.

- **Reduce practices that lead to feelings of disconnection from others.** These include harmful and excessive social media use, time spent in unhealthy relationships, and disproportionate time in front of screens instead of people.

- **Seek help during times of struggle** with loneliness or isolation by reaching out to a family member, friend, counselor, health care provider, or the 988 crisis line.[316]

- **Be open with your health care provider** about significant social changes in your life, as this may help them understand potential health impacts and guide them to provide recommendations to mitigate health risks.

- **Make time for civic engagement.** This could include being a positive and constructive participant in political discourse and gatherings (e.g., town halls, school board meetings, local government hearings).

- **Reflect the core values of connection** in how you approach others in conversation and through the actions you take. Key questions to ask yourself when considering your interactions with others include:
    How might kindness change this situation?
    What would it look like to treat others with respect?
    How can I be of service?
    How can I reflect my concern for and commitment to others?

Strengths and Limitations of the Evidence

Hundreds of independent studies across several scientific disciplines have examined the objective physical and mental health outcomes of social connection, social isolation, and loneliness for individuals. Despite the variability in conceptual and methodological approaches used in the research, these findings converge to demonstrate a robust and reliable association between social connection and health outcomes.

In addition to significant evidence of correlations between social connection and health, evidence supports a potential causal association. Using the Bradford Hill Guidelines, as well as some newer studies leveraging causal epidemiology and experimental evidence in animals, together suggests a likely causal association between social isolation and a variety of poor health outcomes, including death. In humans, experimental evidence and intervention-based studies using randomized controlled trials also supports the likelihood of a causal association between broader social connection and better health and longer life expectancy.

Importantly, there is evidence of a dose-response relationship between social connection and health. This means that incremental increases in social connection correspond to decreases in risk to health, and conversely, decreases in social connection correspond to increases in risk. Evidence demonstrates this dose-response relationship exists for developmental stages across the lifespan, suggesting that social connection is a continuum from risk (when low) to protection (when high). This suggests social connection is relevant to all humans regardless of our individual positions along the risk trajectory.

Despite the strength of the evidence linking social connection to various health outcomes, certain gaps and limitations in research still exist. For example, few studies examine more than one social connection component (structural, functional, and quality indicators) in the same sample to disentangle the independent, additive, and synergistic effects. This complicates the measurement of an individual's risk associated with lack of social connection (e.g., social isolation, loneliness, social negativity) and confounds the understanding of the unique and

complex pathways by which social connection influences health. Further, despite significant changes in the way in which we interact socially, many research studies do not distinguish remote or technology-mediated social connection from traditional means of connecting socially to determine equivalencies and to discern the influence on long-term health and mortality risk. Yet, despite these challenges, the extensive and replicated body of existing evidence offers a compelling basis for elevating the discourse on promoting social connection and addressing social disconnection with targeted public health policies, initiatives, and actions.

In regard to the study of community-level benefits, significant differences exist in how researchers approach community-level social connection across scientific studies. For instance, variations exist in the indicators researchers use to define and measure social connection. While social cohesion, social capital, belonging, and trust are all indicators of connected communities, many studies examine only one of these concepts and few examine all of these to disentangle their relative influence or relate them directly to loneliness and isolation. Complicating matters, some studies also use different terms to refer to the same concept or use the same term to refer to different concepts. Much of this research is correlative in nature and necessitates further study, including among often underrepresented groups, in order to understand causative factors that produce community-level benefits.

Another layer of complexity is how different each community is along a multitude of dynamics and factors such as policies, customs, cultures, assets, challenges, demographics, and more. This variation means there is no “one-size-fits-all” approach to community connection, and it means that different communities will have different needs and desires. Despite all of these differences and complexities, there is strong evidence that points to social connection as an important factor in strengthening communities and community-level outcomes. While more research is needed, the evidence we do have suggests that enhancing community connection may help us address many important community and societal issues.

Social Media and Youth Mental Health

The U.S. Surgeon General’s Advisory

Office of the Surgeon General (OSG).

Washington (DC): US Department of Health and Human Services; 2023.

Social media use by youth is nearly universal. Up to 95% of youth ages 13–17 report using a social media platform, with more than a third saying they use social media “almost constantly.” Although age 13 is commonly the required minimum age used by social media platforms in the U.S., nearly 40% of children ages 8–12 use social media. Despite this widespread use among children and adolescents, robust independent

safety analyses on the impact of social media on youth have not yet been conducted. There are increasing concerns among researchers, parents and caregivers, young people, healthcare experts, and others about the impact of social media on youth mental health.

About the Advisory

A Surgeon General's Advisory is a public statement that calls the American people's attention to an urgent public health issue and provides recommendations for how it should be addressed. Advisories are reserved for significant public health challenges that require the nation's immediate awareness and action.

This Advisory calls attention to the growing concerns about the effects of social media on youth mental health. It explores and describes the current evidence on the positive and negative impacts of social media on children and adolescents, some of the primary areas for mental health and well-being concerns, and opportunities for additional research to help understand the full scope and scale of social media's impact. This document is not an exhaustive review of the literature. Rather, it was developed through a substantial review of the available evidence, primarily found via electronic searches of research articles published in English and resources suggested by a wide range of subject matter experts, with priority given to, but not limited to, meta-analyses and systematic literature reviews. It also offers actionable recommendations for the institutions that can shape online environments—policymakers and technology companies—as well as for what parents and caregivers, young people, and researchers can do.

Social Media and Youth Mental Health

Social media[1] use by youth is nearly universal. Up to 95% of youth ages 13–17 report using a social media platform, with more than a third saying they use social media "almost constantly."[2] Although age 13 is commonly the required minimum age used by social media platforms in the U.S.,[3] nearly 40% of children ages 8–12 use social media.[4] Despite this widespread use among children and adolescents, robust independent safety analyses on the impact of social media on youth have not yet been conducted. There are increasing concerns among researchers, parents and caregivers, young people, healthcare experts, and others about the impact of social media on youth mental health.[5, 6]

More research is needed to fully understand the impact of social media; however, the current body of evidence indicates that while social media may have benefits for some children and adolescents, there are ample indicators that social media can also have a profound risk of harm to the mental health and well-being of children and adolescents. At this time, we do not yet have enough evidence to determine if social media is sufficiently safe for children and adolescents. We must acknowledge the growing body

of research about potential harms, increase our collective understanding of the risks associated with social media use, and urgently take action to create safe and healthy digital environments that minimize harm and safeguard children's and adolescents' mental health and well-being during critical stages of development.

Up to 95% of youth ages 13–17 report using a social media platform, with more than a third saying they use social media "almost constantly."

Social Media Has Both Positive and Negative Impacts on Children and Adolescents

The influence of social media on youth mental health is shaped by many complex factors, including, but not limited to, the amount of time children and adolescents spend on platforms, the type of content they consume or are otherwise exposed to, the activities and interactions social media affords, and the degree to which it disrupts activities that are essential for health like sleep and physical activity.[6] Importantly, different children and adolescents are affected by social media in different ways, based on their individual strengths and vulnerabilities, and based on cultural, historical, and socio-economic factors.[7, 8] There is broad agreement among the scientific community that social media has the potential to both benefit and harm children and adolescents.[6, 9]

Brain development is a critical factor to consider when assessing the risk for harm. Adolescents, ages 10 to 19, are undergoing a highly sensitive period of brain development.[10, 11] This is a period when risk-taking behaviors reach their peak, when well-being experiences the greatest fluctuations, and when mental health challenges such as depression typically emerge.[12, 13, 14] Furthermore, in early adolescence, when identities and sense of self-worth are forming, brain development is especially susceptible to social pressures, peer opinions, and peer comparison.[11, 13] Frequent social media use may be associated with distinct changes in the developing brain in the amygdala (important for emotional learning and behavior) and the prefrontal cortex (important for impulse control, emotional regulation, and moderating social behavior), and could increase sensitivity to social rewards and punishments.[15, 16] As such, adolescents may experience heightened emotional sensitivity to the communicative and interactive nature of social media.[16] Adolescent social media use is predictive of a subsequent decrease in life satisfaction for certain developmental stages including for girls 11–13 years old and boys 14–15 years old.[17] Because adolescence is a vulnerable period of brain development, social media exposure during this period warrants additional scrutiny.

The Potential Benefits of Social Media Use Among Children and Adolescents

Social media can provide benefits for some youth by providing positive community and connection with others who share identities, abilities, and interests. It can provide

access to important information and create a space for self-expression.[9] The ability to form and maintain friendships online and develop social connections are among the positive effects of social media use for youth.[18, 19] These relationships can afford opportunities to have positive interactions with more diverse peer groups than are available to them offline and can provide important social support to youth.[18] The buffering effects against stress that online social support from peers may provide can be especially important for youth who are often marginalized, including racial, ethnic, and sexual and gender minorities.[20, 21, 22] For example, studies have shown that social media may support the mental health and well-being of lesbian, gay, bisexual, asexual, transgender, queer, intersex and other youths by enabling peer connection, identity development and management, and social support.[23] Seven out of ten adolescent girls of color report encountering positive or identity-affirming content related to race across social media platforms.[24] A majority of adolescents report that social media helps them feel more accepted (58%), like they have people who can support them through tough times (67%), like they have a place to show their creative side (71%), and more connected to what's going on in their friends' lives (80%).[25] In addition, research suggests that social media-based and other digitally-based mental health interventions may also be helpful for some children and adolescents by promoting help-seeking behaviors and serving as a gateway to initiating mental health care.[8, 26, 27, 28, 29]

The Potential Harms of Social Media Use Among Children and Adolescents

Over the last decade, evidence has emerged identifying reasons for concern about the potential negative impact of social media on children and adolescents.

A longitudinal cohort study of U.S. adolescents aged 12–15 (n=6,595) that adjusted for baseline mental health status found that adolescents who spent more than 3 hours per day on social media faced double the risk of experiencing poor mental health outcomes including symptoms of depression and anxiety.[30]

As of 2021, 8th and 10th graders now spend an average of 3.5 hours per day on social media.[31] In a unique natural experiment that leveraged the staggered introduction of a social media platform across U.S. colleges, the roll-out of the platform was associated with an increase in depression (9% over baseline) and anxiety (12% over baseline) among college-aged youth (n = 359,827 observations).[32] The study's co-author also noted that when applied across the entirety of the U.S. college population, the introduction of the social media platform may have contributed to more than 300,000 new cases of depression.[32, 33] If such sizable effects occurred in college-aged youth, these findings raise serious concerns about the risk of harm from social media exposure for children and adolescents who are at a more vulnerable stage of brain development.

Limits on the use of social media have resulted in mental health benefits for young adults and adults. A small, randomized controlled trial in college-aged youth found that limiting social media use to 30 minutes daily over three weeks led to significant improvements in depression severity.[34] This effect was particularly large for those with

high baseline levels of depression who saw an improvement in depression scores by more than 35%.[35] Another randomized controlled trial among young adults and adults found that deactivation of a social media platform for four weeks improved subjective well-being (i.e., self-reported happiness, life satisfaction, depression, and anxiety) by about 25–40% of the effect of psychological interventions like self-help therapy, group training, and individual therapy.[36]

In addition to these recent studies, correlational research on associations between social media use and mental health has indicated reason for concern and further investigation. These studies point to a higher relative concern of harm in adolescent girls and those already experiencing poor mental health,[37, 38, 39] as well as for particular health outcomes like cyberbullying-related depression,[40] body image and disordered eating behaviors,[41] and poor sleep quality linked to social media use.[42] For example, a study conducted among 14-year-olds (n = 10,904) found that greater social media use predicted poor sleep, online harassment, poor body image, low self-esteem, and higher depressive symptom scores with a larger association for girls than boys.[43] A majority of parents of adolescents say they are somewhat, very, or extremely worried that their child's use of social media could lead to problems with anxiety or depression (53%), lower self-esteem (54%), being harassed or bullied by others (54%), feeling pressured to act a certain way (59%), and exposure to explicit content (71%).[44]

What Drives Mental Health and Well-Being Concerns: A Snapshot of the Scientific Evidence

Scientific evidence suggests that harmful content exposure as well as excessive and problematic social media use are primary areas for concern.

Go to:

Potential Risk of Harm from Content Exposure

Extreme, inappropriate, and harmful content continues to be easily and widely accessible by children and adolescents. This can be spread through direct pushes, unwanted content exchanges, and algorithmic designs. In certain tragic cases, childhood deaths have been linked to suicide- and self-harm-related content and risk-taking challenges on social media platforms.[45, 46] This content may be especially risky for children and adolescents who are already experiencing mental health difficulties.[47] Despite social media providing a sense of community for some, a systematic review of more than two dozen studies found that some social media platforms show live depictions of self-harm acts like partial asphyxiation, leading to seizures, and cutting, leading to significant bleeding.[48] Further, these studies found that discussing or showing this content can normalize such behaviors, including through the formation of suicide pacts and posting of self-harm models for others to follow.

Social media may also perpetuate body dissatisfaction, disordered eating behaviors, social comparison, and low self-esteem, especially among adolescent girls.[49, 50, 51, 52] A synthesis of 20 studies demonstrated a significant relationship between social media use and body image concerns and eating disorders, with social comparison as a potential contributing factor.[41] Social comparison driven by social media is associated with body dissatisfaction, disordered eating, and depressive symptoms.[53, 54, 55, 56] When asked about the impact of social media on their body image, nearly half (46%) of adolescents aged 13–17 said social media makes them feel worse, 40% said it makes them feel neither better nor worse, and only 14% said it makes them feel better.[57]

Additionally, roughly two-thirds (64%) of adolescents are “often” or “sometimes” exposed to hate-based content.[58] Among adolescent girls of color, one-third or more report exposure to racist content or language on social media platforms at least monthly.[24] In a review of 36 studies, a consistent relationship was found between cyberbullying via social media and depression among children and adolescents,[40] with adolescent females and sexual minority youth more likely to report experiencing incidents of cyberbullying.[59, 60] Nearly 75% of adolescents say social media sites are only doing a fair to poor job of addressing online harassment and cyberbullying.[61]

In addition, social media platforms can be sites for predatory behaviors and interactions with malicious actors who target children and adolescents (e.g., adults seeking to sexually exploit children, to financially extort them through the threat or actual distribution of intimate images, or to sell illicitly manufactured fentanyl).[62, 63, 64] Adolescent girls and transgender youth are disproportionately impacted by online harassment and abuse, which is associated with negative emotional impacts (e.g., feeling sad, anxious or worried).[65, 66] Nearly 6-in-10 adolescent girls say they’ve been contacted by a stranger on certain social media platforms in ways that make them feel uncomfortable.[24]

Go to:

Potential Risk of Harm from Excessive and Problematic Use

Excessive and problematic use of social media can harm children and adolescents by disrupting important healthy behaviors. Social media platforms are often designed to maximize user engagement, which has the potential to encourage excessive use and behavioral dysregulation.[67, 68, 69, 70] Push notifications, autoplay, infinite scroll, quantifying and displaying popularity (i.e., ‘likes’), and algorithms that leverage user data to serve content recommendations are some examples of these features that maximize engagement. According to one recent model, nearly a third (31%) of social media use may be attributable to self-control challenges magnified by habit formation.[71] Further, some researchers believe that social media exposure can overstimulate the reward center in the brain and, when the stimulation becomes excessive, can trigger pathways comparable to addiction.[68, 72] Small studies have shown that people with frequent and problematic social media use can experience

changes in brain structure similar to changes seen in individuals with substance use or gambling addictions.[73, 74] In a nationally representative survey of girls aged 11–15, one-third or more say they feel “addicted” to a social media platform.[24] Over half of teenagers report that it would be hard to give up social media.[2] Nearly 3-in-4 teenagers believe that technology companies manipulate users to spend more time on their devices.[68] In addition, according to a survey of 8th and 10th graders, the average time spent on social media is 3.5 hours per day, 1-in-4 spend 5+ hours per day and 1-in-7 spend 7+ hours per day on social media.[31]

Excessive and problematic social media use, such as compulsive or uncontrollable use, has been linked to sleep problems, attention problems, and feelings of exclusion among adolescents.[43, 75, 76, 77] Sleep is essential for the healthy development of adolescents. A systematic review of 42 studies on the effects of excessive social media use found a consistent relationship between social media use and poor sleep quality, reduced sleep duration, sleep difficulties, and depression among youth.[42] Poor sleep has been linked to altered neurological development in adolescent brains, depressive symptoms, and suicidal thoughts and behaviors.[78, 79, 80] On a typical weekday, nearly 1-in-3 adolescents report using screen media until midnight or later.[58] While screen media use encompasses various digital activities, social media applications are the most commonly used applications by adolescents.[58]

In a recent narrative review of multiple studies, problematic social media use has also been linked to both self-reported and diagnosed attention-deficit/hyperactivity disorder (ADHD) in adolescents, although more research is necessary to understand whether one causes the other.[81] A longitudinal prospective study of adolescents without ADHD symptoms at the beginning of the study found that, over a 2-year follow-up, high-frequency use of digital media, with social media as one of the most common activities, was associated with a modest yet statistically significant increased odds of developing ADHD symptoms (OR 1.10; 95% CI, 1.05-1.15).[82] Additionally, social media-induced fear of missing out, or “the pervasive apprehension that others might be having rewarding experiences from which one is absent,”[83] has been associated with depression, anxiety, and neuroticism.[84]

Critical Questions Remain Unanswered

Nearly every teenager in America uses social media, and yet we do not have enough evidence to conclude that it is sufficiently safe for them. Our children have become unknowing participants in a decades-long experiment. It is critical that independent researchers and technology companies work together to rapidly advance our understanding of the impact of social media on children and adolescents. This section describes the known gaps and proposes additional areas for research that warrant urgent consideration.

Known Evidence Gaps

The relationship between social media and youth mental health is complex and potentially bidirectional.[19] There is broad concern among the scientific community that a lack of access to data and lack of transparency from technology companies have been barriers to understanding the full scope and scale of the impact of social media on mental health and well-being. Most prior research to date has been correlational, focused on young adults or adults, and generated a range of results.[85] Critical areas of research have been proposed to fill knowledge gaps and create evidence-based interventions, resources, and tools to support youth mental health.[86] Thus, there is an urgent need for additional research including on, but not limited to, the following questions:

- How do in-person vs. digital social interactions differ in terms of the impact on health, and what are the unique contributions of social media behavior to social connectedness, social isolation, and mental health symptoms?
- What are the potential pathways through which social media may cause harm to children's and adolescents' mental health and well-being? For example:

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How does social comparison affect one's sense of life satisfaction and in-person relationships?

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How does the use of social media, including specific designs and features, relate to dopamine pathways involved in motivation, reward, and addiction?

- What type of content, and at what frequency and intensity, generates the most harm? Through which modes of social media access (e.g., smartphone, computer) and design features? For which users and why?
- What are the beneficial effects of social media? For whom are the benefits greatest? In what ways, and under what circumstances?
- What individual-, community-, and societal-level factors may protect youth from the negative effects of social media?
- What types of strategies and approaches are effective in protecting the mental health and well-being of children and adolescents on social media (e.g., programs, policies, design features, interventions, norms)?
- How does social media use interact with a person's developmental stage for measuring risk of mental health impact?

It is critical that independent researchers and technology companies work together to rapidly advance our understanding of the impact of social media on children and adolescents.

We Must Take Action: A Way Forward

Our children and adolescents don't have the luxury of waiting years until we know the full extent of social media's impact. Their childhoods and development are happening now. While social media use can have positive impacts for some children, the evidence noted throughout this Surgeon General's Advisory necessitates significant concern with the way it is currently designed, deployed, and utilized. Child and adolescent use of platforms designed for adults places them at high risk of "unsupervised, developmentally inappropriate, and potentially harmful" use according to the National Scientific Council on Adolescence.[87] At a moment when we are experiencing a national youth mental health crisis, now is the time to act swiftly and decisively to protect children and adolescents from risk of harm.

To date, the burden of protecting youth has fallen predominantly on children, adolescents, and their families. Parents face significant challenges in managing children and adolescents' use of social media applications, and youth are using social media at increasingly earlier ages.[4, 88] Nearly 70% of parents say parenting is now more difficult than it was 20 years ago, with technology and social media as the top two cited reasons.[89] While nearly all parents believe they have a responsibility to protect their children from inappropriate content online,[89] the entire burden of mitigating the risk of harm of social media cannot be placed on the shoulders of children and parents. Nearly 80% of parents believe technology companies have a responsibility to protect children from inappropriate content as well.[89]

We must provide children and their families with the information and tools to navigate the changing digital environment, but this burden to support our children must be further shared. There are actions technology companies can take to make their platforms safer for children and adolescents. There are actions researchers can take to develop the necessary research base to support further safeguards. And there is a role for local, state, and federal policy to implement protections for our children and adolescents.

The U.S. has a strong history of taking action in such circumstances. In the case of toys, transportation, and medications—among other sectors that have widespread adoption and impact on children—the U.S. has often adopted a safety-first approach to mitigate the risk of harm to consumers. According to this principle, a basic threshold for safety must be met, and until safety is demonstrated with rigorous evidence and independent evaluation, protections are put in place to minimize the risk of harm from products, services, or goods. For example, the Consumer Product Safety Commission requires toy manufacturers to undergo third-party testing and be certified through a

Children's Product Certificate as compliant with the federal toy safety standard for toys intended for use by children.[90] To reduce the risk of injury from motor vehicle accidents, the National Highway Traffic Safety Administration requires manufacturers to fit new motor vehicles with standard airbags and seat belts, among other safety features, and conduct crash tests to be compliant with the Federal Motor Vehicle Safety Standards.[91] Medications must demonstrate safety to the Food and Drug Administration before being made available and marketed for use.[92] Given the mounting evidence for the risk of harm to some children and adolescents from social media use, a safety-first approach should be applied in the context of social media products.

To better safeguard the mental health and well-being of children and adolescents, policymakers, technology companies, researchers, families, and young people must all engage in a proactive and multifaceted approach. Through the recommendations below, we can provide more resources and tools to children and families, we can gain a better understanding of the full impact of social media, and we can maximize the benefits and minimize the harms of social media platforms to create safer, healthier online environments for children.

We can maximize the benefits and minimize the harms of social media platforms to create safer, healthier online environments for children.

Go to:

What Policymakers Can Do

Policymakers play an important role in addressing the complex and multifaceted issues related to social media use and in protecting youth from harm.

- **Strengthen protections to ensure greater safety for children interacting with all social media platforms**, in collaboration with governments, academic organizations, public health experts, and technology companies.

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Develop age-appropriate health and safety standards for technology platforms. Such standards may include designing technology that is appropriate and safe for a child's developmental stage; protecting children and adolescents from accessing harmful content (e.g., content that encourages eating disorders, violence, substance abuse, sexual exploitation, and suicide or discusses suicide means); limiting the use of features that attempt to maximize time, attention, and engagement; developing tools that protect activities that are essential for healthy development like sleep; and regularly assessing and mitigating risks to children and adolescents.

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Require a higher standard of data privacy for children to protect them from potential harms like exploitation and abuse. Six-in-ten adolescents say they think they have little

or no control over the personal information that social media companies collect about them.[32]

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Pursue policies that further limit access—in ways that minimize the risk of harm—to social media for all children, including strengthening and enforcing age minimums.

- **Ensure technology companies share data relevant to the health impact of their platforms** with independent researchers and the public in a manner that is timely, sufficiently detailed, and protects privacy.
- **Support the development, implementation, and evaluation of digital and media literacy curricula in schools and within academic standards.** Digital and media literacy provides children and educators with digital skills to strengthen digital resilience, or the ability to recognize, manage, and recover from online risks (e.g., cyberbullying and other forms of online harassment and abuse, as well as excessive social media use).
- **Support increased funding for future research** on both the benefits and harms of social media use and other technology and digital media use for children, adolescents, and families.
- **Engage with international partners** working to protect children and adolescents against online harm to their health and safety.

Go to:

What Technology Companies Can Do

Technology companies play a central role and have a fundamental responsibility in designing safe online environments and in preventing, minimizing, and addressing the risks associated with social media.

- **Conduct and facilitate transparent and independent assessments of the impact of social media products and services on children and adolescents.** Assume responsibility for the impact of products on different subgroups and ages of children and adolescents, regardless of the intent behind them.

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Be transparent and share assessment findings and underlying data with independent researchers and the public in a privacy protecting manner.

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Assess the potential risks of online interactions and take active steps to prevent potential misuse, reducing exposure to harms. When proactive responses fail, take immediate action to mitigate unintended negative effects.

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Establish scientific advisory committees to inform approaches and policies aimed at creating safe online environments for children. Scientific advisory committees should be comprised of independent experts and members of user subgroups, including youth.

- **Prioritize user health and safety in the design and development of social media products and services.**[93, 94, 95, 96] Prioritize and leverage expertise in developmental psychology and user mental health and well-being in product teams to minimize risks of harm to children and adolescents.

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Ensure default settings for children are set to highest safety and privacy standards. Provide easy-to-read and highly visible information about policies regarding use by children.

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Adhere to and enforce age minimums in ways that respect the privacy of youth users.

- **Design, develop, and evaluate platforms, products, and tools that foster safe and healthy online environments for youth,** keeping in mind the needs of girls, racial, ethnic, and sexual and gender minorities. The platform design and algorithms should prioritize health and safety as the first principle, seek to maximize the potential benefits, and avoid design features that attempt to maximize time, attention, and engagement.
- **Share data relevant to the health impact of platforms and strategies employed to ensure safety and well-being** with independent researchers and the public in a manner that is timely and protects privacy.
- **Create effective and timely systems and processes to adjudicate requests and complaints from young people, families, educators, and others** to address online abuse, harmful content and interactions, and other threats to children's health and safety. Social media platforms should take these complaints seriously, thoroughly investigate and consider them, and respond in a timely and transparent manner.

Go to:

What Parents and Caregivers Can Do

The onus of mitigating the potential harms of social media should not be placed solely on the shoulders of parents and caregivers, but there are steps they can take to help protect and support children and adolescents against the risk of harm.

- **Create a family media plan.**[97] Agreed-upon expectations can help establish healthy technology boundaries at home – including social media use. A family media plan can promote open family discussion and rules about media use and include topics such as balancing screen/online time, content boundaries, and not disclosing personal information. For information on creating a family media plan, visit www.healthychildren.org/MediaUsePlan.
- **Create tech-free zones and encourage children to foster in-person friendships.**[98] Since electronics can be a potential distraction after bedtime and can interfere with sleep, consider restricting the use of phones, tablets, and computers for at least 1 hour before bedtime and through the night. Consider keeping family mealtimes and in-person gatherings device-free to build social bonds and engage in a two-way conversation. Help your child develop social skills and nurture his or her in-person relationships by encouraging unstructured and offline connections with others and making unplugged interactions a daily priority. See the American Academy of Pediatrics (AAP) guidelines for media use.
- **Model responsible social media behavior.** As children often learn behaviors and habits from what they see around them, try to model the behavior you want to see.[97, 99] Parents can set a good example of what responsible and healthy social media use looks like by limiting their own use, being mindful of social media habits (including when and how parents share information or content about their child), and modeling positive behavior on your social media accounts.
- **Teach kids about technology and empower them to be responsible online participants at the appropriate age.**[100] Discuss with children the benefits and risks of social media as well as the importance of respecting privacy and protecting personal information in age-appropriate ways. Have conversations with children about who they are connecting with, their privacy settings, their online experiences, and how they are spending their time online. Empower and encourage them to seek help should they need it. Learn more about the benefits and risks of social media use and get guidance from experts at AAP's Center of Excellence on Social Media and Youth Mental Health and from the American Psychological Association's Health Advisory on Social Media Use in Adolescence.
- **Report cyberbullying and online abuse and exploitation.** Talk to your child about their reporting options, and provide support, without judgment, if he or she tells or shows you that they (a) are being harassed through email, text message, online games, or social media or (b) have been contacted by an adult seeking

private images or asking them to perform intimate or sexual acts. You or your child can report cyberbullying to the school and/or the online platform, or your local law enforcement.[101] Visit CyberTipline, Take it Down, or contact your local law enforcement to report any instances of online exploitation.

- **Work with other parents to help establish shared norms and practices and to support programs and policies around healthy social media use.** Such norms and practices among parents facilitate collective action and can make it easier to set and implement boundaries on social media use for children.

Go to:

What Children and Adolescents Can Do

The burden of mitigating the potential harms of social media does not rest solely on the shoulders of children and adolescents, but there are measures they can take to navigate social media in a safe and healthy way.

- **Reach out for help.** If you or someone you know is being negatively affected by social media, reach out to a trusted friend or adult for help. For information from experts, visit AAP's Center of Excellence on Social Media and Youth Mental Health. If you or someone you know is experiencing a mental health crisis, contact the 988 Suicide and Crisis Lifeline by calling or texting 988 for immediate help.
- **Create boundaries to help balance online and offline activities.** Limit the use of phones, tablets, and computers for at least 1 hour before bedtime and through the night to enable sufficient and quality sleep. Keep mealtimes and in-person gatherings device-free to help build social bonds and engage in two-way conversations with others. Nurture your in-person relationships by connecting with others and making unplugged interactions a daily priority.
- **Develop protective strategies and healthy practices** such as tracking the amount of time you spend online, blocking unwanted contacts and content, learning about and using available privacy and safety settings, learning and utilizing digital media literacy skills to help tell the difference between fact and opinion, and ensuring you are connecting with peers in-person. See this Tip Sheet on Social Media Use and Mental Health for healthy social media use created for and by young people.
- **Be cautious about what you share.** Personal information about you has value. Be selective with what you post and share online and with whom, as it is often public and can be stored permanently. If you aren't sure if you should post something, it's usually best if you don't. Talk to a family member or trusted adult to see if you should.

- **Protect yourself and others.** Harassment that happens in email, text messaging, direct messaging, online games, or on social media is harmful and can be cyberbullying. It might involve trolling, rumors, or photos passed around for others to see – and it can leave people feeling angry, sad, ashamed, or hurt. If you or someone you know is the victim of cyberbullying or other forms of online harassment and abuse:

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Don't keep online harassment or abuse a secret. Reach out to at least one person you trust, such as a close friend, family member, counselor, or teacher, who can give you the help and support you deserve. Visit stopbullying.gov for helpful tips on how to report cyberbullying. If you have experienced online harassment and abuse by a dating partner, contact an expert at Love is Respect for support or if your private images have been taken and shared online without your permission, visit Take it Down to help get them removed.

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Don't take part in online harassment or abuse. Avoid forwarding or sharing messages or images and tell others to stop. Another way is to report offensive content to the site or network where you saw it.

Go to:

What Researchers Can Do

Researchers play a critical role in helping to gain a better understanding of the full impact of social media on mental health and well-being and informing policy, best practices, and effective interventions.

- **Establish the impact of social media on youth mental health as a research priority and develop a shared research agenda.**[102] Research should include but not be limited to:

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Rigorous evaluation of social media's impact on youth mental health and well-being, including longitudinal and experimental studies. This could also include research on specific outcomes and clinical diagnoses (e.g., sleep duration and quality, attention, depression, anxiety, and body image), among specific populations (e.g., racial, ethnic, and sexual and gender minorities), and based on specific aspects of social media (e.g., designs, features, and algorithms).

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Role of age, developmental stage, cohort processes, and the in-person environment in influencing the onset and progression of poor mental health outcomes among social media users.

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Benefits and risks associated with specific social media designs, features, and content.

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Long-term effects on adults of social media use during childhood and adolescence.

- **Develop and establish standardized definitions and measures** for social media and mental health outcomes that are regularly evaluated and can be applied across basic research, population surveillance, intervention evaluation, and other contexts.
- **Evaluate best practices for healthy social media use** in collaboration with experts including healthcare providers, parents, and youth.[94, 103, 104]
- **Enhance research coordination and collaboration.** Example opportunities include developing an accessible evidence database and forming a consortium of researchers focused on examining the positive and negative effects of social media on mental health and well-being. Researchers should work with community partners to make research findings publicly accessible and digestible.

All notes and references available under Endnotes at https://www.ncbi.nlm.nih.gov/books/NBK594762/

Consumer Engagement, Education and Broker Services

In the conclusion to this text, we'll attempt to combine many of the themes and issues we have discussed. We'll do this around the notion of consumer engagement.

Brokers and other insurance professionals use terms like 'consumer engagement' and 'informed consumer' in two very different – and sometimes opposing – ways. This can create confusion among subscribers and patients, and even among brokers themselves.

To *risk management professionals* – and the medical community - 'informed consumer' means someone who understands treatment options, risks, benefits and trade-offs. An informed consumer - to risk management folks, for example - might prefer a treatment that *differs* from the one recommended by his/her physician.

A case-in-point: an oncologist might recommend a mastectomy for a woman with early stage breast cancer, based on *his* analysis of the risk-reward tradeoffs. Meanwhile the patient might prefer to watch-and-wait before operating based on *her* analysis. Both analyses may be factually correct, but the doctor and patient value the risks and rewards differently.

An informed consumer, from the risk management or medical point-of-view, thus takes an active role his/her own *medical decision making* and is able to make wise medical care decisions.

To *compliance oriented insurance professionals,* 'informed consumer' means a subscriber who understands the component parts of the health insurance policy and the associated regulations about how to use it.

An informed insurance consumer - to the compliance professional, for example - might prefer to compliment a Health Savings Account with a Flexible Spending Account rather than a Health Reimbursement Account, based on some set of specific medical spending habits and needs. Or the informed insurance consumer might prefer a lower-cost policy that pays for medical services on a reference-based model rather than a higher-cost plan that pays everything over the deductible.

This type of informed consumer is one able to make wise *coverage choices* and use the insurance policy most effectively.

This interview highlights these two different definitions of 'informed consumer'. It occurred in 2012 but remains relevant in our current health insurance environment. One specific note though: the 33% waste factor discussed here in 2012 was an overall, somewhat gross estimate. Some commentators continue to think that waste amount remains approximately valid today. Others, using different definitions of 'unnecessary care', have lower estimates. My own take-away: whatever the exact number, it's a lot of care, a lot of money and a lot of unnecessary patient risk.

The unnamed interviewer – a health insurance broker - articulates the *compliance definition*. He wants to help insurance customers understand policy provisions and tax implications so they can use their policies most effectively.

The interviewer initially wants to leave the consumer alone to decide which medical care is necessary and which providers appropriate; he doesn't, initially, adopt the risk manager perspective. He suggests that the traditional broker advisory responsibility ends when the consumer understands policy provisions.

Meanwhile the responder Gary Fradin – a.k.a. me - uses the *risk manager's - or medical – definition* of informed and engaged consumer. I suggest that consumers who are well informed about medical care options will make better choices for themselves, meaning better outcomes at lower costs.

I also suggest that the process of becoming a 'well informed medical consumer' is one that can be taught and learned, though admittedly, it rarely is today. My comments focus on the types of education one needs to become well informed about medical purchasing and suggest that choosing care based on medical quality metrics generally results is lower total care costs, and probably lower insurance costs too.

The savings available from making informed *medical* choices, I suggest, likely exceed the savings available from making informed *insurance* choices.

I wonder who in our medical care system can teach consumers to become well informed about medical care. Doctors? Hospitals? Carriers? Brokers? Or some other entity.

As you read this interview, ask yourself if either definition of 'well informed' is *sufficient* in our evolving healthcare system and market…or if we need to combine *both*.

The interviewer ultimately suggests that wise and innovative brokers will need to combine both definitions of informed and engaged consumers in order to maintain their advisory role. You can sense his discomfort – and also his excitement – about exactly how to do this.

Do you agree? Do you think he's being too aggressive, defining the broker's future roll too expansively? Or do you think he's being too conservative by not defining the broker's role expansively enough?

Transcript

Interviewer: This morning we're going to spend some time talking about consumer engagement. What does it mean? What is it? So welcome Gary.

As I take a look back in time and think about the notion of Consumer Engagement and Consumer Driven Health Plans, I keep wonder 'what is it'? Ten years ago we saw the introduction of annual deductibles, high deductible health plans sometimes called CDHC or Consumer Driven Healthcare, I think that was the introduction of consumerism

in healthcare. The challenge was the lack of data, the lack of information and so forth. So Gary, in your mind, what is consumer engagement?

Gary Fradin: Great question. You started off with a hard one.

I think consumer engagement means helping healthcare consumers – patients – make medical decisions the same way they would make car-buying decisions, or refrigerator-buying decisions. Use the same types of criteria, ask the same types of questions and bring all the skills that we have developed as a society that make us great consumers to medical care. I think we'll have tremendous benefits, both for the patients and for healthcare costs.

So I'd say consumerism in medical care means the same thing as consumerism in automobiles and other products.

Interviewer: And in automobiles, for those of us buying a new car, you can go online, you can research, you can find out what a dealer paid for the car, the mark-up and all of that.

I think the challenge that we've had in healthcare historically is the lack of information, the costs and quality. So let's talk a little bit about that. What you say seems to be straight-forward, seems to make sense to me in the role that I play as a benefits advisor to companies.

Why is there such a challenge to make it happen? What are the barriers to entry to consumer engagement when it comes to this type of consumerism?

GF: Barriers to entry. Tough question.

There are probably lots of barriers to entry. The one that strikes me as most significant is the fact that we have relatively lousy outcome data about medical care. We simply don't know what works well, what works badly, and exactly *how well* it works.

It's like buying a car if you don't know the miles per gallon. Maybe we can get some pricing information. But if a car dealer tells you a car gets good gas mileage, does this mean 16 miles per gallon or 41?

In medical care, we hear things like 'that's a risk factor for having a heart attack' or 'that's a risk factor for cancer' and this is a good treatment. Well…*how much* of a risk factor, *how good* of a treatment and how will it affect *me*? Those are questions that we're increasingly starting to focus on and we're developing some data to help us get those answers.

Int: What's interesting in the role that I play with clients is that consumer engagement really plays out around product design. The various health insurance carriers have created over the past several years, new products designed to engage the consumer. Deductibles, co-insurance and things of that nature. We have products today designed

to get consumers to make decisions, to learn where providers fall within certain tiers for example, limited networks.

So from a product standpoint there's this notion of consumer engagement, working with employers and employees to understand product.

From your perspective and the topic that we really want to get into today, beyond insurance products, beyond 'where do I go, what hospital is in-network', you're talking about consumer engagement at the physician level, at the choice level, is there an overabundance of prescriptions, of unnecessary medical care. Let's talk a little bit about that from your perspective.

GF: Let me make a couple points because you're raising critical issues here.

One is that researchers estimate, based on lots and lots of medical studies, that we waste up to about 1/3 of all medical spending on unnecessary medical care. That's care that can't help you – because it's unnecessary – but costs you money and could potentially actually harm you.

That estimate hasn't changed much despite plan design changes. We still waste up to about a third.

My comment about plan design changes is that carriers and regulators have tried to organize our healthcare delivery system to become more efficient and cut down on unnecessary care through iteration after iteration after iteration over the past over the past 20 or 30 years, and we have always seen healthcare inflation running about double CPI (the Consumer Price Index inflation rate) or about double the GDP growth rate. We haven't seen that fall significantly despite plan design changes.

I don't think this is a regulatory issue – reducing unnecessary care – and I don't think it's a plan design issue, although high deductibles seem to have some impact. I think the way to reduce unnecessary spending is to educate consumers, educate patients and show why it's in their interest not to get unnecessary care. It doesn't benefit them – it might hurt them.

Int: Let's talk about that a little bit. My firm provides advice and guidance to clients. We do it at the employer level and at the employee level. We have benefit communication meetings and so forth. From your perspective, what are the tools and resources available? What tools exist to engage consumers outside of products, outside of plan designs?

GF: I think that those tools are being developed. We're starting to get the relevant data about quality so people can make medical decisions based on care quality, not necessarily price.

Nobody wants to get bad quality care. Forget price for a moment. I have yet to hear a parent say 'times are tough, we're cutting back on medical care quality for our kids'. I've

never heard that. I always hear parents say ‘I don’t care what it costs, I want my kid to get the best care he or she can get.’

One tool that we’ve been working on a lot is called the Number Needed to Treat. Teaching consumers to ask their doctor ‘what’s the Number Needed to Treat with this medication, this medicine or this screening test?’ NNT simply tells you how many people have to have a medical procedure or take a medication in order for 1 person to benefit.

Int: Can you give an example.

GF: Sure, I can tell you about cholesterol lowering medications. Lots of people think that high cholesterol leads to heart attacks.

Studies have suggested that people with high cholesterol – using all kinds of different definitions of ‘high’ cholesterol, these are generally industry funded studies with, presumably, highly selected data so the numbers may well be skewed – suggest that about 3 people out of 100 with high cholesterol will have a heart attack in the next 5 or so years.[223] Roughly, approximately 3 out of 100. Some studies show somewhat higher rates. These are folks who don’t have heart disease.

If you reduce your cholesterol with a statin, you bring that number from about 3 having a heart attack out of 100 to about 2 having a heart attack out of 100. Again, industry funded studies.

In other words, you have to give 100 people a statin for about 5 years to prevent 1 heart attack. The Number Needed to Treat is about 100.

Let me make 2 points going in 2 different directions here. Some commentators have suggested that insurance not pay for interventions that have a Number Needed to Treat greater than 20. An NNT of 20 means that only 5% of people benefit. So if you learn the Number Needed to Treat, you can learn how efficient or how effective this medical intervention is, so you can choose.

The sister, or cousin if you will, of Number Needed to Treat is Number Needed to Harm.

Int: NNH?

GF: Yes, NNH. Obviously that tells you how many people have to take the medication for 1 person to be harmed.

Let me tie all this together and suggest that knowing the Number Needed to Treat and Number Needed to Harm is basic medical literacy. If you don’t know these numbers and you can’t discuss them, then you’re medically illiterate. It’s sort of like an accountant

[223] This specific estimate comes from number in an ad that ran in several newspapers in the 2004 – 2007 time frame.

saying ‘you made money, but I don’t know what your earnings per share were, or exactly how much you made’.

Int: So is your expectation that individual consumers should know their own NNT and NNH information and should know these facts and be able to go into a physician and discuss them?

I guess I’ll use myself as an example. I happen to have had, 2 days ago, my annual physical. I went in and had my 12 minutes with my doctor and part of the discussion was, ironically, around cholesterol. There have been a lot of articles about cholesterol and statins and the danger of them.

I thought I was being a good consumer, I thought I was engaging by simply asking my doctor and challenging the notion of whether or not I should remain on a statin. And my doctor’s comment to me was that the belief still is that the rewards of being on a statin outweigh the risks.

My doctor went on to say ‘if it’s of any help, I too am on a statin and have been, so I would not be prescribing something to you that I myself am actually not engaged in taking.’

From my standpoint as someone who is in this industry and do what I do, I felt that I had become a better consumer, that I engaged in the process more by asking questions and actually challenging the notion of remaining on this, asking about the risks and rewards. I’m not sure that many people take the step that I took.

But I get the sense from our discussion certainly that there’s more to do, more questions to ask and that I should be armed with NNTs and NNHs and so forth. Is that true?

GF: I think so.

First, let me make one point very strongly: if you’re comfortable with your doctor, do what your doctor says. I in no way want to make people uncomfortable. That is dysfunctional all the way through.

But I hesitate to rely very much on your doctor’s story about himself. Your doctor may have different risk tolerances from you. He may have different orientations. Different family background and genetics. He may or may not exercise the same as you. He may have all kinds of different risk factors. And his decision criteria may not be the same as yours.

To some extent, and I don’t want to belittle doctors, I’m not trying to do that, but to some extent this is like when you buy a used car and you go to a dealer with lots and lots of high quality used cars. You look at a Ford Taurus. The salesman says ‘well, I drive a Ford Taurus’ suggesting a personal endorsement for how good this car is. OK, but I don’t know how he made his decision. Does he drive young kids around? Does he schlep hockey equipment? Is his wife a baker and he makes deliveries for her? Did he

get a particularly good deal on a used Taurus, when, perhaps, he would have preferred a Honda Civic? I don't know how he made his decision.

And I don't know how your doctor made his statin decision. Lots of studies suggest that when patients are well informed about their treatment options, they often choose differently from their doctors. That's why I think you have to know what the outcome numbers are.

Remember, doctors learn how to calculate the Number Needed to Treat and Number Needed to Harm in medical school. But they don't talk to patients about it because they figure that in 12 minutes, they don't have time to teach this to a patient.

But if you go in and ask the question, and say 'I will take a medication that you prescribe, but I want to know the NNT, I want to know the Number Needed to Treat so I know how well it works. In fact, I want to know the Number Needed to Treat for 2 or 3 different options, and then I want to choose the best. And I don't want to take a medication if you don't know how well it's going to work for me.' That's how I would like to see consumers engage with their doctors.

Int: And I like it. I truly do. The question is how to get consumers to be able to take that step, to have the comfort and the confidence to be able to challenge their physician, question their physician – and I don't mean that in a negative or derogatory sense – but to give them the comfort and the confidence.

GF: Yes. Let me turn this into a question for you. We're in a high deductible world where people try to spend their money 'more wisely'. To do this, somebody has to educate people about *how* to spend their money more wisely.

Where in our healthcare distribution system does that entity lie?

- Is it physicians – you have 12 minutes per year. Is that the right entity?
- Is it the hospital – are they going to teach you which questions to ask about your medical care?
- Is it the insurance carrier? The problem with the carrier is we all know why a carrier would tell you about unnecessary care. They want to save money. Or, at least, that's the cynical public perception.
- Is it the employer, who's probably pretty busy making widgets. They don't have a lot of extra resources to teach about medical care.

Where in our healthcare distribution system – our medical distribution system – is there an entity that can take on the responsibility of doing this teaching so we can reduce the waste factor, besides the broker?

Int: I don't think there is, and I think that of all the stakeholders, the various people involved in the process, none others of them have the ability, the bandwidth, the time to do that, and I think you make a very valid point.

It's just an interesting dynamic that for 20 years I've been in the business. We provide advice and guidance and council to employers, more and more to employees, now the notion of wellness which engages a whole different element to all this.

Now all of a sudden, in the role that we play, thinking about education and engagement at a completely different level. To talk about NNTs and NNHs, what questions to ask your provider. It's a completely different way to proceeding, a completely different approach. And at the same time, critically important.

GF: Let me ask you a question.

Int: Please.

GF: You said that at your physical a couple days ago was the first time you pushed back and challenged your doctor. Why? You've had a physical presumably every year for many years. Why now? What happened this year?

Int: A little more knowledge, a little more understanding. Certainly the likes of folks like you. News and information is becoming greater. I don't simply want to take the status quo as many of us have done, when the doctor gives a prescription we take it without asking.

I think the notion of statins and harms and long term effects have really resonated with me and have caused me to push back on that particular item.

I think in general, we can all agree that our healthcare system is flawed, at many levels.

You mentioned waste before, 33% waste. Above and beyond all of that, for me to go in once a year for my personal health, and literally have about 12 minutes to ask questions, review data, update personal information and all that to me is challenging and troubling. I need to become my biggest and my own advocate for my own healthcare.

And I think getting back to your original question 'why this year?' I think because more information is available. We are changing and I think there's a dynamic going on in our industry where we need to challenge where we need to be, in the role that we play providing advice and guidance beyond product, beyond solution, beyond all of that to provide advice and guidance at the employee level.

GF: I think it's really interesting when you make the point about more information becoming available. That resonates with me. More and more information is becoming available to consumers. I think we run the risk of having information overload. The question is 'what information is really useful?' What information is bogus or biased or not terribly useful? How does a consumer figure that out?

Int: That's a complete struggle for me and I'm sure for just about every consumer. What is the right information? If I read the Harvard Business Journal, that's one piece of information. If I read another article, another book…it's very challenging to know what information is accurate. From which stakeholders does this information come and is there any bias or connection back to a provider or manufacturer?

Maybe I can turn this back to a question for you. As a consumer, how do I navigate my way through the various information channels to arrive at what I think is good, solid accurate information so that I can make good, solid, accurate personal choices?

GF: I think that's the question that highlights the broker's role.

A broker clearly can't give medical advice. They're not licensed for this. And a broker can't say 'here is a procedure that works and here is a procedure that doesn't work' according to some study. That's not the broker's role.

It seems to me that the broker's future role and the growth of this part of the business is teaching people the questions to ask. If you ask the right question, you have a pretty good chance of getting a good answer. But if you don't ask the right questions, then you may get all kinds of misinformation or confusing information or biased information.

I think we, the industry, needs to simplify the questioning process by teaching people to ask questions about the Number Needed to Treat and Number Needed to Harm.

I guess my feeling is that if brokers can put on consumer engagement programs and courses for their subscribers that help people ask the right questions of their doctors, then we've gone a big step. We've made progress. And Step 2 I can't tell you about yet. I don't know what it is!

Int: Going back to your question - when you have all these stakeholders and providers being part of the equation, who is best served to do it – for someone who spent 20 years in this business, I have an initial challenge, internally, to think that I am the one, and my firm is the one, to provide consumer engagement at a level that gets so specific to medical care and so forth.

At the same time, I can see the validity to this and that many of us can't hide behind the notion that consumer engagement is teaching and educating about product and all of the elements that go along with that. It's a challenge. It's a shift in thinking for me.

GF: Do you think, as a business owner, you can avoid getting involved in this kind of consumer education?

Int: I don't. I truly don't.

The question is when? How quickly? How broad of a spectrum? How deeply? It's a challenge. I say this openly, it's really a shift. It's a mental shift to think of the role that we play and how we will engage the consumer at a completely different level.

At the same time, it's tremendously exciting.

And then beyond all of that, the complexities to everybody. As we sit in the roles that we play as advisors to employers and employees, you have new products – with all sorts of functionality and limitations, with tiers and networks, and the account based elements of HSAs, HRAs and all that. It has become so complicated. My point being that complexities at the product level and at the distribution level are just immense and enormous, and then you fold in another component and layer.

I guess trying to understand it and articulate it, and taking it back to the role that we play, I have to wonder and ask 'how do we do this?' What is the first, best step for us to do it? I guess I'll put that to you. There was a question, or at least a thought of a question in all that.

GF: I think it's very thought provoking. I don't have an answer. As you were talking, I was thinking about that famous Chinese curse or blessing 'May you live in interesting times.' Yes, it is tough to navigate the future.

Look, it's always tough to navigate. It's always tough to run a small business. I guess the first step I would say to brokers who want to get into this brave new world is to become familiar with some of these consumer aids, these medical decision making aids, to become familiar with this part of the business, and on a case-by-case basis work it in. I wish I had a better and more complete answer.

Int: But I think that your answer is representative of the stage we're at in the development of all this. I truly do.

One of the things that comes to my mind, and I certainly want to garner your perspective on, is this notion of cost and quality. It's at times such a nebulous thing, where many carriers, going back to the product designs, and consumer engagement at the product level, is about cost and quality.

Your thoughts on cost vs. quality, the importance of it. Is cost a real driver and issue or do you believe quality prevails, that someone is going to request and require quality without much notion of cost?

GF: I think transparency is clearly both. You have to know price. You don't want to get the same quality for $2000 that you can buy for $600.

But I think that the first step, the driving force, is quality. Everyone wants the best medical care they can get for themselves and their family. One of the reasons that so many people use expensive hospitals is that we equate higher costs with better quality care. Or high credentials with better quality. Or medical school affiliation with better quality. I think people want quality. Then, if you find 2 procedures that have the same NNT and the same outcomes, then sure, go for the least expensive one.

I would warn people against assuming that you can learn something about the care quality from the price, because you can't. A broker once said to me 'this quality information is too complicated. If you assume the quality is all the same, then you can shop based on price'. My response was 'besides that Mrs. Kennedy, how was your trip to Dallas? I heard you had a nice breakfast.'

The ballgame is quality. And price is a secondary consideration. I have yet to meet a person who wants poor medical care, and I have yet to meet someone who wants the cheapest *un*necessary medical care. I only meet people who want good, necessary care.

Int: I think you bring up a great point, and the challenge that we see every day is also the waste in care. People don't want bad care, but I think it still goes back to waste. It goes back to that 33% waste factor, it goes back to how the system is currently structured, and I think that is a tremendous challenge. The complexities of the system. Waste continues to be an issue.

But getting back to your NNT, unnecessary care ideas, are these regional? National? International? Is this about how our healthcare is structured here or is it relevant beyond state and even national boundaries?

GF: I think all healthcare consumers in all countries have the same questions. I think all parents want good care for their kids, all sick people want good care for themselves, and if you're in a government funded system, a privately funded system, or a mixed system, you as the consumer still have the responsibility for asking the right questions and getting the best care for yourself. So I don't think the structure of the system matters for consumer responsibility and engagement. I think people are all the same – they all want good medical care. No one wants to have unnecessary care that won't help them but might harm them.

Research is currently being done on all these different kinds of metrics all over the world, with researchers having the same fundamental question: how can we identify good, high quality, necessary care as opposed to poor, unnecessary, low quality, wasteful care. Everyone is interested in the same thing.

My guess would be that there will be an explosion of knowledge in this whole quality arena in the next decade or so. The early adopter brokers who start to educate their clients now, start to learn the programs now, start to learn what this is all about now will put themselves in an awfully strong position as all of this evolves to capitalize on it and grow their businesses in the future.

Int: I think that's a great point. I think that's something that brokers like me need to be mindful of. We have been, and continue to be moving away from product based sales, product based advice and guidance to become a true benefits consultant. I think it's a tremendous opportunity personally for those willing to engage.

GF: It's exciting.

Int: It's tremendously exciting. I think we as brokers have a role to play and I think a unique one. The other stakeholders that we don't believe are equipped to participate in this consumer engagement process, my hope is that that changes at least in some capacity. We really need them to be part of the equation in some way, shape or form, so this becomes a collaboration.

GF: I would agree with that.

Int: This has been a tremendous dialogue.

GF: Yes, it's been interesting. You asked good questions.

Int: Thanks. Hopefully this has been useful for people who want to learn more about the consumer engagement process.

We've discussed a tremendous spectrum of what it means and what it is. Historically, engagement has been around product – how can we engage consumers around products, so they best utilize the plan that they have chosen.

But today we've discussed taking this to a different level and really getting to the medical aspect of consumerism and consumer engagement…asking questions, understanding outcomes, a completely different aspect to the world of healthcare as it stands today. Gary, thank you for your time, your comments, your insights…

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1 Alain Enthoven 'The History and Principles of Managed Competition' Health Affairs Supplement, 1993, page 27

2 ibid., page 29

3 Alain C. Enthoven and Laura A. Tollen, editors 'Toward a 21st Century Health System' Jossey-Bass, 2004, page xxix

4 David Dranove, The Economic Evolution of American Healthcare, Princeton University Press, 2000, page 40

5 ibid., page 39

6 Much of this analysis is based on Regina Herzlinger, Who Killed Healthcare, McGraw-Hill, 2007, pages 36 - 46

7 ibid., page 43

8 ibid, pare 47. Next quote ibid, page 43

9 Much of this section comes from Jan Gregoire Coombs, 'The Rise and Fall of HMOs' University of Wisconsin Press, 2005, chapter 2

10 Gitterman, Weiner, Domino, McKethan and Enthoven, Rise and Fall of a Kaiser Permanente Expansion Region, Milbank Quarterly, Vol 81, No 4, 2003

11 Dranove, op cit. page viii. Much of this section is based on Chapter 3.

12 ibid. page 25

13 ibid. page 58

14 ibid. page x

15 CBO Testimony: Statement of Robert d. Reischauer, Deputy Director, Congressional Budget Office before the Subcommittee on Oversight, Committee on Ways and Means, US House of Representatives, June 27, 1979

16 Dranove, op. cit. pages 78 - 79

17 J. Wennberg, et. al. 'Are Hospital Services Rationed in New Haven or Over-Utilized in Boston?' Lancet 1 (1987): 1185-1188

18 See also Dartmouth Atlas of Healthcare, Jack Wennberg, ed (Chicago: American Publishing, 1996, 1999) which shows variation in a wide range of treatments diagnostic tests and drug therapies.

19 T. Wickizer et. al. 'Does Utilization Review Reduce Unnecessary Hospital Care and Contain Costs?' Medical Care 27 (1989): 632-47

20 V. G. Freeman et. al 'Lying for Patients: Physician Deception of Third Party Payers', Archives of Internal Medicine (1999): 2263 - 70

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24 Dranove, op cit., page 84

25 Herzlinger, Who Killed, page 48

26 Economist, July 15, 2004

27 Alain C. Enthoven 'The History and Principles of Managed Competition' Health Affairs Supplement, 1993; 'Why Managed Care Has Failed to Contain Health Costs' Health Affairs, Fall 1993. Quotes in this section come from these two articles unless otherwise indicated.

28 Much of this discussion comes from Seven A. Schroeder, 'The Clinton Healthcare Plan: Fundamental or Incremental Reform?' Annals of Internal Medicine, Nov 1, 1993, Volume 119, Issue 9, pages 945 - 947

29 Much of this discussion comes from Derek Bok, 'The Great Health Care Debate of 1993 – 1994' available at www.upenn.edu/pnc/ptbok/html

30 Stephen M Shortell and Julie Schmittdiel 'Prepaid Groups and Organized Delivery Systems: Promise, Performance, and Potential' in Enthoven and Tollen, editors, 'Toward a 21st Century Health System' John Wiley & Sons, 2004

31 Herzlinger, Who Killed, page 47. Next quote from same source, page 48

32 Enthoven and Tollen, eds., op cit. Preface, page xxxi

33 This section comes from Gitterman, Weiner, Domino, McKethan and Enthoven, Rise and Fall of a Kaiser Permanente Expansion Region, Milbank Quarterly, Vol 81, No 4, 2003

34 Regina Herzlinger 'Market Driven Healthcare' op cit. page 148

35 Enthoven and Tollen, op cit. page xxxi

36 Stephen M Shortell, op cit. page 14

37 Enthoven, History and Principles of Managed Compeition, page 34. Emphasis added.

37 Dranove, op cit. Introduction