

VALUING HEALTH CARE:

Improving Productivity and Quality

APRIL
2012

Kauffman Task Force
on Cost-Effective
Health Care Innovation

KAUFFMAN

The Foundation of Entrepreneurship



VALUING HEALTH CARE:

Improving Productivity and Quality

Kauffman Task Force on Cost-Effective Health Care Innovation

Introduction and Executive Summary

This report addresses a deceptively simple question: How can the productivity of American health care be substantially improved? Productivity, in lay terms, is the ratio of output to inputs. A more colloquial rendition of the question might be: how can we get a lot more bang for our health care buck?

No one doubts that the question needs answering. By general consent, improving the cost-benefit balance in America's health care is today's most urgent public policy problem. Costs are rising for private payers and government (which now accounts for more than half of all health care spending), but health outcomes are not rising at the same rate. Without changes, health costs could stress federal and state governments to the point of near-insolvency as the Baby Boom generation ages and as ever more expensive technology comes online. Health costs also affect jobs because some employers respond to rising costs by not hiring more workers, or at least constraining the take-home pay of those they retain. Patients, meanwhile, negotiate a fragmented, confusing, and sometimes seemingly uncaring system, a product of accumulated accident and unintended consequences rather than design. Systems built around the assumptions of the 1950s and 1960s, when general practitioners could cope with most health needs, and file cabinets and postage stamps were the main methods of storing and transmitting data, creak and strain in the age of email, the cloud, and increasingly regulatory complexity.

No wonder, then, that health care also receives so much attention. Nonetheless, given its importance, the subject deserves more thoughtful scrutiny and practical recommendations. With these objectives in mind, the Kauffman Foundation, whose primary mission is to promote entrepreneurship and innovation throughout the economy, convened this Task Force on Innovation in Health Care.

We are well aware that there is no dearth of reports and recommendations for health care reform. Why another? In a crowded field, this report seeks to accomplish something different.

First, our task force's composition is unconventional, drawn from experts in a wide range of related, but different, fields: health care regulation, drug development, data sharing, medical specialties as different as cardiac surgery and veterinary medicine, and the policy sciences. The members have affiliations in academia, industry, nonprofit groups, health organization executive suites, medical clinics, labs, and law.¹

Second, given the makeup of the Task Force, it should not be surprising that this report tackles the vexing problem of health care value and productivity

¹ We rely on this collective expertise by, on occasion in this document, reporting a statistic or measure provided by one or more of our panel members.

from some angles different than those typically found in reports or studies in this policy area.

This report represents the distillation of the collective wisdom of the Task Force members. They were not asked to support every suggestion or idea put forth here or to approve the precise wording of this entire report; requiring unanimity would have ruled out too many good ideas. Instead, we present here a “sense of the room” as to which approaches hold the most promise (and which are overrated) and what the basic choices are. Despite our multiplicity of perspectives, we found many points of intersection.

We canvassed what we call the *adjacent possible*—that is, incremental, but important, workable reforms that should improve the productivity of health care and its value independent of whether and how the recently enacted Affordable Care Act of 2010 is ultimately implemented.² We did not seek giant, dramatic steps; we avoided sweeping claims and rejected purported magic bullets. We believe that a quest for sweeping, comprehensive, one-shot reform is problematic because it misconceives the health care system as an engineered “system” rather than a natural ecosystem, perhaps as intricate and complex as anything to be found in nature.

Instead, we focus primarily on incremental changes which, taken together, can cumulate to significantly advance both productivity of health care and its outcomes. These reforms build on or accelerate changes whose implementation runs with, not against, the grain of the health system’s existing stakeholders and structures. We thus sought to avoid

measures requiring massive new expenditures. Some of the regulatory or structural changes we recommend would gore established interests’ oxen. But they have in common the virtue that, as the saying goes, you can get there from here.

Finally, we have chosen measures for their exemplary value, as well as for their intrinsic merits. They point toward a promising general strategy: releasing and putting to work resources that, for whatever reason, the current system has locked up. Japanese automakers’ leap forward in productivity came, in the main, not from technological breakthroughs unavailable to Detroit or from out-investing Detroit, but from better use of existing resources: freeing up the knowledge of assembly-line workers, implementing real-time quality controls, reorganizing and streamlining supply chains, and putting the customer at the center of the system. In that sense, the Japanese automakers unlocked a leaner, more productive, more modern form within the confines of an older system.

In much the same way, we propose the “jail-breaking” of health care. Our health care system is rife with opportunities to improve productivity by using existing resources better—resources that include not just money, but the talent, organizational skill, and knowledge of practitioners, providers, researchers, and (especially, in our view) patients. Much as the cheapest and often fastest source of new energy is the more efficient use of old energy, so the cheapest and fastest road to a more productive health system is to put untapped value to work.

² We borrow the term “adjacent possible” from Steven Johnson, who coined it. See Steven Johnson. *Where Good Ideas Come From: A History of Innovation* (Riverhead Trade, 2011, reprint edition).

Localism is another common thread running through many of our suggestions. Although cross-cutting changes to policy or regulation sometimes are needed, too much time and energy are focused on top-down, Washington-directed reforms. This is true especially now, as the new Affordable Care Act (ACA) effectively has exhausted, for the time being, the country's capacity for sweeping change at the federal level. Particularly while the ACA is being digested, implemented, and perhaps modified, most effective change will be locally designed or adapted to local conditions, often varying from region to region, provider to provider, and even patient to patient.

What we can generalize, however, are changes in incentives that help identify and propagate productivity improvements. Much as a hydrologist uses general principles of geology and fluid dynamics to understand where to build or to remove dams or levees to change flows through a larger system, so understanding and using incentives better can point the way toward health productivity improvements tailored to particular regions, providers, and patient populations.

By design, we have brought together a varied assortment of ideas and suggestions, illustrating the messy, grab-bag nature that effective changes often need to take. Yet our proposals do fall (albeit with some overlap) into four broad categories, which structure the recommendations section of this report. Our specific policy recommendations are summarized in the table at the end of this Introduction.

- *Harnessing information:* how systematically gathering and sharing data can unlock knowledge that produces systematically better choices. The key here is to incentivize a new corps of data entrepreneurs to collect and analyze existing medical data to discover and then disseminate the use of new therapies.
- *Improving research:* encouraging more collaboration across institutions and funding more translational research (aimed at “translating” basic scientific discoveries into medicines and therapies).
- *Legal and regulatory reform:* modernizing medical malpractice systems, removing counter-productive restrictions on health insurance premiums, and streamlining new drug approvals.
- *Empowering patients:* there are large benefits of giving more power to the people who matter most—patients—to make informed decisions about their own care.

The ideas here are not new, though many of them are familiar only to the cognoscenti. To the contrary, we have sought ideas that have showed promise in the field, and then attempted to set them in a context that exploits the adjacent possible.

If this report can focus more minds in the health policy community and general public on finding and implementing those changes, in everything from clinical practices to regulatory structures, it will have succeeded.

Data Recommendations

Policy Recommendation	Description	Deployment
Portable consent	Allow patients and research subjects in studies to give their consent for their health data to be included in large research databases.	The government should permit patients the right to let whomever they choose access their medical records efficiently and easily. The Department of Health and Human Services could provide regulatory assurance that there will be no punitive action against experimental pilot projects to pool health data. If HHS does not believe it has this authority, it should request it from Congress.
Data from outside the health care system	Circumvent the health care system, which is not designed for the collection of data, and legal privacy concerns by collecting health data outside the medical system.	The thousands of nonprofit organizations actively involved in studying diseases should partner to build a national health database. Employers should include as part of health benefits packages information on how employees can contribute their health data.
Sharing publicly funded data	Similar to how the National Institutes of Health already requires the sharing of research funded by the federal government, data developed from federal grants also should be publicly available.	The National Institutes of Health could more strictly enforce existing rules and otherwise require that federally funded data be shared, and that all grants require data-sharing plans. Follow-on NIH funding could be conditioned on data making it to the public domain and being re-used.
Curating data	As more data becomes available, the need for interoperability and ease of using the data becomes even more important.	Research grants could include some funding for data scrubbing, whether performed by the original researchers or by outside experts. The federal government or a nonprofit organization also could take the lead in developing computer programming scripts that could automatically re-compile data into a standardized, accepted format.

Data Recommendations—continued

Policy Recommendation	Description	Deployment
Life certificate	Birth and death certificates already exist. The “life certificate” is a bundle of standardized health information that would travel with consumers and accumulate as they pass through health-related gateways: vaccinations, procedures, medications, family history, and so on.	The federal government should fund research and development of the life certificate concept.

Research Recommendations

Policy Recommendation	Description	Deployment
Teams for research	Break down the isolation of researchers and encourage collaborative, crosscutting research by creating teams of researchers from across multiple institutions.	The National Institutes of Health could condition a portion of its R01 and other grants on being awarded to teams of researchers, with larger average grants made available to larger teams.
Encouraging translational research	Efforts to encourage translational efforts, such as the National Center for Advancing Translational Sciences at NIH, should be strengthened and accelerated.	Translational research should be viewed as a discipline in its own right, supported by funding models that encourage interdisciplinary, applied research and nourished by a stream of researchers trained specifically in college for translation.

Research Recommendations—*continued*

Policy Recommendation	Description	Deployment
Conducting comparative effectiveness research (CER)	The 2009 stimulus bill and 2010 Affordable Care Act both provide for the federal government to both fund and become more directly involved in conducting CER, studies that compare the effectiveness of new drugs and treatments against existing options.	<p>Comparative effectiveness research should be pursued in both the private and public sectors. While public good considerations favor public sector involvement, policymakers also should recognize that the federal government can have out-sized impacts on private sector practices potentially before definitive results are in and innovations have a chance to prove themselves.</p> <p>Efficiency research on the delivery system deserves the same level of attention from federal funding as research on new treatments; whether that effort should be located within NIH, in HHS's Agency for Healthcare Research and Quality, or in some new center or institute is a subject of debate. Employers can and should demand that providers do a better job of tracking efficiency and subject health care costs to the same kinds of negotiations with vendors as are other expenses and inputs. The government should report Medicare data with a lag of weeks or months, and the cost to receive it should be reduced.</p> <p>Efforts to promote patient-centric Value-driven Engineering should be expanded. VdE holds promise for streamlining the development of new drugs and the delivery of health care, with better results for patients at lower cost.</p>

Legal and Regulatory Reform Recommendations

Policy Recommendation	Description	Deployment
Options for malpractice reform	Malpractice reform has long been on the health system's agenda and is far past due. Patients, jurors, and judges involved in malpractice lawsuits generally lack the expertise to evaluate medical decision-making, the incentive to do so with detachment, or both.	A "no fault" system that sets up a compensation system outside of the courts, with expert evaluators providing payments based on fee schedules is one approach. A second approach is to change liability rules by capping noneconomic damages and eliminating punitive damages. A third option is to channel medical malpractice claims into special "health courts" where the decision-makers are former or retired physicians or other medical experts. The Affordable Care Act has taken the first step by encouraging pilot projects for health courts at the state level.
Reform the "Medical Loss Ratio" Rule	The Affordable Care Act dictates that every health insurer must spend at least 80 percent to 85 percent of premiums on medical care (payouts as a share of total premiums). This rule gives no incentive for insurers to reduce overhead beyond minimal requirements.	Eliminate the medical loss ratio mandate. A second-best option would be to expand MLR to make greater allowance for profit.
Consider QALY	A "quality-adjusted life year" is a concept used by health care analysts to examine benefits versus cost tradeoffs in health care treatment. QALY is a key consideration in reducing low-value care.	Overturn the ban from the Patient Protection and Affordable Care Act that bars the government from developing guidelines or policies based on QALYs.

Legal and Regulatory Reform Recommendations—continued

Policy Recommendation	Description	Deployment
Encourage diagnostics	Diagnostic tests are a largely underutilized form of preventive medicine. The medical research system, public and private, should invest more in diagnostics relative to treatments.	Medicare and other government programs should make a definitive decision on reimbursing most diagnostic procedures, and the Food and Drug Administration should make a definitive decision on whether diagnostics will be regulated. Resolving this uncertainty would give an economic incentive for commercial researchers to develop and clinicians to adopt them.
Interim approval for new drugs and devices	Clinical trials can only go so far in establishing the safety of new drugs and devices. A post-trial “interim” approval stage would provide a good balance between safety and bringing new drugs and devices to market faster.	The FDA could establish an interim approval stage for new drugs and devices. During this phase, the new drug or device would be released only to physicians who have been trained to handle it and monitor the results. Developers would receive protection from legal liability during the probationary period; a share of sales proceeds could be set aside for a fund to pay for compensatory care for patients with bad reactions.

Patient Involvement Recommendations

Policy Recommendation	Description	Deployment
Promote shared decision-making	Shared decision-making refers to the practice of a physician advising patients on their options, laying out pros and cons for a procedure, and helping patients understand and make choices about the kind of treatment they receive. Some states have experimented with measures to promote shared decision-making.	Policy should strive to move shared decision-making through the experimental stage and toward broader adoption. The government’s new Center for Medicare and Medicaid Innovation (created by the Affordable Care Act) should make a point of funding pilot programs in every state; state legislatures should revise laws to make shared decision-making the gold standard of informed consent.

Organization and Delivery Reform Recommendations

Policy Recommendation	Description	Deployment
Expanding Accountable Care Organizations	The Affordable Care Act seeks to promote ACOs, networks of providers that are accountable for and reimbursed based on patient outcomes.	Policymakers of both parties should continue the ACO and Accountable Care Community (ACC) experiments for a sufficiently long period to assess whether their promise is fulfilled.
Focus physicians in acute and integrative care; allow others to take charge of wellness and integrative care.	Health care can largely be categorized into four kinds of care—acute, chronic, wellness, and integrative. Chronic and wellness care mostly are routine and do not need high-priced physicians to actively manage them.	Reform state licensing restrictions to allow nurse practitioners and other non-physicians to do more with respect to chronic and wellness care, and change Medicare rules to allow reimbursement for more treatments performed by nurse practitioners.
Reducing over-capacity and over-use	Use Medicare’s payment leverage to encourage more focus on high-value care.	Medicare should not pay to use drugs in ways the FDA deems ineffective, nor support treatments regarded as inappropriate by standard guidelines.
Developing electronic medical records (EMRs)	The health care industry lags behind other sectors in the adoption and integration of information technologies. EMRs are viewed by many as the next big step in bringing health care to the modern technological age.	The development of EMRs should focus on improving service—reducing repetitive patient paperwork and integrating billing and other back-office processes with medical functions; it is unlikely that EMRs will contain the sort of information that will be useful for research, nor are EMRs likely to be a “silver bullet” answer to cost problems.

CHAPTER ONE

Contours of the Problem

12

A Record of Innovation

If the United States had accomplished nothing else in the past hundred years, it would be remembered in history for its extraordinary record of medical innovation. In a century of staggeringly rapid improvements in medical knowledge and technology throughout the West and Asia, the United States towers over others. Odd though it may seem, at the dawn of the twentieth century, the United States was a medical backwater relative to Europe; but the second half of the century saw a remarkable flowering of science, technology, and innovation, supported and driven by the world's largest economy and the world's greatest scientific and academic infrastructure. One might say, without undue fear of exaggeration and despite the current angst over health care cost and quality in the United States, as the Italy of the High Renaissance is to art, so America of the past sixty or so years has been to medicine.

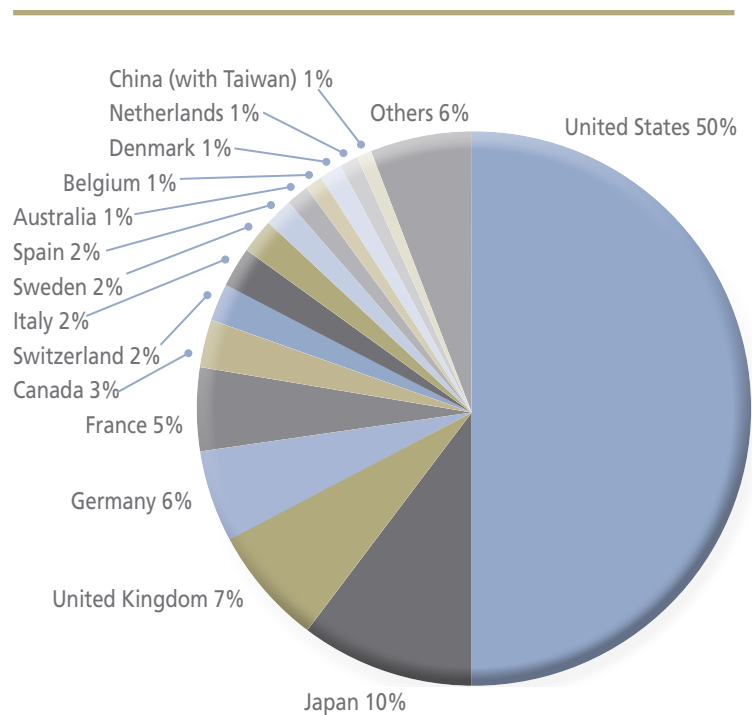
Benefits from these advances have been valued in the trillions of dollars and have led to a consistently higher quality of life for people all over the world. Quantity of life has improved, too. Health care advances have contributed—along with improvements in living standards, safer workplaces and childhood vaccinations—to an increase in life expectancy at birth, which for Americans rose from forty-seven in 1900 to seventy-seven in 2000 (an astonishing gain of 110 days per year or two days per week during the twentieth century).³ One reason for this remarkable improvement is the dramatic drop in infant mortality of more than 90 percent (coupled with the 99-plus percent decline in maternal mortality) over the century. In addition, the two decades from 1930 through 1949 alone, a period including the Great Depression, remarkably saw the introduction of electrolyte therapy and use of antibiotics, accompanied by a 52 percent drop in infant mortality.⁴

³ *National Vital Statistics* 59(1): 33–34, Table 12 (June 28, 2010).

⁴ CDC, *MMWR Report* 48(38): 849–858 (October 1, 1999).

Gains in both general wellness and in treatments and cures for specific diseases have generated large welfare gains. Although those gains cannot, of course, be fully assessed in terms of dollars, their economic value is impressive nonetheless. Kevin Murphy and Robert Topel estimate that, from 1970 to 2000, national wealth increased by \$3.2 trillion per year and cumulatively (in present discounted value) by more than \$95 trillion total (about half of GDP) through increases in longevity.⁵ For heart disease alone, reduced mortality contributed roughly \$1.5 trillion per year to the value of life since 1970.⁶ William Nordhaus estimates that *increases in longevity have been as valuable as all other sources of economic growth combined.*⁷

Generating many of these medical improvements have been substantial investments in research and development. To spur medical innovation, the United States funds (publicly and privately) more than \$60 billion per year in medical research.⁸ Real spending on medical research increased 61 percent from 1980 to 1995 and 23 percent from 1990 to 1995 alone.⁹ The largest single health research agency is the National Institutes of Health (NIH), whose annual appropriations rose by more than 4,000-fold in inflation-adjusted dollars, from \$700,000 going into World War II to \$30 billion in 2010.¹⁰ Even compared to other developed countries, the United States



Sources: Global Forums for Health Research estimates based on official data from official reports to OECD and RICYT, national surveys, pharmaceutical associations, and other publications.

poured a large amount of funding into such research. In 2000, for example, countries that make up the European Union devoted just \$3.7 billion to medical research for a population that was 25 percent larger. As the chart shows, the United States, by itself, accounted in 2005 for roughly half the world's annual health R&D expenditures.¹¹

⁵ Kevin M. Murphy and Robert H. Topel, "The Value of Health and Longevity," *Journal of Political Economy* 114, no. 5, (2006): 871–904.

⁶ Ibid.

⁷ William D. Nordhaus, "Health of Nations: The Contribution of Improved Health to Living Standards," in *Measuring Gains from Medical Research: An Economic Approach*, ed. Kevin M. Murphy and Robert H. Topel (Chicago: University of Chicago Press, 2003) 9–40.

⁸ Forty percent of this amount comes from the federal government. Kevin M. Murphy and Robert H. Topel, "The Value of Health and Longevity," *Journal of Political Economy* 114, no. 5, (2006): 871–904.

⁹ Kevin M. Murphy and Robert H. Topel, "The Economic Value of Medical Research," in *Measuring Gains from Medical Research: An Economic Approach*, ed. Kevin M. Murphy and Robert H. Topel (Chicago: University of Chicago Press, 2003) 41–73.

¹⁰ See Chart of NIH appropriations adjusted by OMB price deflator.

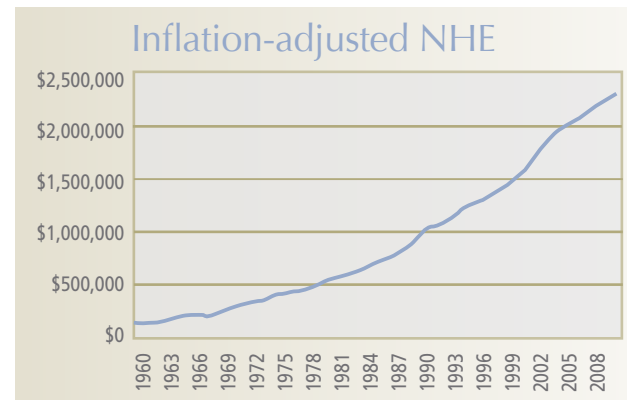
¹¹ Mary Anne Burke and Jean-Jacques Monot, "Global financing and flows," in Mary Anne Burke and Stephen A. Matlin, eds., *Monitoring Resource Flows for Health Research 2008* (Geneva, CH: Global Forum for Health Research), p. 29 and Fig. 2.3.

The Price of Progress

No one would deny the importance and beneficence of medical progress, other things being equal. And few ordinary Americans like to entertain the question of, for example, how much an extra year of life is worth; most people esteem the value of life as infinite. Policymakers cannot afford to think that way, however. They are required to ask, as in every other area of life, not just whether something good happened as a result of a dollar spent, but whether that dollar might have been better spent elsewhere—the concept of *opportunity cost*, as economists call it. If a dollar spent on cleaning up the water supply can prevent as many deaths as hundreds of dollars spent on hospital beds, then, in a world of limited resources, sewage treatment is the better investment. In the United States, medical progress has been paired with ever-increasing expenditure on health care, leading many to question whether such expenditures and their allocation are worthwhile investments in the first place.

In principle, medical research spending should generate huge payoffs. For example, Murphy and Topel estimate that a 1 percent decline in cancer mortality would be worth about \$500 billion, which implies that an additional \$100 billion in research would be worthwhile even if there were only a one-in-five chance that such spending would lead to that 1 percent reduction in mortality. Whether medical research funding—especially by the federal government—is leading to *optimal* results, however, is another matter. There is reason to believe it is not.

The large investments in medical R&D have been accompanied by even larger and more rapidly growing



national health care expenditures, as the chart above indicates. Between 1960 and 1998, per capita real spending on health care went up by 4.9 percent per household, while wages only increased 2 percent.¹² In the first decade of the present century, the situation grew, if anything, even worse. According to the Bureau of Labor Statistics, the inflation-adjusted average hourly *compensation* of American workers—that is, the value of workers' total pay packages, including health insurance and other employer-provided benefits—grew by 1.3 percent a year from 2000 to 2009. By postwar standards, even that rate of growth would be counted by most as disappointing. Greatly compounding the sting of slow growth, however, has been that less than half of the increase in real *compensation* (including benefits) has flowed through to workers' average *wages and salaries* (their paychecks), with the remainder (0.7 percentage points per year) being siphoned off by rising health insurance costs.¹³ One way to think of this is the rising costs of health care exact a painfully escalating health care tax on a hard-pressed workforce. And yet, adding insult to injury, the growing hit to paychecks has not reduced personal spending on health care: in 1960, the average person spent \$700 on health care, but by 2006 that number had grown to \$6,000, while the ratio of health spending to GDP had tripled.¹⁴ Directly and indirectly, Americans are paying more for health care—and more, and more.

¹² Kevin M. Murphy and Robert H. Topel, "The Economic Value of Medical Research," in *Measuring Gains from Medical Research: An Economic Approach*, ed. Kevin M. Murphy and Robert H. Topel (Chicago: University of Chicago Press, 2003) 41–73.

¹³ <http://www.whitehouse.gov/blog/2010/03/12/exploring-link-between-rising-health-insurance-premiums-and-stagnant-wages>, accessed July 29, 2011.

¹⁴ David Cutler, Allison B. Rosen, and Sandeep Vijan, "Value of Medical Innovation in the United States: 1960–2000," *New England Journal of Medicine* 355, no. 9 (2006): 920–927.

Many countries face their own versions of a health care cost crisis, but the United States, unfortunately, leads the way. Compared to other countries, the United States spends much more than similar economies do. In 2006, 15 percent of the United States' GDP was spent on health care, compared with 11 percent in France and Germany, and 10 percent in the United Kingdom and Japan.¹⁵

Rapidly escalating health care costs are also at the heart of the long-term structural deficits of the state and federal governments. At the federal level alone, Medicare and Medicaid spending represented 5.3 percent of GDP in 2009,¹⁶ and unless the benefit structures in these programs are changed, their combined costs should reach 11 percent by 2035 and keep rising thereafter.¹⁷ Clearly, this "excess" health care growth—the amount by which health care costs grow faster than GDP—is unsustainable in the long run. As is now widely recognized, the cost trends in health care—consistently increasing at roughly 2.5 percentage points faster than the general rate of inflation—cannot continue forever, and perhaps not even for much longer.

Finally, to make matters even worse, the huge United States government-funded research effort is not delivering the best bang for the buck, either. By one measure, research productivity has dropped noticeably over time: despite a major increase in federal funding for the National Institutes of Health

between 1993 and 2010, the number of new FDA-approved drugs dropped from more than fifty in 1996 to just twenty-one in 2010.¹⁸

Drivers of Cost

Why the rapid cost growth? Partly for "good" reasons; that is, because of changes that either are desirable or inevitable. One factor is that the population is getting older as people live longer. Longer lives are desirable, and no one wants to shorten them; but, in medical terms, added years toward the end of life are expensive. Moreover, the country has grown richer, and wealthier people spend more on health care—a perfectly reasonable choice for them to make, at least if the choice is based on sound information and is guided and constrained by accurate market signals.¹⁹ Where the market functions efficiently, rising discretionary expenditures efficiently reflect changing preferences.

Unfortunately, no one seriously disputes that health care markets are far from efficient. A combination of insufficient information, poor incentives for cost control (indeed, the very opposite) created by third-party insurance (both private and public), and inefficiencies in health care research—all of those factors have led to much waste.²⁰ By one estimate, of the \$2.5 trillion spent on health care in the United States in 2010, *\$700 billion was not necessary*.²¹

¹⁵ Alan M. Garber and Jonathan Skinner, "Is American Health Care Uniquely Inefficient?" *Journal of Economic Perspectives* 22, no. 4 (September 2008): 27–50.

¹⁶ Carmen Reinhardt and Kenneth Rogoff, *This Time is Different: Eight Centuries of Financial Folly* (Princeton: Princeton University Press, 2009).

¹⁷ Congressional Budget Office, "The Long-Term Budget Outlook." Congress of the United States, November 2010.

¹⁸ For NIH appropriations, see <http://www.nih.gov/about/almanac/appropriations/part2.htm>. For new drug approval, defined as New Molecular Entities and New Biological Agents, see the historical data at <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/UCM123959.pdf> and the most recent fully completed calendar year 2010 and <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/UCM242677.pdf>.

¹⁹ Cutler, *et al.*, 2006, Cutler 2004, Murphy and Topel 2006, Hall and Jones 2007.

²⁰ See Amitabh Chandra and Jonathan S. Skinner, "Technology and Expenditure Growth in Health Care," (National Bureau of Economic Research, Cambridge, 2009) and David Cutler, "Where Are the Health Care Entrepreneurs? The Failure of Organization Innovation in Health Care," (Working Paper 16030, National Bureau of Economic Research, Cambridge, 2010).

²¹ David Cutler, "Where Are the Health Care Entrepreneurs? The Failure of Organization Innovation in Health Care," (Working Paper 16030, National Bureau of Economic Research, Cambridge, 2010).

An important reason for the inefficiency—some experts argue it is *the* most important reason—is that, with the tax incentives employers and employees have to purchase excessive, and excessively costly, health care insurance, all health care *providers* thus have incentives to provide increasingly expensive health care products and services. Now, the widespread availability of health insurance is, without doubt, a good thing. In an era when critical medical intervention often involves complex and ruinously expensive procedures undreamt of several decades ago, few Americans would question the value—indeed, often the indispensability—of insurance coverage for non-routine health care costs, or the medical equivalent of major car accidents or natural catastrophes. Creating a hybrid public-private health insurance infrastructure was one of the great social-policy achievements of the postwar era. But most Americans with private insurance get it through their employers, so they have little incentive or ability to shop around—indeed, they have every reason to press their employers for a Cadillac health plan instead of a Chevrolet that covers *virtually all health care spending*, minus a modest annual deductible and per-physician deductible. Each member of the chain—patient, provider, insurer—feels comfortable offloading higher costs onto the next, so crucial trade-offs are never made.

With costs hidden by insurance from ultimate consumers, and with the public insatiably hungry for new high-tech elixirs, health care innovation to date in the United States has been largely cost-enhancing. Gone are the days when physicians would be careful about ordering tests or diagnostics. To the contrary, today, doctors routinely order an x-ray (or many x-rays), or frequently an MRI or CT scan, before even attempting a diagnosis and treatment. They are heavily influenced by the knowledge that their patients' insurance will pay for the procedures, a knowledge compounded by fear of a malpractice

lawsuit if some patients suffer a major misfortune and not every test had been ordered. Moreover, ordering the test helps the hospital or clinic that bought the machine recoup its investment and covers the salaries of the folks in the radiology department. The test does, of course, sometimes produce useful information, even if only in some cases and at the margin, or if it only corroborates a clinical impression.

More Knowledge, Better Incentives

As we hope the discussion so far brings home, the knots in the U.S. health care system would be comparatively easy to untie if they all were the result of purely irrational flaws or historical flukes. Some undoubtedly are; the linkage of health insurance to employment, for example, arose as a result of a quirk in the tax code, but its persistence today causes pervasive economic distortions and leaves millions of Americans stranded without health insurance when they lose their jobs and thus are at their most vulnerable.

But the central problem is that many of health care's problems, to the contrary, are byproducts not of the system's flaws but of its virtues. That is why we reject the quest for magic bullets, whether in the form of single-payer national insurance, at one extreme, or at the other, by getting the government out of subsidizing care, even solely by vouchers. Whatever the merits or shortcomings of either of those approaches, neither can change the fact that any innovation that helps people live longer and higher-quality lives will tend to increase the consumption of care by ensuring that more people are around to consume it; any system that provides the security of insurance will insulate consumers from many of the costs of their health care choices; and any breakthrough in treatment of a medical condition is likely to make people more complacent about prevention.

Our approach, then, is to accept the inevitability of tradeoffs and second-best outcomes while looking for ways to better design incentives. Fortunately, there is plenty of room for improvement, even recognizing the complexity of the innovation ecosystem for health care and health-related technologies, the elusiveness of causal networks, and the fact that medical spending and technology often are highly beneficial. Today's health care system provides insufficient incentives to develop and use *lower-cost, higher-return technologies* instead of higher-cost, lower-return ones.

For example: today's incentives seem to induce creation of very high-cost, incremental improvements (think Avastin® for cancer care) that financially reward those who develop and commercialize the innovations, but provide little improvement in health outcomes and relatively weak incentives to stop smoking, get exercise, and eat right, or to invest in health information systems that might increase system efficiency. How could we get cheaper cancer therapies and more polio vaccines, rather than innovations of relatively little incremental benefit? How can we better harness patients' own immune systems to prevent and treat disease, rather than relying on devices and drugs to do these jobs? The need for answers intensifies as the wave of baby boomers becomes eligible for Medicare and costs continue to rise for both Medicare and Medicaid.

Building a cost-effective health care system of the future can and should be done in layers—just as is done in technical networks—to allow the separation of concerns in such a way that it is possible to experiment in new layers while continuing to rein in costs in the existing ones. If the experiments pay off, they can be integrated, rather than ripping out the existing system for something entirely untested.

In our view, too many of the changes under public discussion would move money around in the system without revising the underlying incentives or gathering the knowledge that determines how efficiently the money is spent. We are struck that the state of the debate seems to be something like, on the one hand, "If you want more cures, let drug companies make more money" (by extending the life of drug patents, for example, and developing me-too drugs); and, on the other hand, "If you want to reduce costs, reduce government spending" (by limiting federal liability or simply cutting entitlements and assuming that the system will adjust to lower payment). Instead, we propose measures that introduce new efficiency-driving information into the system, reduce wasted motion, or both.

The Centers for Medicare and Medicaid Services now administer almost \$900 billion a year in spending;²² add another hundred billion or so for the VA, military health systems, the Indian Health Service, and the Federal Employee Health Benefits Plan, and we are at more than \$1 trillion federal dollars spent on health goods and services every year—about the same as the United Kingdom's *entire* government budget (including the National Health Service).²³ Add another trillion or so on health care spending in the private sector, overwhelmingly reimbursed by private insurers. This complex aggregate we know as the "U.S. health care system" is a huge and complicated organism that takes in huge amounts of dollars and generates immeasurable amounts of information. But what do we currently do with all the data created? Without an infrastructure to support it, all this information goes to waste. The next chapter speaks to how to leverage this information to combat inefficiencies in our health care system and improve patient outcomes.

²² In 2009, combined Medicare and Medicaid Services' national health expenditures were roughly \$867 billion, as reported by the Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group, <https://www.cms.gov/NationalHealthExpendData/downloads/tables.pdf>.

²³ Total U.K. public spending was about £632 billion in 2010–2011, or just over \$1 trillion in July 2011. Data: http://www.hm-treasury.gov.uk/d/pesa_2011_tables_chapter4.xlsx (downloaded from http://www.hm-treasury.gov.uk/pespub_pesa11.htm).

CHAPTER TWO

Unlocking and Unleashing the Power of Information

Conventional wisdom holds that modern information management holds great untapped potential for health care quality improvements and cost savings. This is an instance where the conventional wisdom is right. Less widely understood, however, especially among the general public, is where that potential lies. The answer is: not in doctors' offices, nor in hospitals.

When most Americans think about "health care IT" (health care information technology), they think about electronic medical records. And well they should. Medical record-keeping in the United States is, in general, pitifully obsolete, with records still scrawled on paper charts and stored in file drawers and cubbyholes, as they were a century ago. Correcting this problem holds promise of dramatically improving the experience of the health care customer, and also promises to reduce back-office inefficiency—points we will return to later in this report.

Creating a more seamless consumer experience and a more efficient back office, however, merely scratches the surface of what can be done with information technology—and the key is not so much the *technology* as the *information*. An information revolution now is taking place in retailing via Amazon, entertainment via Netflix, and targeted advertising via Google and Facebook, among many other examples. Digital merchants, social networks, and data mining entrepreneurs are assembling countless bits and bytes of information about consumer preferences, transactions, and outcomes, agglomerating them, and creating algorithms that can predict what people need, help them find it, and deliver it efficiently. Every day, millions upon millions of grocery store purchases and reward card scans generate electronic records that pour into databases, telling retailers and

distributors who their customers are, what customers want more of, what kinds of promotions work, and where inventories are tight. Yet virtually none of these tools is in use in medicine, where it could work far greater wonders than in retailing.

For instance, about 70 percent to 80 percent of women who develop breast cancer do not have a first-degree-relative family history of the disease, so clearly non-genetic factors must be at work.²⁴ As one clinician puts it, “We’re missing something big.” Or, perhaps more accurately, we’re missing much that is small. The country faces more than 200,000 new breast cancer cases every year, each treated as individual cases, or a few occasionally bundled together for research purposes. Studies can compare selected patient populations in detail on a small scale, and they can make gross comparisons on a large scale. But the factor or factors that cause those 70 percent to 80 percent of unpredictable breast cancer cases are, as of today, falling through the cracks, invisible to the crude optics of the health care sector’s data systems.

Instead, imagine a world in which breast cancer cases, their courses of treatment, and their outcomes were routinely uploaded to a database. Another river of data would flow in from women who have not had breast cancer. Pattern analysis could search and compare many thousands of cases across hundreds of variables for clues as to which factors increase or decrease risk of disease, which methods most effectively and safely extend life, which do so at the lowest cost relative to years gained, which treatments

produce highest patient satisfaction, and, no less important, which therapies are not cost-effective. In principle, with proper privacy safeguards, medical data could be cross-referenced with DNA data to uncover new targets for drug research, to design individualized therapies, and to tailor best-practice guidelines not just for whole diseases but for particular patients. For cancer, for example, doctors prescribe first-line therapies that they know will not work in three-fourths of patients with metastatic breast and colon cancer—they just don’t know *which* three-fourths.²⁵ Combining larger datasets on drug response with genomic data on patients could steer therapies to the people they are most likely to help. The result would be to reduce substantially the need for trial-and-error medicine, with all its discomforts, high costs, and sometimes tragically wrong guesses.

So why hasn’t all this been done? There is no shortage of *raw information* in the health care system. But it is locked in medical offices and hospitals across the country, and in the files of pharmaceutical companies who guard the results of their failed clinical trials. To become *data*, medical information needs to be collected, unlocked, converted to standardized formats, and then entered into databases. And to become *knowledge*, these data must be sorted and analyzed by information experts and their algorithms, teasing out hidden patterns and thereby finding needles in the haystacks. Finally, to become *care*, knowledge needs to be disseminated and acted upon by clinicians, insurers, regulators, and politicians.

²⁴ Top Breast Cancer Myths, American Cancer Society.

²⁵ See, e.g., Burzykowski, *et al.*, “Evaluation of Tumor Response, Disease Control, Progression-Free Survival, and Time to Progression as Potential Surrogate End Points in Metastatic Breast Cancer,” *Journal of Clinical Oncology*, 2008: 26, 1987–1992.

Each of those steps poses challenges. Among the leading causes of resistance are:

- *Legal barriers and privacy concerns.*

Patient records are treated as confidential by HIPAA (the Health Insurance Portability and Accountability Act of 1996) and other laws, and for good reason. Also for good reason, medical ethics rules require patients to give informed consent before they can be treated as research subjects. Though well intentioned, these sorts of rules have a rising cost. Written in an age before data mining and its potential benefits were well understood, they introduce friction into the process of collecting, sharing, and analyzing data. Instead of balancing privacy against discovery, the current system puts policy's thumb so much on the side of privacy that it has the practical effect of locking in information, restricting it to the smallest possible "need-to-know" circle.

- *Technical and semantic issues.* Merely uploading information into a database is not very useful if the data are in a multiplicity of formats that cannot "talk" to each other or be easily compared. Nor can information be compared widely if semantics are not standardized; if, that is, different data gatherers use the same labels to mean different things. In the health sector, there is no equivalent of the domain-name standardization of the Internet. Some kinds of analysis, such as a Google search, can tease out valuable information merely by looking at where words appear and how they connect, without knowing what people think the words mean. In medicine, however, consistent conceptual categorization is particularly important.

- *Constraints on talent and expertise.* In the financial and Internet sectors, the economic value of data collection and analysis is high, and the cost of gathering and accessing data is low. As a result, Wall Street and Silicon Valley are magnets for data-jockeying talent. In today's health sector, by contrast, the economic value of data collection and analysis is low, and the cost of gathering and accessing data is high. Predictably, therefore, the health sector draws little data mining talent and offers few financial rewards with which to attract it; nor is data mining talent being systematically trained and acclimated for the health care sector. In effect, the cost and reward structures in health care send a two-word message to potential data entrepreneurs: "Don't bother."

- *Cultural and policy resistance.*

Physicians and principal investigators usually are acculturated to protect and hoard information, not routinely share it. The default assumption is that information collected here stays here, unless there is a particular reason to move it somewhere else. This cultural predilection often exacerbates the already-restrictive effects of privacy constraints—and privacy constraints, in turn, often excuse the hoarding of information. Moreover, at the policy level, processing and uploading information, where infrastructure exists to do so, is costly, and currently neither public programs nor private insurers pay for it. Moreover, if the research funder does not require the sharing of data, it doesn't happen. Not surprisingly, people prioritize that which they are compensated for doing or are required to do.

These barriers are daunting. They are aggravated by the fact that much information that would be of use in a productive health data mining effort is not even in an individual's medical record, either because a doctor never asked for it, or because a patient would never even be aware of what might be useful.

But two considerations militate against despair. First, the potential payoffs of surmounting them are more than proportionate to the effort. The McKinsey Global Institute estimates that mobilizing health care information could yield more than \$300 billion a year in additional value, or almost \$1,000 a year for every person in the United States. Of these sums, at least two-thirds would take the form of reduced national spending on health care.²⁶ If even a fraction of that unlocked value could be returned to providers and patients, they would have strong incentives to join the data revolution.

The push for "open data" is often gauzy and rhetoric-driven. There are some clear directions to take: polling patients to determine if their medicines work or not, and then mapping those answers to genetic variations to detect correlations. The results can help cut reimbursement costs for drugs whose effectiveness can be predicted, in advance, as less likely to work for a given patient population. This is simply one of many potential cost savings from opening up data.

Second, sweeping reforms are not the only way forward. Incremental improvements, we believe, can make a significant difference, because benefits of data sharing can begin to flow before the whole health care system is networked. Similar to attempts to overhaul technical networks, asking vendors to throw everything out to adopt an ostensibly "perfect" new

system will encounter significant resistance. Adopting instead incremental, but open and extendable, approaches makes it possible to detect where the value emerges and to target additional investments there rather than to bet big and risk failure. This is particularly true with strategies that change incentives at the health sector's data choke points, or which bypass those bottlenecks altogether.

Better Data and More of It: Reducing and Circumventing Obstacles

How can data entrepreneurship be incentivized, rather than discouraged? Data entrepreneurs are analysts who, seeking profits, or knowledge, or both, wade into seas of data, much of which may seem valueless on its face, and discover innovative ways to mine it for new insights. Though data entrepreneurs are no substitute for the patient trials and controlled experiments that are the gold standard for clinical and scientific research, they can process large amounts of information very quickly: in days or hours, as opposed to years for traditional research. Perhaps more important, they need not know what it is they are looking for. In many cases, entirely unexpected patterns may fall out of the data.

The role of the data entrepreneur, then, is to invest time and expertise prospecting for patterns. Doing that, in turn, requires that the data supply be reasonably large and the cost of accessing and analyzing it be reasonably low—conditions that do not exist in American health care today. Indeed, the cost of data entrepreneurship is probably higher in health care than in almost any other sector of the economy. Many of the finest data analysts in the country, for example, are focused on visualization, analysis,

²⁶ McKinsey Global Institute, *Big Data: The Next Frontier for Innovation, Competition, and Productivity*, May 2011, pp. 49–50.

interpretation, and monetization—but of data related to music, social media, and advertising. We must draw on their talents and their investors, and induce them to enter the health care arena by providing “bait” in the form of large, well-formatted, low-transaction-cost pipelines full of data.

How, then, can incentives be rebalanced to make data entrepreneurship attractive in American health care? We believe that much can be done through a combination of reducing and circumventing institutional obstacles.

Consent You Carry Around

One major obstacle is the elaborate system of informed consent protocols for research on human subjects. The kinds of safeguards that make sense in the context of, say, drug trials and other forms of research on people often are unnecessary and counterproductive in the context of research on data.

In particular, patients and other research subjects currently are able to give their consent to be studied in only a single research venture or at a particular venue. Consent attaches to the research project or site, not to, as it were, the person granting consent. Outside the boundaries of any given study, or after that study is completed, further research on the study’s subjects is nearly always off limits. As a result, study populations are incredibly expensive to assemble, in one-off fashion, and typically impossible to integrate with other data collected by other scientists. This blocks the reuse and repurposing of information that is commonplace in other parts of the economy and society. Indeed, the great irony is that the health care sector is one of the *only places* where this kind of integration is prevented.

For an analogy, imagine that supermarkets could collect purchase data only for individuals who gave advance approval to do narrowly targeted research. Instead of sweeping up all your purchase data automatically, you and a few dozen other shoppers might be asked, when you entered the store, if you would be willing to have your produce purchases tracked that day. Then you might be asked to read and sign an off-putting consent form. Your purchasing behavior at other stores, or in the same store a few months from now, or how your produce purchases interact with your beverage selections—all of that might be beyond the purview of the study. No doubt, retailers could glean valuable insights from this kind of targeted research, but the larger flows of information they need to make efficient inventory decisions would be nearly impossible to gather.

Retailers have discovered a better way. By opting in for club cards and other preferred-buyer programs, many shoppers give what amounts to *portable informed consent*. That is, permission to use data attaches to the shopper, not the study. And there isn’t a law that blocks it.

Chemotherapy treatments are, of course, far more personally sensitive than cat food purchases. Yet, the same broad principle applies: an important step toward reducing the costs of health data entrepreneurship is to allow members of the public—health care users and the general public—to pre-approve the anonymized use of health and lifestyle data about themselves for purposes of broad, non-individuated research.

As of now, a well-defined legal regime for portable informed consent has yet to be developed, though there are a few projects expected to launch in 2012. It likely will take a series of pilot programs and

experimentation to learn the correct balance between the privacy of patients, the uncertainty of the effects of public health research, and the technological capacity emerging to capture and integrate personal data. An important measure to move the ball forward could be taken right now, however: the Department of Health and Human Services could provide regulatory air cover, so to speak, for pilot projects by creating a safe harbor for experimentation. What investigators need is simply some assurance that learning what works will not result, later, in punitive action by the government. If HHS does not believe that it has this authority, it should request it from Congress.

It bears repeating that pre-approved informed consent applies to research on data, not on people. Rules need to take all reasonable measures to prevent researchers from identifying named individuals in the database, something that can be avoided with technologies that decouple data from names and other individuating characteristics when data are uploaded. Similarly, protocols need to penalize efforts to identify individuals and target them with marketing or fundraising pitches. There are currently no penalties with which to punish researchers who violate normative or contractual requests to avoid re-identifying patients whose detailed, but impersonalized, records are the basis of research.

Health Information, Not Health Care

Rules and technology can go a long way toward protecting anonymity. But they won't be perfect. No technology or penalty will be sufficiently robust to prevent all determined data crunchers from ever identifying individuals. And the special sensitivities pertaining to information gathered by physicians

and hospitals cannot and should not be eliminated.

How, then, can privacy concerns specific to the practice of medicine be squared with the need to provide far more data available to enterprising (and sometimes nose-y) data miners? An important part of the answer, we think, lies in circumventing a second obstacle: the health care delivery system itself.

This may sound counterintuitive. Where, after all, could one conduct health care research except inside the health care system? That is where the doctors and patients are, it is where the care is delivered, and where the diagnoses and prescriptions are made. And it is, of course, where medical research has gone on until now.

In fact, however, the health care system is in critical ways a particularly *bad* place for health care data collection, for several reasons. One is simply that it is organized for treatment, not for collecting data and putting it in usable forms. The forms that patients fill out in doctors' offices are designed to help providers understand the patient's clinical situation, not to build a broadly cross-referenced dataset including variables, such as lifestyle choices and family history, which may have no bearing on the treatment at hand. Even if the forms they have patients fill out were designed for easy upload, which of course they are not, health care providers are not paid or trained as data collectors.

Another reason is that, apart from an occasional clinical study, the medical system gathers information only when people are in that system seeking care—which is to say, when they think they are sick. A truly powerful dataset would turn its searchlight on the healthy population, helping to understand what it is that makes and keeps people healthy, and not merely what makes them sick.

Yet another reason, and perhaps the most important, is the privacy problem to which we just alluded. Health care providers are culturally trained and legally constrained to treat patient information with maximum sensitivity. Providers and patients alike have reason to be squeamish about uploading data to a system whose security might be breached.

We believe current data-sharing rules within the medical system are more overprotective than they need to be. The consensus of the task force is that health care data, suitably anonymized, should be treated as a “public good”—something that benefits society broadly and whose benefits cannot be restricted to just a few. Some members of this task force believe policy should be changed to allow anonymized treatment data (for example, doctors might upload data linking prescriptions to treatments or ailments, but not to individuals) to be reported to databases. Whether this would be automatic unless patients request to opt out, or require patients to opt in is up for debate. The position of allowing for anonymous databases, however, is not a consensus view either within our task force or in American society. One potential interim step is to create safe harbors for sharing and redistributing anonymous data, which doesn’t carry names or Social Security numbers but still hasn’t been so de-identified that the data are rendered useless for research or prevent a secure way to re-contact the patient for enrollment in a clinical study or trial. Nonetheless, it probably will take years to prepare the medical culture and privacy laws such as HIPAA for thoroughgoing change.

An even more promising approach, we believe, would circumvent the problems created by medical records by collecting health data *outside* the medical

system. The potential here is vast; literally countless organizations and venues can lend themselves to easily and enthusiastically participate in data sourcing efforts. The United States is host to 2,000 or more nonprofit organizations that actively study and fight diseases. Many of them would be natural partners in an enterprising effort to build a national health database. Employers could provide another nexus, dispensing information for employees interested in contributing to the understanding of disease and wellness. This is more about observation of outcomes “in the wild” than about the controlled, double-blind studies that have formed the bedrock of clinical practice for decades.

A current, highly successful example of collecting data outside the health care system is provided by the Army of Women, which is putting into practice the scenario with which we began this chapter. Sponsored by the Dr. Susan Love Research Foundation and the Avon Foundation for Women, this project has since 2008 signed up over 350,000 women (out of a goal of 1 million) to volunteer to participate in breast cancer research; it then matches volunteers with studies, sometimes quickly enough to populate entire studies in a day or two. By contract, researchers agree to share the data they develop with the Army of Women, which thereby accumulates an ever-growing database. Significantly, four-fifths of the women in the Army’s volunteer pool are not current or former breast cancer patients. It is, indeed, an army of *women*, not an army of patients.

There are many advantages to collecting health data outside the medical arena. Dedicated operations are optimized for collecting data instead of treating patients. Survey instruments are devised by experts

who understand massive datasets and cast their nets much more broadly than, say, physicians do. The net effect is to ask better questions and to ask them in a better way, so that results can be efficiently compared and correlated. Nor is the population being surveyed limited to the ill and others who are or were “patients;” outside the medical system, survey populations can include millions who, in any given year, have no business with a doctor at all—and whose wellness may be able to teach just as much as others’ sickness.

Just as important, “information volunteers,” as one might call those willing to be surveyed about medical questions, can be tapped for new information or follow-up questions as often as desired, not just when (and if) they seek treatment. Online interviews can easily be conducted for, say, fifteen minutes every three months indefinitely, with questions automatically tailored to participants. If the right question was not asked in the past, it can be added next time. And, of course, HIPAA and other medical-privacy rules do not apply to information freely given by people outside the context of medical treatment—a compelling advantage of the non-medical approach.

One natural objection is that, in a voluntary sample, data donors will self-select in ways that skew the results. After all, not everyone will offer information or respond to requests for it, whether out of apathy, busyness, or privacy concerns. Responding populations may therefore be unrepresentative of the national population, the patient population, or both.

Self-selection, however, is not as big a problem as it might appear on first blush. It turns out that many Americans are quite happy, indeed positively eager, to share health information in the cause of improving research, which could improve their health

or that of families and friends. When asked, people often respond enthusiastically; a frequent complaint, indeed, is that there is not enough research to participate in. Privacy concerns are real, but experience suggests that many, if not most, people will be content with reasonable safeguards. Today’s public is well accustomed to Facebook and, by and large, understands that 100 percent privacy protection is neither possible nor desirable. In the age of Google, many view the health care system’s information lockdown less as a protection than as an artificial barrier to progress. So it is reasonable to hope for quite high response rates from broadly representative populations.²⁷

In addition, statisticians can, to a large extent, use sampling and other methods to control for self-selected populations. And, even a self-selected population contributing to a national health database would be a vast improvement over what exists today. If only, say, 5 percent of the population—or even just 1 percent or 2 percent of the population, a figure in the low millions—were to connect themselves to an information network, the resulting dataset would be more than large enough to support an impressive amount of important research. The explosion of data entrepreneurs outside the health care sector means that we have an enormous well of talent, experience, and tools to draw on in normalizing the processing and integration of vast and diverse datasets. If we can make data available and connectable, the sheer size of the health care market will draw the data analytics talent toward it.

Which brings us to a final advantage of this “outside of medicine” approach to collecting health data, and a reason why we stress it as an example of smart innovation in health care: it is practicable. No

²⁷ A cautionary note, however: confidence would erode in the event of one or more major episodes in which *identifiable* health data were leaked or stolen. Underlying this discussion of data gathering is the assumed premise that every reasonable precaution will be taken to de-identify and protect data, so that, insofar as possible, individual identities are not known to the system.

radical break with existing policy, nor any extensive demolition of existing infrastructure, is needed. All the tools and technologies are at hand. Converting locked-in health information from a record-keeping burden to a resource is, indeed, the adjacent possible.

Barriers to Sharing: Opening the Silos

Meaningful information comes in nuggets; data comes in sets. Individuals learn slowly; networks can learn very fast. To turn information into data and to link minds into networks, it is essential that information be shared, not hoarded. Yet, at many stages and in many ways, today's health care incentives encourage hoarding. At the level of patient care, there are those aforementioned airtight privacy rules. In commercial health care R&D, the process of conducting drug trials and seeking patents discourages public exposure of information that may reveal failures or assist competitors. In academia, tenure and promotion flow from publication and citation of finished work; there is no reward for going to the time and trouble to share the data that underlie the finished work that may, especially when linked with other datasets, reveal many valuable secrets.

To some extent the problem is cultural and cannot be changed overnight. Yet, here, too, we find promising incentive adjustments in the realm of the adjacent possible.

Like it or not, the federal government is knee-deep in the business of medical research, through its own research, through its grants to private researchers, through the Food and Drug Administration's oversight of drug approval, and its support of higher education. Libertarians may wish the government's role were smaller, and

liberals may wish for more federal activism, but the size of government per se is not the issue here. Rather, we point out that, in whatever role it assumes, the government necessarily creates incentive structures. On balance, those structures can and should be tilted to break down research silos and encourage data sharing rather than repressing it.

Silo-Busting at NIH

A place to begin is the National Institutes of Health, an amalgam of twenty-seven research centers which, together, spend more than \$30 billion a year—half the entire world's medical research budget. Proposing reform of the NIH is something of a cottage industry in the health policy world, and that is not a subject we propose to cover here. In several specific ways, however, the NIH can be a potential catalyst for an information-sharing culture.

The so-called R01 grant, NIH's mainstay form of support for researchers, emerged decades ago, at a time when research tended to focus on specific diseases and fairly narrowly defined problems. If, as much evidence suggests is the case, the marginal productivity of medical research has declined over the past few decades, that is partly because so much of the low-hanging scientific fruit has been picked. Meanwhile, the exponential rise of genome science and the growing prevalence of chronic, multifactor maladies have only made medical biology more complicated, as more genetic targets and more physiological systems clamor for attention.

A system, then, that relies heavily on grants to only one or several investigators within a single institution is bound to be less productive today than in the 1950s and 1960s, when the archetypal

example of breakthrough medical research was the lone researcher hunched over a microscope. Today, making progress relies more than in the past on cross-disciplinary teamwork: efforts that span multiple investigators, and institutions, and disciplines. The unit of research looks more like a network, so to speak, and less like a pod. Yet, as one of our task force noted, nearly 90 percent of the researchers who hold R01 grants (and the R01-equivalent R23, R29, and R37 activity codes) hold only one such grant, which, in 2010, averaged roughly \$400,000.²⁸

Although much good work is done on the traditional “let a thousand flowers bloom” model, small, siloed grants are less and less adequate to the task of assembling the broad skill sets needed to tackle the problems before us. Many private philanthropic funders of research understand this team concept, and approve and fund grants accordingly. NIH could and, we believe, should more energetically steer its grant-making authority to encourage cross-cutting research, with larger average grants made available to larger teams, many of them with participants from multiple institutions, and by requiring data sharing across institutions. This change would incentivize knowledge sharing at arguably the very most critical stage, when questions are being asked and research is taking shape.

The same imperative to break down silos and combine minds from many disciplines also applies to the publication of data and code *after* research is published. Academic investigators have strong incentives to publish good finished work, which is a strength of the current U.S. medical research system. At the same time, however, these researchers have

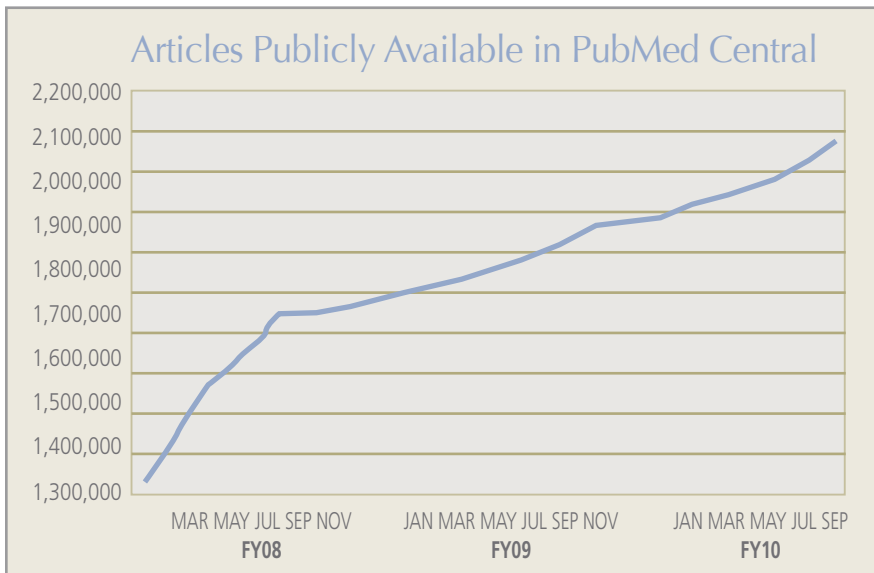
very little incentive to make available, in a digestible form, the data that underlie the published research. If anything, incentives flow more in the other direction: to process and share data requires time and resources, and it invites second-guessing. Data sharing allows for more than merely checking prior research, important although that is; it also allows subsequent research to compile and use the original data in ways that the original investigator could not have anticipated, and to combine it into larger datasets that create still more opportunities for discovery.

Here, again, part of the problem is a long-embedded culture that prizes publication and citation in the tenure and promotion process and which places a particular premium on crediting researchers for doing original work. The scramble for priority fosters scientific competition between discrete individuals and institutions, but impedes joining forces across individual and institutional lines in large, interdisciplinary efforts that rely on accumulating and sifting data and attacking complex problems from many directions.

Here, too, private organizations have shown that incremental incentives make a difference. Many private grantors require data sharing as a condition of grant-making. This is an incentive structure that we believe federal research funding—a major motivator in the research market—should emulate. Indeed, making the sharing of data, coupled with a requirement to deposit the complete raw dataset plus the source code for the analytical algorithms used to interpret, should be the default expectation for federal funding. These requirements would do more than any other single measure, or possibly more than every other measure

²⁸ R01-Equivalent grants: Average size. <http://report.nih.gov/NIHDataBook/Charts/Default.aspx?chartId=158&catId=2>.

combined, to change the culture that treats data as proprietary. When NIH began *requiring* that finished research it funds be deposited in a public database, compliance rose from 4 percent to 85 percent.²⁹ As shown in the chart below, this has had a dramatic effect on the number of publicly available research articles in the PubMed database.³⁰



Requiring that publicly funded *data* be shared in the same way is likely to be similarly effective. NIH already requires researchers receiving grants of more than \$500,000 to submit plans to share their data.³¹ Alas, compliance with the plan is not effectively monitored. The time to do that, we believe, is when grants come up for renewal.

Likewise, it is important to ensure that access to the literature is seamless and not firewalled, so that **machines**, and not just humans, can access text. So long as publications are walled in proprietary databases and require human interfaces to enter (e.g., passwords and logins), the immense power of semantic web, or even simple text-searching, cannot be achieved. Yet, it has long been apparent that the

medical literature has become so vast and complex that no human mind or set of eyes can master even a clinically relevant subsector of it. We need help from computers, but we have made it impossible for computers to get ready access.

A further important step is encouraging that data be shared in an intelligent, digestible way.

Merely uploading data to a central location may be better than nothing—technology can do some of the work of organizing data and bridging variegated formats—but far more valuable is to reward not just quantity, but quality, by encouraging the sharing of manicured, “sushi-grade” data that emphasizes interoperability and ease of use. Standardization of data is

a huge concern for the possibility of medical research we talk about here, and for the use of electronic medical records, which we discuss in the next chapter.

Curating data and putting it in usable formats, though not hugely expensive, costs money, and not all researchers are adept at doing it. It would be helpful, we believe, if grants included some funding for data scrubbing, whether performed by the original researchers or by outside experts. The task force discussed the need for developing intelligent computer programming scripts that could automatically recompile data into a standardized, accepted format. There was not a consensus about whether the federal government should take on this role of developing the scripts and maintaining

²⁹ Conversation with Neil M. Thakur, program manager for the NIH public access policy.

³⁰ National Institutes of Health 2010 Office of Extramural Research Report, http://grants.nih.gov/grants/2010_oer_report.pdf.

³¹ National Institutes of Health. “Final NIH Statement on Sharing Research Data.” February 23, 2003. <http://grants.nih.gov/grants/guide/notice-files/not-od-03-032.html>.

standards, or whether a non-profit organization should take the lead.

A challenge here is measuring the quality of data in order to reward it. Fortunately, counting how often data is downloaded, and thus how much use it receives, is relatively straightforward and increasingly easy. This is a measure to which, we believe, federal grant-makers would do well to pay more attention. Other metrics, which more precisely measure whether data is reused in subsequent work (rather than merely downloaded), are emerging; federal grantors should encourage and adopt such indicators as their availability and reliability grows.

Private Pathways to Data Sharing

In suggesting that the government use its leverage to promote data sharing (and to help ensure that shared data is of good quality), we do not mean to suggest that there is no role for private efforts. Some are already under way—still embryonic, to be sure, but pointing the way toward a completely new system of open-source medical discovery.

By way of example, consider Sage Bionetworks, a nonprofit medical research organization whose mission is not to conduct or finance new research, but to create and link data depositories that promise to let researchers work together in teams of hundreds or thousands, not twos or even tens. Sage Bionetwork projects include:

- A repository of genomic and disease-model datasets, allowing researchers to efficiently query a wide range of curated, collated data using an interactive online tool.
- An online software platform creating a common workspace for online research collaboration, potentially allowing whole research communities to self-organize online.
- A common data stream into which pharmaceutical companies could pour research data they feel they can safely share. Early indications are that pharmaceutical firms are eager to join such a data pool, because it helps them eliminate duplicative research, a major contributor to high drug development costs. (The average pharmaceutical research target has five companies working on it, each ignorant of the others' failures.) Better still, the data stream could be opened to the outside world, "crowdsourcing" discoveries that drug companies focused on commercial products likely would miss.
- The provision of "priority review vouchers" for companies that share all their failed trials data over a multi-year period. Such PRVs have a predictable cash value, can be traded and sold, and could serve as easy rewards for sharing data.
- A project to help identify "non-responders," patients on whom expensive drugs would be wasted or counterproductive. Three-fourths of cancer patients are non-responders for any given drug regime; much money and suffering could be saved by finding clues that help rule out ineffective treatments.

These projects and others like them, we think, provide just a hint of the benefits that efficient, large-scale data sharing may bring. Reducing the regulatory and cultural obstacles to data sharing and using government's leverage to promote it should be leading priorities for health policy.

Lost in Translation: Making Knowledge Count

The final stage of the data chain that turns information into outcomes is to embody knowledge in concrete treatments and protocols and make sure that it reaches health care's "street," the practitioners and patients on the front lines.

An important place to begin is in the area of so-called translation, the process by which science becomes clinical medicine. The U.S. medical research system is strong on basic health research: understanding the causes of disease at the molecular level, for example, and finding potential targets for treatment. It is weaker, and less systematic, at translating basic knowledge into clinical applications. Translating basic research into high-value treatments does not happen automatically. Rather, it requires embodying laboratory discoveries as usable drugs, devices, and procedures; finding out if those new methods really work in people (they usually don't, because human biology and culture are complicated and ornery); and then disseminating and applying that knowledge. Knowing a lot about how a molecule affects a protein is of little help in bridging those synapses; the translational stage often requires its own kind of research.

This is an area, fortunately, in which we are not a voice in the wilderness. Francis Collins, the NIH director, announced in 2011 the establishment within NIH of a new National Center for Advancing Translational Sciences, whose mission is to "catalyze the development and testing of novel diagnostics and therapeutics across a wide range of human diseases and conditions."³² Collins argues for a "reengineering" of translational science akin to the focused, coordinated approach brought to human genomics a generation ago: "Little focused effort has been devoted to the translational process itself as a scientific problem amenable to innovation. As was the case with genomics, translational science needs to shift from a series of one-off solutions toward a more comprehensive strategy."³³

We welcome this new translational emphasis. The impact of a new center remains to be seen, but Collins's larger point is correct: translational research needs to be viewed as a discipline in its own right, supported by funding models that encourage interdisciplinary, applied research, and nourished by a stream of researchers trained for translation rather than merely seconded from other disciplines. "The triple frustrations of long timelines, steep costs, and high failure rates bedevil the translational pathway," Collins correctly writes. "The average length of time from target discovery to approval of a new drug currently averages [approximately] 13 years, the failure rate exceeds 95 percent, and the cost per successful drug exceeds \$1 billion, after adjusting for all of the failures."³⁴ To date, the record suggests an unfavorable international division of labor: the

³² Francis S. Collins, "National Center for Advancing Translational Sciences: How Will It Work?" Presentation to Clinical Research Foundation Annual Meeting, April 27, 2011. <https://www.dtni.duke.edu/website-administration/files/Collins%20NCATS%20slides.pdf>. Accessed August 13, 2011.

³³ "Reengineering Translational Science: The Time Is Right." *Science Translational Medicine*, July 6, 2011. <http://stm.sciencemag.org/content/3/90/90cm17.full>. Accessed August 13, 2011.

³⁴ *Ibid.*

United States conducts the best basic medical research, but other countries do better in applying it—increasing their health competitiveness relative to our own. And while the United States may generate the most high-tech medical innovations, other countries are better in applying low-tech medicine. The effort to encourage translational efforts, if anything, should be strengthened and accelerated.

More basic data “blocking and tackling” also is in order. For difficult diseases, especially those that are debilitating and life threatening, physicians should, as a matter of course, use established protocols and record medical information on standardized forms. Electronic health care records, the benefits from which we elsewhere stress not be overstated, nonetheless can be useful in this regard. Once digitized and standardized, patient data, disease status, and treatment outcomes are much better positioned to be analyzed.

But Will It Cut Costs?

In most industries, new technologies and discoveries tend to drive costs down, as competition selects for innovations that increase productivity. So far, unfortunately, health care has not worked this way. For some of the reasons sketched in the previous chapter—third-party payment, for example, and the perceived necessity of the very “best” treatment, regardless of cost—technological innovation has been a major cause of health care inflation. Often, generally adequate technologies and drugs are replaced by successors that cost much more but produce results that are little better. Arguably, the single most fundamental problem in the health care sector is the sad fact that innovation and productivity have been at loggerheads, creating a vicious cycle instead of a virtuous one.

Unlocking the power of modern techniques for gathering, sharing, and analyzing data can encounter the same problem. One can certainly imagine that sifting through mountains of data on, say, breast cancer or Parkinson’s disease might lead to expensive new therapies with only marginal health benefits. We believe that unleashing information will almost invariably improve treatment. But will it also improve productivity, the cost-effectiveness of treatment? That is a very different question.

On the whole, we think the answer is yes. “Informationizing” the health care system not only brings to light new possibilities for research and treatment, but also sheds light on the comparative value of research and treatments. In other words, it generates not just knowledge that allows providers and patients to pursue better health; it also surfaces knowledge that allows them to set better priorities, focusing resources where they are more likely to pay off.

That is why bringing the information revolution to health care offers multiple benefits. First, it will generate many innovations that improve health outcomes. Second, it will generate some innovations (new preventive measures and screening regimens, for example) that reduce costs in *absolute* terms, saving some money compared with the status quo.

Of course, to gain the benefit of the priority-setting knowledge that data networking will uncover, Americans must set priorities. Alas, the system is rife with political and institutional obstacles to doing that, which brings us to the subject of the next chapter: changing incentives to reduce waste.

CHAPTER THREE

Harvesting Waste

“Harvesting” waste? Don’t we mean “eliminating” waste? Or at least “reducing” waste?

Yes, certainly. But a better way to begin than by thinking of waste as a failure or a nuisance is as an opportunity. Waste is a resource.

In the 1970s, many futurologists predicted that the world would soon run short of vital natural resources. Among the reasons they were wrong is that they failed to appreciate the potential of waste. In the United States, where the most accessible oil and mineral deposits had long ago been exploited, copper companies, for example, developed technology that allowed them to go back to the mountains of tailings and other waste they had left behind and re-mine them for new copper. The oil industry developed directional drilling, in-hole sensors, and other techniques that let them recover new oil in old wells. Though some waste is indeed a result of pernicious or pointless behavior (as in “waste, fraud, and abuse”), much “waste” is better thought of as a resource that we have yet to discover how to exploit.

The bad news—and the good news—about the health care system is that it is shot through with this kind of waste. Once a company or entrepreneur identifies waste and develops a way to eliminate or reduce it, that company has, in effect, created a new resource. Between 1997 and 2006, United Technologies, an industrial manufacturer, set ambitious goals to reduce energy use by taking measures that ranged from recycling waste steam to replacing light bulbs. It reduced its energy consumption by 20 percent over ten years even as its revenues more than doubled. The resulting savings—\$50 million a year in lower energy bills, and \$300 million a year less than if energy consumption had grown in line with revenues—dropped straight to the bottom line.³⁵

³⁵ Jonathan Rauch, “Turning Lights Down, and Profits Up.” *National Journal*, April 20, 2007.

In health care, the problem is that savings from reducing waste generally go straight to *someone else's* bottom line. Because of third-party payment and government subvention, everyone in the system (except, ultimately, the taxpayer) is in a position to pass on costs, which means no one has a strong incentive to reduce them. Doctors are not rewarded for ordering fewer MRIs, hospitals for forgoing unnecessary new beds, patients for declining discretionary procedures, or insurance companies for reducing paperwork. Not even the taxpayer is necessarily rewarded for reducing health care costs, since any savings may go back out the door as other government spending. Where waste is concerned, the low-hanging fruit still dangles unpicked on the trees.

Depressing though that may sound, the upside is, of course, that there is an abundance of low-hanging fruit to be picked. This is not to say it is easy pickings. Repairing broken incentives requires diverting resources from current beneficiaries and asking providers and patients to make hard choices. If that were easy, it would have been done already. Nor do we harbor any illusions that efficiency can turn around rising health costs any time soon; on the cost front, the country is rowing against a strong demographic current. But there are many billions of dollars to be harvested even from modestly incremental changes, and potentially trillions, over time, from ambitious ones.

"Our health care system isn't broken," we were told by one health care analyst: "it's getting exactly what it incentivizes." In this chapter, we clarify what we mean by waste, briefly assess some current efforts to reduce it, and go on to draw attention, in more detail, to ideas we believe deserve more attention and development—all with an eye toward improving incentives.

What Is "Waste," Anyway?

In economic jargon, waste can refer to *deadweight loss* or *opportunity cost*. Deadweight loss occurs when people engage in activity that has no economic value or actually destroys value. Opportunity cost occurs when people engage in activity that has some value, but less value than a more efficient use of resources would produce.

Health care offers many examples of both kinds. Deadweight loss often occurs, for instance, as a result of duplicative and pointless transactional friction in billing practices. Some antiquated business practices are not just suboptimal but lead to mistakes and essentially throw providers' and patients' time and energy out the window; illegibly scrawled and inconveniently stored medical records come to mind. The "dirty little secret" about the redundant medical history forms that patients laboriously fill out every time they visit the doctor, we were told, is that no one reads them. Another widely cited source of deadweight loss is litigation, which often yields judgments only randomly related to either fairness or deterrence of medical misbehavior.

Though deadweight loss is a serious problem and obviously should be vigorously addressed, we believe that still larger losses fall into the category of opportunity cost, in the form of *low-value care* (a more precise and compassionate term, we believe, than "unnecessary" care). This is where the big money lies, and it is here where the country will need to drill in order to "bend the cost curve." But because *low-value care* is not always *no-value care*, reducing it requires making choices that people will resist. Low-value care brings us back to that familiar health care dilemma: the knottiest problems stem not from the system's fault but its virtues, among which

is its reluctance to stint on any care that might conceivably do any good.

We define low-value care as that which has a relatively low probability of improving the quality or quantity of life. Measuring quality and quantity of life is difficult, but the concept of the “quality-adjusted life year,” sometimes known as the QALY (“qualy”), provides a productive way for analysts, if not the general public, to think about it.³⁶ Unfortunately, in the rush to provide reassurance that health reform would not bring about “death panels” or other forms of cold-blooded rationing, the 2010 Affordable Care Act (the health reform law) barred the government from developing guidelines or policies based on QALYs. Though we are not holding our breath, we would hope for that ban to be overturned, because the country cannot easily solve a problem that it cannot openly think about.

Three Current Approaches: An Assessment

Recent legislation and other policy initiatives feature three prominent efforts to improve value in health care delivery. We offer some descriptive and evaluative comments here.

A. Comparative Effectiveness Research

The medical system generally knows if a medication is safe and effective in controlled trials. But it knows much less about comparative effectiveness of drugs due to a dearth of head-to-head trials, even less about the effectiveness of drugs in day-to-day use, as actually taken by patients. If a drug is being prescribed but patients won’t take it, because of inconvenience, or side effects, or for some

other reason, it is not effective. The same is true of medical devices, surgical procedures, and “off-label” drug uses, all of which receive less (or no) pre-approval screening in the first place. As reported by *The Washington Post*, the medical research ecosystem has mostly failed to evaluate drugs and devices after they reach the market:

Only 1.5 percent of money spent on medical research goes to “outcomes research,” of which comparative effectiveness is a sub-category. About 13,000 new clinical studies start up each year; about 112,000 are running now. A meticulous search in 2008 revealed only 689 studies that fit the general description of “comparative effectiveness.” Many experts believe that’s not enough.³⁷

In an attempt to plug the gap, the 2009 economic stimulus package included more than \$1 billion for comparative effectiveness research, and the Affordable Care Act established an independent entity, the Patient-Centered Outcomes Research Institute, to help set priorities for effectiveness comparisons and to provide a permanent stream of funding.

We believe comparative effective research can be a sound investment, and that the federal government has an important role to play. Information about effectiveness of various therapies is a public good, and, for that reason, comparative effectiveness research is likely to be under-funded if left solely with the private sector.

At the same time, however, there are dangers associated with having the federal government being the *sole actor* in conducting comparative effective

³⁶ See, generally, Peter Schuck and Richard Zeckhauser, *Targeting in Social Programs: Avoiding Bad Bets, Removing Bad Apples* (Washington, D.C.: Brookings Institution Press, 2006).

³⁷ “‘Comparative Effectiveness Research’ Tackles Medicine’s Unanswered Questions,” August 16, 2011. http://www.washingtonpost.com/national/health-science/comparative-effectiveness-research-tackles-medicines-unanswered-questions/2011/08/01/gjQA7RJSJ_story.html.

analysis. This is because the government, through its Medicare program in particular, can have out-sized impacts on private sector practices potentially before definitive results are in. New therapies and procedures take time to be perfected and evaluated, and, if judgments about their cost-effectiveness are made too soon, many potential breakthroughs may not be paid for. If payments are not forthcoming, then innovators won't try innovating in the first place.

In contrast, at least in principle, with multiple parties evaluating the cost-effectiveness of medical procedures, the market can help determine what gets reimbursed and what does not. The problem is that, because of free riding, no private sector actors may want to get involved in the comparative effectiveness business. One possible solution could be to have the government provide partial funding of multiple health insurers and/or providers to conduct these studies. But even then, once the government picks one particular set of results for any particular condition for purposes of reimbursement, that decision alone can drive reimbursement decisions by private actors.

In the end, we see no perfect solution to the potential downsides to full or partial government funding of CER. The upsides of publicly financed CER are sufficiently great, in our view, that they are likely to more than offset the downsides.

In any event, research can only be as good as the data it is based upon, and traditional clinical research can only do a piece of the job. Just as important, if not more so, is the "big data" approach that tells us what is going on in the real world. That is why—reinforcing the message of the previous chapter—it is so important to mobilize and share data on a far wider scale than in the past, and why the role of "data entrepreneurs" in mining databases for

unlooked-for knowledge is so important. Much of the best comparative effectiveness research can be done in the wild, not in experimental settings, by capturing data currently lost in the system.

Value-driven Engineering (VdE) can be an important complement to CER. Whereas CER compares (by definition) the effectiveness against standard or best care of a given product or service whose production costs already have been incurred, VdE seeks to optimize savings and care for *patient and the health care system* through better design, development, and manufacturing of new pharmaceuticals, and the delivery of health care. In effect, with VdE, the health care system is treated as an engineering challenge focused on solving the problems with greatest medical payoffs. With VdE principles incorporated in the regulatory approval and reimbursement processes, less money would be spent on me-too drug research, which would reduce the numbers of drugs pursued and the money spent on them.³⁸

B. Electronic Medical Records

Only a minority of physicians and hospitals maintain comprehensive information-technology systems. As any patient who has been told to fax an insurance preauthorization or put X-rays in the mail can attest, the need to bring medical information technology into the current century is dire. Like everyone else, we support it in principle. But we also urge caution about what to expect from it.

In our view, the principal virtues of electronic records lie in the realm of improving service, not reducing cost. When records travel electronically with patients, or are shared automatically with multiple doctors, communication and coordination will be

³⁸ For a more detailed explanation of VdE, see Austen BioInnovation Institute in Akron, *Value-driven Engineering for Global Competitiveness: A Call for a National Platform to Advance Value-driven Engineering*, June 2011. Task Force Member Frank Douglas is the chair of the steering committee that produced this report and developed the VdE concept.

smoother. When software “knows” which medications a patient is using and automatically alerts doctors to potential conflicts, or when it flags inconsistent instructions, it can help prevent medical error. By integrating billing and other back-office processes with medical functions, IT can improve workflow. Not least, getting paperwork hassles out of patients’ faces can improve patients’ experiences.

Some electronic medical records advocates predict large cost savings. In particular, by integrating medical records with comparative effectiveness findings and clinical recommendations, IT theoretically could automatically flag procedures that are out of line with best practices or utilization rates that are conspicuously high.

While we support the use of IT to nudge providers toward better value (who wouldn’t?), we also caution against expecting too much, too fast. Success stories at particular institutions are all well and good, but getting a multiplicity of proprietary and frequently incompatible IT systems to talk to each other is a challenge that will take years to resolve. In the short term, the adoption of IT will likely *raise* costs, because there is so much infrastructure to build and debugging to do. Not least important, the power of IT to save money will not actually be used that way unless saving money is incentivized. For those reasons, a long, sometimes bumpy, and probably expensive transition period lies between the present and the routine realization of the cost-saving integration that electronic medical records seem to promise.

We do not mean to throw cold water on bringing health records and administration into the digital age, an idea which, to reiterate, we support and which will eventually do much good. Continuing

contentedly with scribbled charts in file folders while the rest of the world has moved on to Google Docs would be absurd. We merely caution that electronic medical records may be necessary but are far from sufficient, and overhyping them risks diverting attention and resources from other important tasks.

C. Accountable Care Organizations

The recognition that incentives need to change has led to wide interest in accountable care organizations (ACOs), which the Affordable Care Act seeks to promote. In the traditional care model, what providers provide is not accountability for a patient’s overall health but individual procedures, each separately coded and paid for—which is a bit like buying a car one part at a time, without regard to how it drives. Volume, not value, is rewarded.

ACOs are an effort to rewire these incentives for at least part of the health care system. With ACOs, the government pays networks of providers to manage the health of at least 5,000 Medicare patients for at least three years. If they do the job efficiently and spend less than Medicare allots, they keep the difference, provided they adhere to specified quality standards.

The payment structure is designed to incentivize cost-consciousness; the encouragement to form large networks is designed to stimulate vertical integration, so that providers will coordinate across disciplines and work in teams; basing payment on serving patients rather than delivering procedures is designed to reward value rather than volume.

Together, those features are intended to seed what some have called “mini-Mayos:” smaller versions of the Mayo Clinic, a renowned health provider that is considered a model of relatively efficient vertical

integration and is popular with physicians and patients alike. (The Clinic's employed 3,700 physicians are salaried and the system sees a million patients a year in facilities in Arizona, Florida, and Minnesota.)³⁹

Like everyone else, we look upon the experiment with ACOs with curiosity and hope. Reasonable expectations will help keep the experiments on track. Near-term cost savings are likely to be small. The government estimates that the health reform law's ACO initiative could save Medicare up to \$960 million in the first three years, or "far less than 1 percent of Medicare spending during that period," according to *Kaiser Health News*.⁴⁰ And Mayo owes its success at providing team-based care and vertical integration not only to its structure but, perhaps even more important, to its culture, which may be difficult to replicate. Whether ACOs can foster cultural change among their members remains an open question.

That said, no one really knows how much money ACOs ultimately might save if they were to catch on and if they are given incentives to continue wringing out waste beyond the initial pilot programs. Nor can we predict how much they might improve upon today's fragmented, often incoherent patient experience—potentially a great deal, if they prove to be an effective new paradigm. For that reason, we hope that policymakers of both parties will continue the ACO experiment for a sufficiently long period to assess whether their promise is fulfilled. We suggest similar efforts be made to experiment with a related concept, the Accountable Care Community, which focuses on patients, directing them to the appropriate provider in their immediate community to handle acute, chronic, or wellness problems.⁴¹

Who Does What? Putting Doctors in Their Place

As we have continued to stress, incremental change is the only kind that will be effective and sustainable in health care. That said, however, there is room to consider fundamentals that existing reforms may not do enough to address. Most fundamental of all is a question rarely asked: Who needs doctors?

"Health care" is a rubric that today obscures as much as it reveals. That wasn't always the case. Years ago, "health care" meant going to the hospital for emergency treatment and to a primary care physician (or a dentist) for almost everything else. In that world, it made sense to think of medicine as synonymous with doctors. That is no longer the case in today's world, with its proliferating specialization, complex chronic conditions, and care delivery in settings ranging from teaching hospitals to boutique clinics and grocery stores.

Although we can imagine various ways to slice the pie, we think it most useful to think of today's health care as comprising four related, but distinct, categories of care:

- **Acute:** care for urgent or unstable conditions, or major interventions like surgery—generally provided in hospital;
- **Chronic:** ongoing care for stable or predictably changing conditions;
- **Wellness:** preventive and other measures to keep people healthy—generally provided at home and in the community; and

³⁹ <http://www.mayoclinic.org/about/facts.html>.

⁴⁰ Jenny Gold, "FAQ on ACOs: Accountable Care Organizations, Explained." March 31, 2011. <http://www.kaiserhealthnews.org/Stories/2011/January/13/ACO-accountable-care-organization-FAQ.aspx>. Accessed August 21, 2011.

⁴¹ The ACC model is being tested through a planning grant from the Centers for Disease Control in the Akron, Ohio, area.

- **Integrative:** oversight to ensure that the other three categories gel to provide coherent care.

In today's system, physicians routinely are involved in all four kinds of care. That was logical in the days when most patients saw only one physician for all their needs. Today, however, it means that too much high-priced talent is devoted to tasks that could be done just as well (or better) and much less expensively by non-physicians.

We believe physicians should be lead providers of acute and integrative care; that is, they should make critical decisions when patients enter the medical system with a new problem, they should supervise and execute interventions until the patient is stable or well, and they should bear ultimate responsibility for (though not necessarily day-to-day management of) ensuring that the overall treatment program is sound.

However, they should play a much more limited role in delivering chronic and wellness care. Patients who are managing stable and ongoing conditions such as diabetes, chronic lung disease, or even chronic heart disease generally do not need to see a doctor unless there is some change in their conditions; nurse practitioners or technical aides can evaluate them and provide such services as blood and pulmonary function tests, health coaching, and routine monitoring.

The potential savings from concentrating physicians where they really make a difference are large. The health care system is built for accidents and emergencies, yet more than 75 percent of U.S. health care spending is on chronic disease and its complications.⁴²

After many decades in which “go see the doctor” was the automatic injunction for anyone who needed any kind of medical services, making patients comfortable with the idea of seeing the nurse practitioner, or even a health coach or nutritionist instead, will require a cultural change. Fortunately, the change is already under way. MinuteClinics, where people can get routine lab tests, vaccinations, and treatment for minor wounds and infections, have sprung up in CVS Pharmacy and Walgreens stores around the country; care is provided by nurse practitioners and physician assistants, and clinics often are open on weekends.⁴³ RediClinic, a smaller but similar outfit, operates in more than forty H-E-B grocery stores in Texas.⁴⁴ Overall, according to the Convenient Care Association, more than 1,200 such clinics operate in thirty-five states.⁴⁵

Although still a drop in the bucket, the growing popularity of the nurse practitioner model suggests consumers are receptive to user-friendly care in convenient locations. Moreover, many practitioners welcome being freed to do more of what they do best. As one physician told us, most cardiologists do not particularly want to be responsible for administering maintenance doses of statin medications or supervising weight loss, and they aren't particularly good at it.

Even for emergency care, cheaper but no less effective alternatives to high-cost medicine at hospitals are emerging. Urgent-care clinics are beginning to spring up around the nation to provide acute care for a wide variety of non-life threatening accidents (cuts, broken bones, and the like) and illnesses (e.g., strep throat).⁴⁶ Health insurance plans

⁴² <http://www.cdc.gov/chronicdisease/resources/publications/AAG/chronic.htm>.

⁴³ <http://www.minuteclinic.com/about/history.aspx> and <http://www.minuteclinic.com/about/pressrelease.aspx?num=132>, accessed August 19, 2011.

⁴⁴ http://www.rediclinic.com/news/opening_20_clinics_12-2010.php and <http://www.rediclinic.com/faq.php>, accessed August 19, 2011.

⁴⁵ http://www.ccaclinics.org/index.php?option=com_content&view=article&id=4&Itemid=11.

⁴⁶ Laura Landro, “At the Mall: New Clinics Let Patients Skip the ER: *The Wall Street Journal*, November 22, 2011, p. D1.

can encourage the patronage of these facilities through lower copays, thereby freeing up already crowded hospital emergency rooms for the treatment of more serious conditions.

More could and, we believe, should be done to free the system to redeploy doctors. One step is to reform state licensing restrictions to allow nurse practitioners and other non-physicians to do more. Another is to change Medicare reimbursement rules to pay for treatments by nurse practitioners. The ACO model may be another way to encourage providers to use allied health professionals such as nurses to greater effect (if an ACO can employ a nurse in a doctor's place it will save money and reap the reward of shared savings in the program). Still another idea is to encourage individuals to establish directives for end-of-life decisions, which would reduce use of physicians and other medical resources.⁴⁷

What Do They Do? Incentivizing Value

According to the Congressional Budget Office, around \$700 billion, or one-third of annual health care spending in America, is of the low-value variety ("some, if not much, of it entirely unnecessary").⁴⁸ Dollar figures, however, mask an assortment of oft-difficult questions and judgments. When we talk about reducing the utilization of low-value care, we are really asking: What care should the system provide? And what should it *not* provide?

To see how best to answer those questions, it may be helpful to distinguish two meanings of "low-value," one absolute, the other relative.

To say a treatment is of low value in *absolute* terms is to judge that the improvement it purports

to offer just isn't very helpful (perhaps a CT for abdominal pain after an emergency doctor has already diagnosed appendicitis on the basis of a clinical exam) or unlikely to be beneficial (various species of back surgery). But judging value in absolute terms presents fraught choices and implies, to the public, valuing some people's lives or wellbeing more than others'. We believe such value judgments are both inevitable and, in real life, common, even if most people prefer to look the other way. But we recognize their inherently contentious and painful nature. We think the most politically palatable path toward making better absolute-value choices for many types of care, particularly elective surgeries and tests, is to place more such decisions in front of patients themselves, a point we will explore in the next chapter.

To say a treatment is of low value in *relative* terms is to say that there is a better or cheaper way to do it. Judgments of relative value, though still not easy, are less fraught. Most people would rather do things in better or cheaper ways when given the choice, provided they have a financial stake in the decision. Additionally, determinations of relative value often can be made by physicians and other health professionals in ways that are not transparent to patients. (The doctor, not the patient, decides whether to order a CT scan or make do with an X-ray.)

Two categories of (relatively) low-value care are particularly problematic, in our view. The first is *elective* or preference-sensitive procedures and tests.⁴⁹ This might include a joint replacement, much cosmetic surgery, and, indeed, some cardiac interventions. U.S. regions vary up to tenfold in their elective-treatment rates, a variability too large to be explained by

⁴⁷ See Schuck and Zeckhauser (2006).

⁴⁸ Peter Orszag, Statement before the U.S. House of Representatives Committee on the Budget, "Increasing the Value of Federal Spending on Health Care," July 16, 2008, <http://www.cbo.gov/ftpdocs/95xx/doc9563/07-16-HealthReform.pdf>.

⁴⁹ See J.E. Wennberg, E.S. Fisher, and J.S. Skinner, "Geography and the Debate over Medicare Reform." *Health Affairs*, Jul-Dec 2002; Suppl Web Exclusives: W96-114.

illness rates or patient preferences.⁵⁰ So what accounts for the variation? “Who you see is what you get,” as one analyst told us: the choice of elective care is highly sensitive to physicians’ recommendations, and physicians tend to follow the practices of their nearby peers. If everyone else is recommending spinal fusion for uncomplicated low back pain, and cardiac catheterization for low-risk patients, then I should, too. This is herd instinct, not science.

Moreover, many patients get care that the best current guidelines suggest is inappropriate for them.⁵¹ Twelve percent or so of angioplasties, stents, and angiograms are inconsistent with accepted guidelines, yet Medicare pays for them. It also pays for the use of drugs against FDA guidelines, such as Avastin® for breast cancer.

A second problematic category is *supply-sensitive* care. Especially common in routine care of the chronically ill, this is care whose utilization depends in some significant measure on the availability of providers and equipment—all of which generate income when put to use. Rates at which patients see physicians, are admitted into the hospital, or receive tests (such as CTs) vary between regions and hospitals by a factor of two to three.

The decision to hospitalize—a quite expensive decision—deserves particular attention. What determines whether you get sent to the hospital? In non-acute cases, not science: scientific guidelines on when to hospitalize are next to nonexistent. The decision to hospitalize is entirely discretionary, and doctors are influenced by the supply of medical resources and the practice patterns they see around them—which, of course, are influenced by the resource supply. Other things being equal, more

hospital beds translate into more hospitalization.⁵²

In principle, comparative effectiveness research and propagation of best-practices guidelines can help reduce the incidence of low-value care over the medium and long term, but will not eliminate it. What might do even more in the short run, however, is to use Medicare’s payment leverage to encourage more focus on high value. For example, Medicare should not pay to use drugs in ways the FDA deems ineffective, or to support treatments regarded as inappropriate by standard guidelines. Medicare could help curb the uncontrolled expansion of health care system capacity (more beds, more doctors, which leads to more spending) by penalizing hospitals and organizations whose high capacity and cost make them outliers. This would help break the cycle of oversupply that creates its own demand. Medicare might tell hospitals whose per-capita delivery of end-of-life care (some of which is of marginal utility to patients, at best, and probably no-value at worst) is in, say, the top 5 percent, that they cannot receive any more in total payments than they did in the prior year. Discouraging outliers would force them, and the bond markets, to reconsider the use of capacity construction as a cash cow.

What Are We Paying For? Buying Outcomes

For many health care experts, the holy grail of payment reform is to pay for health outputs, not inputs: that is, to reimburse for value, not volume. Payments to providers should, it’s widely agreed, be based not on how many procedures they perform, but on how much patients’ health and wellbeing improve. The movement for accountable care organizations,

⁵⁰ S. Brownlee, et al. “Improving Patient Decision-Making in Health Care: A 2011 Dartmouth Atlas Report Highlighting Minnesota, Dartmouth Atlas Project, February 24, 2011, www.dartmouthatlas.org/publications/reports.aspx.

⁵¹ P.S. Chan, et al. “Appropriateness of Percutaneous Coronary Intervention,” *JAMA*, 2011, July 6: 306(1): 53–61.

⁵² John E. Wennberg, *Tracking Medicine: A Researcher’s Quest to Understand Health Care* (New York: Oxford University Press, 2010).

discussed above, is a variation on that theme; ACOs are paid to treat patients, not administer procedures, and they pocket any gains they find by improving value—so that, in effect, they are being incentivized to improve the ratio of outputs to inputs.

We also support other, more direct methods to change to an outcomes-based payment system, and here, too, incremental change—albeit, in this case, too incremental—is already under way. Policymakers have been nudging Medicare providers to measure value-added since at least 2003.⁵³ The 2010 health care reform legislation added provisions that not only measure value but reward it: for example, a “value-based purchasing program,” which directs Medicare incentive payments to hospitals that meet certain performance standards.⁵⁴

Expectations should be limited; moving a behemoth like Medicare is like steering the proverbial aircraft carrier, except with many competing hands on the steering wheel. But the principle of purchasing value is gaining traction, and Medicare is the right policy lever to use. And there is considerable “low-hanging fruit” to be harvested by substituting more cost-effective drugs and therapies for less-effective ones.

Where Are the Barriers? Getting Law and Regulation Right

Moving from fee-for-service to fee-for-value will take years, if not decades. In the nearer term, a good place to harvest waste is by removing or reforming legal and regulatory obstacles that, in effect, encourage nonproductive behavior. There are many

to consider, far more than could fit within the compass of this paper, so we choose to focus on three possibilities.

A. Medical Malpractice Reform

The medical malpractice system is hardly new to the health care reform agenda. Physicians and politicians have been up in arms about it for decades. Some states have made important reforms, largely by capping damages for “non-economic” losses (pain and suffering), but progress is fitful because the politics are contentious and opposition from the trial bar is strong. Furthermore, the threat of liability, if focused correctly on the truly negligent cases, can be an important device for reducing physician errors. Nonetheless, we believe malpractice reform is worth pursuing, because the current system is both ineffective and excessively expensive.

Ineffective, because malpractice lawsuits frequently are driven by dissatisfaction with the doctor-patient relationship—that is, with patients’ anger at their doctors, justified or not—rather than by any objective nexus between a bad outcome and malfeasance.⁵⁵ In medicine, after all, bad outcomes happen all the time, even when physicians do their jobs well. Patients, jurors, and judges generally lack the expertise to evaluate medical decision-making, the incentive to do so with detachment, or both. The result is that damages are awarded little better than randomly. Many awards flow to patients who were not, in fact, victims of malpractice, while most victims of malpractice never sue and thus are not compensated.

⁵³ See, e.g., Jane Hyatt Thorpe and Chris Weiser, “Medicare Quality Measurement and Reporting Programs,” February 9, 2011. Published by Health Reform GPS, a project of George Washington University’s Hirsh Health Law and Policy Program and the Robert Wood Johnson Foundation. <http://www.healthreformgps.org/resources/medicare-quality-measurement-and-reporting-programs/> Accessed Aug. 20, 2011.

⁵⁴ Jane Hyatt Thorpe and Chris Weiser, “Medicare Value-Based Purchasing Programs,” March 30, 2011. Published by HealthReformGPS, a project of George Washington University’s Hirsh Health Law and Policy Program and the Robert Wood Johnson Foundation. <http://healthreformgps.org/resources/medicare-value-based-purchasing-programs/>. Accessed Aug. 20, 2011.

⁵⁵ Beth Huntington and Nettie Kuhn. “Communication gaffes: a root cause of malpractice claims.” *Proc (Bayl Univ Med Cent)*. 2003 Apr;16(2): 157–161; discussion 161. <http://www.ncbi.nlm.nih.gov/pubmed/16278732>.

Malpractice litigation is expensive, because soaring malpractice insurance premiums flow through to the public by way of higher provider charges, and because fear of lawsuits encourages physicians to overprovide care. Estimates of the cost and pervasiveness of so-called defensive medicine vary (and are not terribly reliable) but are non-trivial. One 2010 study found that the medical liability cost was about \$56 billion a year in 2008 dollars, or about 2.4 percent of total health care spending, of which \$46 billion, or more than 80 percent, resulted from defensive medicine.⁵⁶

A number of directions have been proposed for reform, and, in truth, we believe any of them, or some combination, would be preferable to the status quo. One approach would recognize medical error and bad outcomes as facts of life and would set up a compensation system outside of the courts, with expert evaluators providing payments based on fee schedules. Under such a “no-fault” approach, more people would be compensated, compensation would be more closely linked to science, and the process would be more predictable and less scary for doctors and patients alike.⁵⁷ Not least important, the doctor-patient relationship may improve when physicians feel they can apologize to patients without teeing up a lawsuit. One disadvantage, however, would likely be higher, rather than lower, cost, precisely because more compensation would be delivered. Another is the political difficulty of creating what amounts to a whole new kind of adjudication system, which would need to be built and debugged from scratch—not, in our judgment, the most realistic of prospects.

A second approach, although more modest, is

demonstrably workable inasmuch as some states are trying it: change the liability rules. When Texas capped noneconomic damages, the dollars flowing through the state’s medical tort system substantially dried up, partly because fewer cases were brought and partly because damage awards were lower, according to task force member David Hyman. Although pain and suffering are real and deserve sympathy (and perhaps payment, if jury discretion can be limited), they are impossible to quantify in any consistent or objective way, while their deterrent function continues to be the subject of vigorous debate. Another liability reform is to eliminate punitive damages, which are inappropriate for medical malpractice and invite incensed jurors to levy damages out of proportion to reason. Their only legitimate function is to deter deliberate misbehavior or negligence—which is not a serious problem with physicians, and not a deterrent inasmuch as insurers, not doctors, pay the claims.

A third and, so far, promising approach is to channel medical malpractice claims into special “health courts” where the decision-makers are former or retired physicians or other medical experts.⁵⁸ Given the complex and highly specialized nature of medicine, the notion of having real experts has much appeal. The 2010 health care reform legislation encourages pilot projects for health courts at the state level. We endorse this idea as well as efforts to evaluate the results.

One final reason to get on with malpractice reform is to remove it from the agenda. It has hung around for decades and has become something of a mantra, which, frankly, distracts policymakers and the public from the need for many other reforms. We are, again, under no illusion that malpractice reform (or

⁵⁶ Michelle M. Mello, Amitabh Chandra, Atul A. Gawande, and David M. Studdert, “National Costs of the Medical Liability System.” *Health Affairs*, September 2010. <http://content.healthaffairs.org/content/29/9/1569.abstract>. See also <http://blogs.wsj.com/health/2010/09/07/how-much-does-defensive-medicine-cost-one-study-says-46-billion/>.

⁵⁷ The no-fault approach has been adopted by New Zealand. See Peter H. Schuck (2009), “Tort Reform, Kiwi-Style,” *Yale Law & Policy Review*.

⁵⁸ This idea has been developed and actively promoted by Common Good, and its President and Founder, Phillip Howard.

almost anything else in the world of health care) is politically easy, but the sooner it is attended to, the sooner the debate can move on.

B. Reform the “Medical Loss Ratio” Rule

The Affordable Care Act sought to reduce the share of health insurance dollars flowing to administrative overhead, but it went about the task in a heavy-handed and arbitrary way. Depending on the size of its coverage base, every health insurer must spend at least 80 percent to 85 percent of premiums, net of certain taxes, on medical care and specified activities that improve quality (as opposed to administration). The current average “medical loss ratio” (medical payouts as a share of total premiums), including estimated premiums for employers’ self-funded plans, is around 87 percent; the rule thus takes aim at inefficient insurers, or so it hopes.

The approach is perverse, however. The loss ratio rule encourages expenditures that increase health care costs while discouraging insurer activities and coverage designs, such as certain types of utilization review and higher-deductible plans, that could help reduce costs.

We believe the medical loss ratio rule is an example of the kind of regulation that stifles innovation on the business side of health care, where innovation is almost as important as on the medical side. But some regulation of the health insurance industry—one of America’s least popular and least trusted—is inevitable. We think there is an opportunity here to reconceive incentives dynamically, so that insurers have more incentives to innovate in ways that lower costs.

The physician we mentioned earlier who bills for four separate procedures every time he places an I.V. does so because the current system provides no

incentives for insurers to reduce red tape. At times, the system does just the opposite. The health insurance industry’s name is a bit of a misnomer; unlike, say, property and casualty insurance, it has generally played a more modest role in managing risk. Instead, much of the industry acts more like a financial-services business, processing payments and collecting fees. As with credit-card companies and brokerages, the more transactions insurers process, the more they earn (other things being equal).

Increased concern with cost growth by employers and other customers, however, is helping to encourage innovations that help manage risk. With additional dynamic incentives, the insurance industry, we believe, could become a powerful force for modernization and innovation on the business side of the health care business. It has more data on medical utilization than any other player (except Medicare) because most procedures and prescriptions get billed through insurance companies. If the industry were further encouraged to use its knowledge base to predict and manage utilization and costs, and if it worked with providers to do the same, it could become a proactive source of new productivity and much less of a passive conduit for funding cost growth.

C. Interim Drug and Device Approval

Another regulatory flaw, and one that is politically easier to redress, puts a drag on innovation. Currently, once a drug or device attains FDA approval, it goes on the market without further scrutiny. Yet a drug is completely safe only if it doesn’t do anything, and even the most exhaustive clinical trials will not find all the problems that may arise in real-world, large-scale use. If a new drug causes bad reactions, the likely result will be panic and a potentially crippling legal assault on the company that made it. For

pharmaceutical firms, putting a new medication or device on the market can be a high-risk and costly endeavor.

A better approach would be to allow interim approval. During this stage, new drugs and devices could be placed in the hands of physicians who have been trained to handle them and who could monitor the results. In exchange for putting new technologies “on watch,” their developers would receive protection from legal liability during the probationary period, and some assurance of coverage and reimbursement, with a share of sales proceeds set aside for a fund to pay for compensatory care for patients who have bad reactions. The result would be to allow manufacturers and physicians to say to patients, in effect, “try it, you’ll like it,” and to bring innovations into the market at lower risk and therefore, presumably, lower cost. That interim approval would need to be accompanied by a robust post-market surveillance effort that would more rapidly weed out ineffective or dangerous devices and drugs, thus speeding up the innovation cycle by making room for better products.

Another attractive idea, outlined more than a decade ago, is to provide conditional coverage during the research phase for promising but expensive interventions, provided that researchers contribute data to studies that can evaluate risks, efficacy, and cost-effectiveness.⁵⁹

Rediscovering Diagnostics: An Opportunity Renewed

We conclude with a point that shows how the themes of the previous chapter (harnessing information) and this one (harvesting waste) can

powerfully reinforce one another.

The graying of the Baby Boom generation presents the country with a daunting health care cost problem. Consider just cancer. According to the National Cancer Institute, by 2020 the incidence of malignancies in the population will rise by 20 percent to 40 percent. If therapies are applied as at present, the annual cost of treating cancer will rise from \$124 billion today to more than \$200 billion in 2020.⁶⁰

A commonly cited floodwall against the rising gray tide is to detect and treat diseases earlier, e.g., catching cancer before it metastasizes or invades. Now, there is nothing new about prescribing early diagnosis. In cancer treatment, it has been a mantra for years—and it has often led to over-diagnosis and over-treatment. Controversies have dogged PSA screening for prostate cancer and mammograms for breast cancer.

The story does not end there, however. The advent of data-intensive medicine, discussed in the previous chapter, along with quick and inexpensive genomic profiling, suggests the prospect of a more selective kind of diagnostic screening—or, rather, two kinds. The first uses biomarkers to identify individuals who are at elevated risk of developing particular diseases. Rather than trying to screen the whole population, over-diagnosing many and treating all detected tumors based on gross statistical probabilities, this form of diagnosis bases screening and treatment on individual genomes (individual genotyping), assessment of which genes are turned on and off (gene expression profiling), and granular probabilities based on studying genes and proteins in tumors and tissues. With the use of diagnostic biomarkers to detect pre-metastatic

⁵⁹ H. J. Aaron and H. Gelband, eds. *Extending Medicare Reimbursement in Clinical Trials*. National Academy Press: Washington, D.C. 2000.

⁶⁰ See, e.g., Angela B. Mariotto, K. Robin Yabroff, Yongwu Shao, Eric J. Feuer, and Martin L. Brown, “Projections of the Cost of Cancer Care in the United States: 2010–2020,” *Journal of the National Cancer Institute* 2011:103, 117–128, http://www.oxfordjournals.org/our_journals/jnci/press_releases/mariotto.pdf.

carcinomas in high-risk individuals, cancers that otherwise would develop into complicated and frequently devastating cases often could be treated by removing a tumor no larger than a centimeter. According to Dr. George Poste, one of our task force members, the ability to detect and diagnose malignancies and to surgically remove them before metastasis occurs would eliminate more than 80 percent of the rapidly escalating cost of cancer care. Unfortunately, however, only about 3 percent of public and private investment in cancer research focuses on diagnostic biomarker technology, as opposed to, say, searching for the latest drug.

A second form of test diagnoses not people's susceptibility to diseases but their responsiveness to medications. Oncologists, as one expert told us, too often "assault people with drugs they know probably aren't going to work." Any particular drug might work, but the odds are against it, so physicians try one after another, a process that is both expensive and physically and mentally exhausting for patients.

New diagnostics based on genome sequencing and proteomics can help preemptively rule out treatments that are likely to fail in particular patients. To take just one example, KRAS testing—a test of patients with colorectal carcinomas—can detect a genetic mutation that renders patients unlikely to respond to two first-line immunotherapies that block a cell-surface receptor called EGFR. According to the American Society of Clinical Oncology, if every colorectal cancer patient were profiled with this test on first diagnosis, the health care system would save about \$600 million a year; yet the adoption rate of the test is only about 10 percent. Extending the same technique through other altered molecular targets in the same molecular pathways could exclude almost 80 percent of patients from getting ineffective drugs, producing even more impressive savings. At present, however, there is little economic incentive for

researchers to develop such diagnostics or for clinicians to adopt them; in a fee-for-service system, no one makes money by providing less care.

We believe the medical research system, public and private, should invest more in diagnostics relative to treatments. Medicare and other government programs can encourage this by making a point of making most diagnostics reimbursable, just as treatments are.

There is a broader point here that relates to more than just diagnostics. Two important opportunities now present themselves. One is the advent of "big data," the availability of vast amounts of health information which, combined with genomic profiling and comparative effectiveness research, increasingly allows diagnostics to find needles in haystacks, rather than examining entire haystacks.

For example, as science marches on, the cost of sequencing the whole genome eventually will come close to the costs of conducting genetic tests for just one or a few genes. Whole-genome sequencing will provide an enormous amount of baseline data that will become part of a person's individual and family history, which, together with lab tests, surely will prove to be extremely valuable and life-extending for many individuals. Put simply, the odds that, during one's life, genomic sequence data will prove to be more valuable than several thousand dollars, the current cost of obtaining it, have to be overwhelming.

Similarly, the emergence of value-driven payment models is highly likely to make looking for medical needles economically worthwhile. Combine this with genomics sequencing, and surely we can develop more effective diagnostics and use them more efficiently than in the past. Through the still-misty but unmistakably visible terrain ahead, we can surely begin to see a path toward higher-value health care that awaits us.

CHAPTER FOUR

Empowering Patients

If we come to the role of patients last, it is not because they matter least. Quite the contrary. Patients' needs and decisions—how healthy or sick they are, whether to see a doctor, whether to accept medication, whether to risk an operation, and so on—remain the most important determinants that drive and steer health care decision-making. It also is, perhaps, the most broken feature.

For all the time and money spent on them, patients, or health care consumers (in some respects a better term, because it includes able-bodied users of preventive and other health services), often feel marginalized—and, in important ways, they are. Physicians tell them what to do; insurance companies tell them what will be covered; employers tell them who will be their insurer; and politicians make policy in negotiations where consumers are the least-organized voice at the table. Running the gauntlet of specialists, and tests, and hospitals, and offices, patients feel like mice in a maze of someone else's (or, worse, no one's) devising, with little real responsibility for or control over the system of which they are part. There are few, if any, other sectors of the private economy in which the end user has so little influence over the product and its delivery.

That said, most people, though unhappy with "the system," are happy with their own doctors and the care they personally receive. Most are understandably conservative about change, which is one reason the political system has been slow to embrace some of the reforms we and others advocate. Any reform that is presented as taking something away from consumers will be greeted with skepticism, if not outright hostility. This does not mean never downsizing or retrenching; in today's fierce fiscal headwind, the country will have no choice but

to both shrink and trim. It does mean, wherever possible, conceiving of and couching reforms in a framework of *giving* to patients: giving more information, more control, better success rates, and a better experience. Offering them today's experience at a higher cost to themselves is a political loser, even if it were a fair proposition.

In this chapter, we consider some ways in which patients can add value to the system rather than just consuming it, by being given tools and incentives to make better decisions, share in productivity gains, and take full ownership of their own information stream.

Give Patients the Tools for Better Decisions

We begin with the most fundamental decision of all: the decision to undergo treatment. We believe this is one of the most promising and least appreciated leverage points for making the system simultaneously more humane and more productive.

From time immemorial, “Doctor’s orders” has meant, “Gotta do it—no choice.” Although, in the Internet age, patients often show up for medical appointments seeking purported cures they saw online, most people still look upon physicians as authoritative experts. And, trust in doctors is a good thing. As one physician told us, “The patient *has* to think you’re God to let you cut them up.”

However, there is growing reason to doubt a related assumption, which is that patients want all the treatment doctors can throw at them, especially if someone else is paying—or that they are too confused to think about value. It is true, as opponents

of shifting more health care costs to patients like to point out, that patients experiencing health crises often are too frightened, bewildered, or ill-informed to make hard medical decisions. Something can be done about this.

About a third of health care is *preference-sensitive*. Such care is often called elective because there is more than one way to treat the condition and no treatment is often an option. In other words, patients have a legitimate choice about the kind of treatment they prefer to receive. Common examples include treatment for early-stage prostate and breast cancer; hip, knee, and spine osteoarthritis; chest pain and stroke risk associated with arterial heart disease; and so on.⁶¹ For early-stage prostate cancer, four or five treatment pathways often are available. Or take early-stage breast cancer. Women have a choice between mastectomy, which involves the removal of the entire breast, and lumpectomy, which involves surgical excision of the tumor itself, with radiation after surgery. Clinical evidence suggests that either treatment offers women the same chances of survival. What differs is the impact on an individual patient’s sense of herself and her wellbeing—and that varies from patient to patient.⁶²

How do patients choose? Often they do as their doctor recommends, which is one reason treatment patterns vary so dramatically from region to region: as we have seen, “who you see is what you (often) get,” and doctors follow local practice patterns and market signals. For example, a recent study by the Dartmouth Atlas Project found that rates of mastectomy and a

⁶¹ Benjamin Moulton and Jaime S. King. Aligning Ethics with Medical Decision-Making: The Quest for Informed Patient Choice. *Journal of Law, Medicine & Ethics*, Spring 2010. Moulton is a member of this task force.

⁶² Shannon Brownlee, Vanessa Hurley, and Ben Moulton, “Patient Decision Aids and Shared Decision Making,” Policy Brief (New America Foundation Health Policy Program, September, 2011).

number of common cardiac procedures, including angioplasty and stents, varied ten-fold across hospital referral regions.⁶³ Such variation can be driven by a single physician practice, as was the case in the city of Elyria, Ohio, where one prominent group of cardiologists drove the angioplasty rate for Medicare patients to four times the national average.⁶⁴

This high variation in rates of preference-sensitive treatments has obvious implications both for medical ethics and health care spending. In many cases, however, patients receive (or feel they receive) too little medical information to make an informed choice, and still less guidance to help them understand and act on their underlying values and preferences. As a result, write Benjamin Moulton and Jaime S. King, patients “adopt not only their physician’s treatment choices, but also their physician’s values, levels of risk aversion, and personal preferences.”⁶⁵

That might be all right if doctors’ recommendations were reliable proxies for patients’ preferences, or even if doctors could reliably assess preference; but this is not the case. Moreover, studies find that physicians tend to skew their discussions toward emphasizing the benefits of surgery and understating risks.⁶⁶ As a result, clinical evaluation research studies suggest that patients are routinely asked to make decisions about treatment choices in the face of what can only be described as avoidable ignorance:

In the absence of complete information, individuals frequently opt for procedures they

would not otherwise choose. Mounting clinical evaluative evidence suggests that the number of surgical procedures performed, even when justified by practice guidelines, actually exceeds patients’ desires when they are fully informed through a shared decision-making process.⁶⁷

“Shared decision-making” refers to a budding movement that converts what today is often the patient’s rote signature on an (ironically named) informed consent form into a guided dialogue between patient and provider. The idea is to lay out for the patient, and then help them work through, the pluses and minuses of treatment options—in a way that not only conveys medical information but that also helps the patient understand and make value choices about the relevant lifestyle implications and risk-reward tradeoffs.

In one common model, a patient with early-stage prostate cancer is provided with a video and a printed guide giving a balanced discussion of the options, including their likely benefits and risks; completes a questionnaire helping providers to understand the patient’s priorities and values and bringing to light conflicting desires; and, with the resulting information in hand, meets with doctors and other health professionals who have been coached on the shared decision-making process. One might think of the process as informed consent raised to a higher power: consent based not just on a yes-or-no recommendation or on a one-size-fits-all summary of medical evidence, but on a “more robust discussion,

⁶³ Shannon Brownlee, *et al.*, “Improving Patient Decision-Making in Health Care: A 2011 Dartmouth Atlas Report Highlighting Minnesota.” Dartmouth Atlas Project, February 24, 2011. http://www.dartmouthatlas.org/downloads/reports/Decision_making_report_022411.pdf.

⁶⁴ Reed Abelson, “Heart Procedure Is Off the Charts in an Ohio City.” *New York Times*, August 18, 2006. <http://www.nytimes.com/2006/08/18/business/18stent.html>.

⁶⁵ Moulton and King, p. 3.

⁶⁶ Brian J. Zikmund-Fisher *et al.*, The DECISIONS Study: A Nationwide Survey of United States Adults Regarding Nine Common Medical Decisions.” *Medical Decision Making*, September-October 2010, 30(5 Suppl): 205-345. http://mdm.sagepub.com/content/30/5_suppl/205.abstract.

⁶⁷ Moulton and King, p. 5, fn. 38.

which engages both the patient and the physician in evaluating the patient's medical goals and lifestyle preferences to come to an informed choice."⁶⁸

The results are impressive. In a review of eighty-six randomized controlled trials, patients given decision aids were better informed about treatment options. Studies found that using patient decision aids improved knowledge of health care choices, increased the proportion of patients with realistic perceptions of benefits and harms, lowered decisional conflict, reduced the number of patients who were passively involved in decision-making, reduced the number of patients undecided after counseling, and improved alignment of patient values and health care options chosen. Moreover, patients were 20 percent less likely, on average, to choose the more invasive option—with medical outcomes that were just as good.⁶⁹ An estimate by the Lewin Group in 2009 found that fully implementing shared decision-making in the Medicare population for eleven conditions that could be treated with surgery could save Medicare \$50 billion over ten years (a benefit in addition to closer alignment with informed patient preferences).⁷⁰

We embrace shared decision-making because it can help reduce utilization of low-value care and because it is a better way of doing business—reasons enough, to be sure. Furthermore, some places already are proving it in practice. Clinical models delivering shared decision-making have been funded in several states.⁷¹ The state of Washington, for example, created incentives for shared decision-making by giving doctors who use it added protection from lawsuits based on allegations that the physician failed

to properly inform patients of risks. The 2010 Affordable Care Act includes shared decision-making among the innovations to be developed and promoted by the Department of Health and Human Services, though Congress failed to appropriate funds. Gradually, support for the concept is building, and a nascent infrastructure is taking shape.

Not least important—here returning to the concept of *absolute value* that we broached in the previous chapter—we also see shared decision-making as a powerful, albeit partial, solution to health care's thorniest political problem. Who decides which care is of low value in absolute terms? That is, which care, and *whose* care, is just not worth the cost and trouble? The public views efforts by politicians or bureaucrats to make such judgments as "death panels" or "rationing." In contrast, a great advantage of shared decision-making, we think, is that instead of kicking absolute-value decisions upstairs to politicians and insurers, it kicks them downstairs to patients—who, it turns out, often will make sound decisions about preference-sensitive care when given sound information. Shared decision-making also should be used for decisions around end-of-life care. The edge of fear and the veil of ignorance, which together skew decisions about medical value and health-care values, need not be accepted as given.

For all of those reasons, we believe it is time to move shared decision-making higher up the list of health reform priorities. Policy should strive to move it through the experimental stage and toward broader adoption. The government's new Center for Medicare and Medicaid Innovation (created by the health reform

⁶⁸ *Ibid.*, p. 6.

⁶⁹ A.M. O'Connor, *et al.* "Decision Aids for People Facing Health Treatment or Screening Decisions." *Cochrane Database System Rev.* July 2009, 8(3): CD 001431.

⁷⁰ The Lewin Group, "A Path to a High Performance U.S. Health System: Technical Documentation," Figure 53 (February 2009).

⁷¹ Foundation for Informed Medical Decision Making, "Questions and Answers," undated.

law) should make a point of funding pilot programs in every state; state legislatures should revise informed consent laws to make shared decision-making the gold standard of informed consent. Such measures are no pipe dream: Washington state already has begun to reform its informed consent statutes; Vermont and Maine have pilots underway; Minnesota, Oklahoma, Massachusetts, and New Hampshire are considering legislation. Still in the planning stages are private and government-backed groups to evaluate and certify decision aids (it is very important that these aids, which can come in the form of a brochure, video, or web-based guide, be clear, accurate, and free of bias and merchandising).

We have no illusions that shared decision-making, by itself, can bend the cost curve dramatically. In some cases, more informed consumers may demand more costly treatments. Moreover, in the long run, shared decision-making can only supplement, rather than substitute for, some difficult public-policy choices about what government programs and private insurers will and will not pay for. What it can do, however, is take important steps toward letting the people who know and care the most—patients—define and seek value. And it can reduce the most egregious examples of medical care departing from patient preference.

Giving Patients Pecuniary Incentives to Find Value

This paper has returned time and again to the theme of incentives. We have discussed the need to rewire incentive structures to give providers and insurers more reason to search for value, and more rewards when they succeed. In our judgment, it is also important to engage consumers in that quest.

In the long run, we think consumers will be happier in a world where they have more influence over the system and more control over their own care. In the shorter term, however, asking consumers to shoulder more of the burden of shopping and paying for care is unlikely to feel like a gift. From a Medicare patient's point of view, what's not to like about going to see a doctor, ponying up a small copayment, and thinking no more about it? The whole problem, however, is that Medicare is eating the government's budget alive, and today's sweet deal is eventually going to go away. Given the available choices, we think, policies that give patients more responsibility and control over their health care are likelier to sit better with the public in the long run than are bureaucratic controls that further reduce the patient's perceived role and influence.

Until now, the usual way politicians have thought about making patients more cost-sensitive is to increase copayments for Medicare and other consumer-borne costs. Employers have been applying the same ratchet by passing on a growing share of health insurance premiums to employees. This kind of additional "skin in the game" succeeds in shifting costs to consumers and, thus, deferring the crunch on corporate and federal treasuries, but it has not, to date, had a discernible impact on the cost curve. Employees and Medicare recipients may reduce their utilization marginally, but not by much, and what they are most likely to cut back on, at least initially, is preventive and routine care, the least costly kind, and where short-term savings can cause long-term expenditures. Today's foregone vaccine is tomorrow's hospitalization for pneumonia. Marginally higher copayments also are likely to have relatively little effect

on the use of high-cost acute care and end-of-life treatment when patients or their families tend to do whatever it takes to resolve an immediate problem or extend life.

More important, however, is this: raising copayments a bit might give consumers a bit more reason to *look* for value, but they also need to be able to *find* it. If they don't know how much care costs, and if they don't know what how much value they are getting, and if, especially, they don't share in any upside from seeking value—in that case, raising copayments may induce them to consume less, but it will not induce them to consume *better*, which is even more important.

What policymakers are looking for, then, are measures that do one or more of these three things:

- *Increase cost transparency*: provide patients with more information about the underlying costs *to them* (not some artificial bill submitted to an insurance company) of the service with which they are being provided—something which, today, they usually cannot find out even if they try;
- *Improve value transparency*: provide patients with more information about the relative *effectiveness* of medical care—something that is scarce today (you can find better and more accessible information when choosing a car or camera than when choosing a doctor or hospital);
- *Create positive as well as negative incentives*: allow patients who discover value to pocket some of the dollars they find.

Policymakers have made various efforts toward embodying those goals. Health savings accounts, for instance, let people set aside tax-favored funds earmarked for health care and insurance and allow people to keep what they don't spend. It is too early, however, to know how effective HSAs will be in reducing cost without sacrificing care.

More far-reaching is a reform we believe is inevitable, and which has had some bipartisan support and heritage: converting government health care assistance from its current fee-for-service reimbursement model to one that pays for insurance premiums. A “premium support” system, ideally one whose support payments are determined progressively (as incomes of recipients increase, their government support payments decline), would permit households to choose their health care insurance coverage packages and providers, just as they do for other forms of insurance now, and, in the process, let individuals choose what kind of coverage they want and what they are willing to pay for.⁷² The best role for government is to assure the minimum amounts of guaranteed coverage to individuals, especially for catastrophic illnesses, but to do so without exposing taxpayers to the runaway costs that currently are embedded in the Medicare and Medicaid programs.

Government also may have a significant role in encouraging price and value transparency. The 2010 reform steps in that direction by collecting performance data on physicians who participate in Medicare and then publishing it online, on a website similar to the existing Hospital Compare and Nursing Home Compare websites.⁷³ As always, expectations for reducing costs by such methods should be

⁷² Ideally, premium support payments also would be tied to regional variations in health care costs and to the health of the individual at the time he or she is eligible for assistance.

⁷³ 2011 *Economic Report of the President*, p. 114.

realistically modest, especially at first. Evidence suggests that, when patients shop for care, they first consider quality and provider reputation, not cost.⁷⁴ Still, we think additional increments of transparency can only redound to the good.

Altering Patient Behavior

Up to this point in the chapter, we have concentrated on how patients, perhaps encouraged by monetary incentives, can take better charge of their own *health care*. But patients' need for health care in the first instance is heavily influenced by their own behaviors. Two of them come to mind: smoking and obesity.

There is much stronger evidence and consensus about the first than the second. The harsh physical toll on those who smoke is now so well established that it is difficult for the current generation of young adults to imagine the world in which their parents (and their parents) grew up, bombarded by advertising about the joy of smoking and by the wide social acceptance of the practice.

Although young people today are less likely to take up smoking than their parents were, too many American adults who already have begun (and larger numbers outside the United States) find themselves unable to quit. Here, too, various incentive schemes may help. One particularly intriguing idea is for smokers to commit to pay a third party if they fail to quit.⁷⁵ A related notion is for employers to pay their employees to quit. Still another promising approach is to bring peer pressure on smokers to quit in Alcoholics Anonymous-like settings.

Obesity is more problematic. Though it has been linked with a variety of ailments, notably diabetes,

the line between being overweight and obese is not a clear one. Nor is it clear how to address the problem. There is a high level of recidivism among even temporarily successful dieters. While research continues to identify and possibly modify the "obesity genes," those outcomes are still in the distant future.

Give Patients a Portal to the Data Stream

A final kind of patient empowerment allows us to revisit an earlier theme: mobilizing data. What is often overlooked is that, although people *have* a lot of knowledge about their health and their experiences with health care, they often do not *own* their knowledge. Strange though it may seem, medical records and samples typically belong to the health provider, not the consumer.

That policy and others like it should be reconsidered, with a default assumption being that any information or sample collected from a health care consumer belongs to the consumer, who can share it as she pleases—for instance, by indicating proactively to health providers that data is to be released for comparative effectiveness studies and other research. We have already discussed portable informed consent, data collection outside of the medical system, and other measures to let willing consumers more easily share their knowledge and experience with researchers and data entrepreneurs. We have yet to discuss how to connect individuals to the river of information and knowledge that will flow from their uploads. A good way forward is with what we think of as a "life certificate."

At present, every American is issued a birth certificate and, eventually, a death certificate. But, between birth and death, little is done to catalog

⁷⁴ See, e.g., Ha T. Tu and Johanna Lauer, "Word of Mouth and Physician Referrals Still Drive Health Care Provider Choice." Center for Studying Health System Change Research Brief No. 9, December 2008. <http://hschange.org/CONTENT/1028/>. Accessed August 24, 2011.

⁷⁵ See Ian Ayres and Barry Nalebuff, *Lifecycle Investing: A New, Safe, and Audacious Way to Improve the Performance of Your Retirement Portfolio* (Basic Books, 2010).

and standardize the large amounts of information collected by medical providers, insurance companies, schools, and other entities about people's health and medical histories—and much of what is collected is not readily available to consumers themselves. Many people, for example, have trouble recollecting which vaccinations they received as children and when; or never learn what type of stent was inserted; or may recall as appendicitis what was, in fact, diverticulitis. And what exactly was that medication they were on thirteen years ago? In an emergency, some of this information might make the difference between life and death, and waiting hours or days to get it—the time it can take to get in touch by phone or fax with the right provider and pull the proper file—is, in today's world, ludicrous. Even in a non-emergency, such information is a diagnostic boon, and asking distracted, anxious patients to fill out forms in the doctor's waiting room is hardly an accurate or efficient way to get it.

The "life certificate" is a bundle of standardized health information that would travel around with consumers and accumulate as they pass through health-related gateways: vaccinations (up to date for tetanus?), procedures (had a tonsillectomy?), medications (which antibiotics?), family history (colon polyps?), and so on. Importantly, the life certificate would belong to the consumer, not the government or providers, and would travel with the consumer. Also importantly, the information would be uploaded in a standardized, machine-readable format, so that the life certificate could immediately "talk" to multiple databases. With a patient's consent, ideally opt-out to ensure maximum coverage, information would be added routinely by providers and, especially, by insurers, who are billed for and therefore know about most treatments that most people undergo.

In the short run, a life certificate would help move people and information through the system more smoothly while preventing errors. But, over time, something grander will be possible. Over time, the life certificate would become, in effect, the consumer's passport to the health care datasphere that we envisioned in Chapter Two. Think of it as his or her portal to the health information "cloud." Combined with information harvested by data entrepreneurs from billions of data points, and with knowledge gleaned from genomic profiling, a swipe of the life certificate could tell a physician—or a physician's assistant or nurse practitioner—a lot of what they need to know about what ails the patient, or what probably *will* ail him, and how (and how *not*) to treat it, before they even set eyes on him.

Who would be tasked with creating and maintaining this life certificate? We think the federal government could help create a demand for it by providing incentives for research and development of the idea. Perhaps most important, participants should be able to get any data generated about them.

Clearly, a variety of technical issues will need to be worked out: encryption, portability, rules for access, and so on—that is what the research and development phase is for. But the main thing is to establish a principle. The combination of consumers who own, or at least are able to access, their own health data suggests the potential for all kinds of knowledge transactions, linking health consumers not just to doctors but also to scholars, data entrepreneurs, disease support groups, drug developers, and many others. Though not a replacement for the stethoscope, this passport to the cloud promises ultimately to be far more powerful an instrument.

CHAPTER FIVE

Conclusion: Coping with Complexity

The Case for (Guarded) Optimism

Over the course of the meetings that laid the groundwork for this report, a convergence developed. On the one hand, we had clinicians and researchers talking about the challenges of innovating in medical science; on the other, economists, administrators, and legal experts talking about the challenges of innovating in health policy. Their two worlds meet, of course, in the nexus between the hospital that provides care and the insurer or government program that pays for it. But they turned out to meet in a more fundamental respect, which can be boiled down to the word *complexity*.

A recurring theme among scientists in the discussion was that medical biology is the hardest of sciences. “If only it were as easy as rocket science!” one task force member bemoaned. Biology is hard because life is complex and adaptive; laboratory biomedicine is harder still, because of the incalculable variety of pathologies and treatments and the even larger numbers of ways they can interact with the body; clinical medicine is hardest of all, because one must deal with human beings, the most complex and unpredictable of creatures. True, the twentieth century produced unprecedented medical innovation, but most of the low-hanging fruits, our biologists agreed, have been plucked. Today, researchers find that almost nothing works in the body as one expects from lab results, and not much works at all. This is not to sound a note of gloom; it is merely to acknowledge the reality that biomedicine is *hard*.

An emergent theme among the policy wonks was that health care is the hardest of policy areas. “If only Medicare were as easy as Social Security!” was a common refrain. Many policy areas need to deal

with tight resources and a fiscal crunch, which is hard; some—public pensions, education, and others—need to cope with periodic and sometimes severe demographic pressures; a few (think of the federal agricultural support programs) must cope with markets that have been distorted by decades of often-counterproductive government policy; and a handful are simply so big that whenever they sneeze, the entire government gets fiscal pneumonia (Medicare, Medicaid, and Social Security head this list). But health policy poses all of those challenges at once, and then some. As with health care, so with health policy: interventions that seem likely to work in principle often mysteriously fizzle amid the complexity of the health care economy and the political ecosystem in which it is embedded. It isn't that nothing works; only that figuring out what works is hard, and getting it implemented can be harder. Politics can make even biology look simple.

This is one reason we have tried to fix our gaze on the adjacent possible: measures capable of producing incremental gains even if adopted on a less-than-grandiose scale, while planting seeds for greater progress in years ahead; measures re-channeling incentives rather than swimming against their currents; and measures that can be and preferably are being tried, tested, and adopted or adapted. It is also why we have tried to emphasize keeping short-term and medium-term expectations realistic, even while remaining inspired by the potential for dramatic improvement in the long term.

We hope, though, that our approach does not induce defeatism or pessimism. Neither is warranted. Rather, our own feeling is one of guarded optimism, based on factors such as:

- *New informational tools are coming on line.* Nothing like the data stream and the tools for tapping into it that are now emerging has ever been available for health care; in a sense, data “microscopy” brings the cellular anatomy of the health care system into view when, heretofore, we had only the informational equivalent of the naked eye.
- *There is wide agreement on the need to reform incentives in fundamental ways.* In our group, there was no one, from any discipline or sector, who defended traditional, procedure-based fee-for-service and transaction-maximizing insurance as a sensible model for medicine. Changing the incentives will be difficult and gradual, but everyone acknowledges it needs to happen.
- *Severe fiscal pressure forces change.* One way and another, the economy and the political system have managed until recently to find new money to pour into the bottomless hole of fee-for-service medicine, but this cannot go on forever. As the late economist Herbert Stein used to say, what cannot go on forever will stop. If health care costs are not increasingly tethered to *value*, rather than soaring ever upward simply because they can, the system will crash. Indeed, it is in the midst of a slow-motion crash already. This is painful, but with the pain of crisis comes opportunity for change, and this remains true even though health care reform ostensibly was “solved” by the Affordable Care Act.

- *The availability of multiple incremental paths forward.* There is one respect in which biomedicine and health policy are *not* alike: when it comes to improving health care efficiency and value, the trees are practically groaning with low-hanging fruit. It may seem odd to draw comfort from the pervasiveness of the current system's flaws, but in one sense we do. *Fixing* the system is hard. *Improving* it is easy.

Health *policy* has never experienced the kind of rapid advance that health *care* experienced in the middle decades of the last century. Perhaps it is on the cusp of doing so now. By way of thinking about how better information, better incentives, and pressure for change might combine to produce many billions or even some trillions of dollars in new value over the next decade or two, we conclude by drawing attention to the emerging science of health care delivery.

The Promise of Comparative Efficiency

Medical patients are not airplanes, but if they were, we would know far more than we do today about how to treat them effectively and efficiently. This is not only because humans are even more complicated than airplanes; it is also because every step of the complicated pathway that turns a heap of aluminum ore into a jetliner has undergone the scrutiny of analysts seeking to find and propagate best practices, whereas virtually none of the complicated pathways that begin when you see your doctor have undergone such scrutiny.

A company that builds airplanes carefully monitors and adjusts its assembly process—or, rather, processes, since hundreds of separate procedures

need to be streamed together. How many steps does assembly require? Is there an unnecessary step slowing everything down? Where are the bottlenecks? Why does one factory produce higher quality or operate more safely than another? Which vendors perform best, and how can underperformers be improved? The costs of inputs—raw materials, labor, parts, subcontractors—are closely monitored and mined for savings. Output, too, gets watched: the airplane quality is checked; the production speed clocked; the customers' approval gauged.

Health care is different. One reason, and a good one, is that people aren't planes and do not want to be treated as objects on an assembly line. Medicine faces inherent limits to the desirability and effectiveness of standardization and benchmarking that no industrial manufacturer needs to think about.

But then, there are the many bad reasons health care is different. One is that, as we have seen, what we call "health care" is, in fact, a huge assortment of procedures, tests, treatments, diagnostic methods, and personnel choices that grew up rapidly in the second half of the last century with minimal testing of whether they actually led to improved health. Once past regulatory approval (if approval was needed), a treatment was subject only to physicians' approval or disapproval—perhaps a reasonable enough arrangement when medicine was a much simpler science, but an invitation to chaos today.

A second bad reason is that, again, as we have seen, health providers, unlike airplane manufacturers, save no money by finding efficiencies; in fact, becoming more efficient normally costs them money by reducing the number of procedures they perform. Given the perverse incentives of fee-for-service payment, it would be a wonder if any health provider ever considered efficiency at all.

Suppose, then, the same patient goes to two hospitals complaining of back pain. Hospital No. 1 gives her an MRI. Her scan turns up something that might be disc damage, so she is sent to a neurologist, who orders more tests, leading to a cascade of further procedures and possibly surgery. Hospital No. 2, looking at the same patient with the same pain—or, for that matter, even Physician No. 2 at Hospital No. 1—diagnoses uncomplicated back pain and tells the patient to take Advil® and see if the pain goes away on its own, and maybe also refers her to a physical therapist.

Which pathway is better, for this particular patient or on average? The startling answer is that no one knows, because patient outcomes of various medical pathways are not systematically measured. Comparative effectiveness research, which we discussed in Chapter Three and which is beginning to receive more effort and attention, can help answer that question. However, another comparative dimension has been even more neglected: comparative *efficiency*. Of many possible care pathways, which achieve the best ratios of outputs to inputs? Where relative value—not just relative efficacy—is concerned, the pathways through treatment have never been systematically compared, analyzed, or rationalized. In many cases, hospitals and providers do not even systematically track the costs of inputs, because they were in a position to pass those costs along.

Very embryonically, this is beginning to change as more providers and policymakers have awakened to the need to analyze and rationalize treatment pathways and input-output relationships. Some hospitals, for example, are instituting “lean”

production processes and quality-improvement techniques inspired by Japanese manufacturing. “We map out the current processes,” an official of University of Iowa Hospitals and Clinics in Iowa City recently said. “We start to identify which steps are non-value-added from the customer perspective.”⁷⁶ Others use software and other analytical tools to track labor costs and treatment flows, reducing waiting times and hospitalization stays.

Meanwhile, some research organizations perform research on comparative efficiency. A prominent example is the Dartmouth Institute for Health Policy and Clinical Practice, whose Dartmouth Atlas project mines Medicare data to document “glaring variations in how medical resources are distributed and used in the United States.”⁷⁷ It documents, for example, the wide range across regions and hospitals in the number of chronically ill patients seeing more than ten doctors in their last six months of life (46 percent in Sun City, a retirement community near Phoenix; only 15 percent in Salt Lake City); in the rates at which patients receive preference-sensitive discretionary surgery such as knee or hip replacements; and in the rates at which patients are admitted to the hospital, a decision that often has little science behind it. “The prevalence and severity of illness accounts for remarkably little of the variation in care,” according to the Institute.⁷⁸

Needless to say, hospitals’ efforts to rationalize their treatment pathways are welcome. Comparative analysis of the sort Dartmouth is performing with Medicare data helps flag outliers whose practices may be particularly costly or inefficient. But hospitals adapting Japanese production methods will themselves remain outliers as long as payment incentives are to maximize inputs

⁷⁶ Dave DeWitte, “Hospitals Keep an Eye on Costs.” *Business380*, July 31, 2011. <http://business380.com/2011/07/31/hospitals-keep-an-eye-on-costs/>. Accessed September 1, 2011.

⁷⁷ Shannon Brownlee, a member of the present task force, is affiliated with the Dartmouth Institute.

⁷⁸ <http://www.dartmouthatlas.org/data/topic/>. Accessed September 1, 2011.

and volume of care delivered. And Medicare data of the sort that Dartmouth analyzes can reveal that some hospitals, say, are more efficient than others, but it lacks the granularity to look into the “black box” of a particular hospital and uncover the particular pathways that account for its relative standing—and, of course, it provides data only on the relatively elderly Medicare population.

We believe that comparative efficiency research is ripe to be taken to a new level. If it were applied in health care with anything like the regularity and granularity taken for granted in, say, manufacturing, the savings could be astronomical, and outcomes would be better to boot. How, then, to reach a new level? We see at least four places to exert leverage:

First, *employers* can and should demand that providers do a better job of tracking efficiency. More than 80 percent of large companies (those with 500 or more employees) self-insure for at least one health plan.⁷⁹ They have clout with providers and in their communities, but to date have made little use of it. Many tend to take a passive attitude toward the health care bills they pay as insurers, rather than viewing those costs as potentially manageable expenses—subject to the same kinds of negotiations with vendors as are other expenses and inputs. Too often, health care is relegated to the HR department and treated as a given, rather than subjected to the MBA-style scrubbing that production expenses receive. If health care production needs to be treated more like aircraft production, at least where efficiency is concerned, that is partly because the kinds of people who produce aircraft have not turned their attention to health care, even when they are paying for it. This lacuna not only ought to change, but, we suspect, gradually will as business, like government, discovers

it can no longer pour money into the black hole of health care (though we acknowledge that there will be resistance from various parties along the way).

Second, that word again: *data*. Medicare data is a start, but it covers only one demographic group (the elderly), records procedures but not medical outcomes (other than death), and is published with long lags. For comparative efficiency analysis to attain anything like its full potential, more data will need to be available more quickly. The government should report Medicare data with a lag of weeks or months, and the cost to receive it should be reduced.

More important, however, is bringing to bear the torrent of data collected by health insurance providers, which, between them, record most of the medical procedures that non-elderly Americans undergo. Unfortunately, insurance companies tend to resist sharing data, even though using it for comparative efficiency research could be a boon to them. We believe that governments could help by providing incentives to share and upload insurance data, and by providing reasonable shelter from litigation for companies that join the information stream.

Even then, however, having the data is only one step. A new system must be created and staffed with the right kind of people. This requires individuals with the right kinds of analytical training to distill knowledge from the more expansive data universe and to learn from experience. All this will need to be carried out while subjecting the people to whom the data pertain to the least acceptable risk, almost surely with rules that foster the common good while protecting individual rights and interests. The data analysts whom we will need to carry out these new and critically important functions will be trained

⁷⁹ U.S. Department of Health and Human Services, *Report to the Congress on a Study of the Large Group Market*, 2011. <http://aspe.hhs.gov/health/reports/2011/LGHPstudy/index.shtml>. Accessed September 1, 2011.

and housed in universities, in hospitals, in pharmaceutical companies, and very likely, in entirely new kinds of entities.

Third, the science of health care delivery deserves its own *national research program*. Today, comparative efficiency research is overshadowed by comparative effectiveness research, which itself claims a mere sliver of the \$30 billion the United States spends on health research—almost all of it devoted to biomedical research; less than 4 percent of research funding goes toward understanding how the care-delivery ecosystem actually works.⁸⁰ If the study of care delivery were a medical science, it would still be in the era of Harvey and Leeuwenhoek, aware that blood circulates and that bacteria exist but not knowing much more than that.

Finally, and not least important: for comparative efficiency analysis to become common currency in American health care, providers need to be given *incentives* to do it. This is yet another reason to move away from fee-for-service payment, with its upside-down incentive structure. Accountable care organizations, discussed previously, are one example of a potentially upright incentive structure. A further step away from fee-for-service would be taken by so-called “global payments,” under which providers are reimbursed not for procedures performed on individuals but for the health outcomes attained with a group of patients over a set period of time. In effect, providers receive a fixed budget to take responsibility for the health of a certain number of people; the more efficiently they do that (within acceptable quality guidelines), the more profitable they will be. As with accountable care organizations—but moving even further than many

ACOs from procedure-based reimbursement—global payments incentivize providers to find savings, not to pass along costs.

Global payments remain in their infancy, and early results are mixed. Examining global payments used by some insurers in Massachusetts, for instance, that state’s attorney general recently found that “globally paid providers do not have consistently lower total medical expenses.” Reforming payment structures alone, the A.G. found, is not enough: “It is [also] essential that businesses and consumers be engaged in efforts to promote a value-based health care market” by being given incentives and information to seek value.⁸¹ That global payments offer no immediate magic bullet solution will come as no surprise to those who appreciate the theme of this chapter, health delivery’s complexity. Reform, like a sophisticated plan of treatment, must take multiple pathways and will take years to penetrate throughout the system.

The case for moving away from fee-for-service is not that it will solve the problem by itself (nothing will do that) or that it will have dramatic effects immediately (nothing will do that, either), but that it is a necessary element of change, especially in the long term. Bringing analytical rigor to the production process will take years in health care, as it did in manufacturing; but getting incentives right is the necessary precondition of making the science of health care delivery part of the everyday fabric of the health care business, which eventually it should become.

Although, as we have often said, we do not believe in magic bullets, we do believe in low-hanging fruit. Developing a science of health care delivery and realizing its findings—rather than going about all

⁸⁰ In 2009, the NIH spent roughly \$1.1 billion of its total research budget on health services research. See Coalition for Health Services Research. “2009 Federal Funding for Health Services Research.” May 2010. <http://www.chsr.org/reports.htm>.

⁸¹ Office of Massachusetts Attorney General Martha Coakley, Examination of Health Care Cost Trends and Cost Drivers, June 22, 2011, pp. 5 and 51.

too much of what health care does in a more or less random fashion—is perhaps the lowest-hanging and ripest fruit on the tree.

A Choice of Paths

We conclude by asking ourselves a question. Where is the American health care system today?

We know, at any rate, where it came from. A half-century and more ago, most doctors were family physicians, and specialists were exotic beasts, seen on rare occasions for difficult cases.⁸² A well-informed physician could know a lot of what there was to know about medicine. Many conditions had only a handful of treatment paths. Insurance did not cost very much because, among other reasons, medicine could not do all that much. Medicare did not exist. Late-life treatment was relatively cheap, because so many retirees died young (by today's standards), instead of living for years with multiple chronic conditions. Insurance was linked to employment because of a World War II era tax break; payment was linked to procedures because, in a less complicated world, that seemed a natural way to bill. Incentives were aligned with the idiosyncrasies of the time, and, in that era, they were more or less functional. America had good health care, given the state of medical science at the time. And it had a good health care *system*.

But where, exactly, is the health care system *today*? The answer is that it might be in either of two places. It might be forging ahead technologically but mired structurally in the past. The system's incentives remain, alas, much as they were fifty years ago, and Medicare's fee-for-service structure has helped

keep them there; but the world has changed and the old incentives are anachronistic to the point of dysfunctionality. If left unchanged, they cannot help but provoke—or, rather, hasten—the systemic crisis that is already beginning to occur.

Or the system might be somewhere else. It might be at the doorstep of a gradual but eventually decisive transition to improvement and efficiency. It might be at a place where previously undreamt-of analytical tools, sifting through mountains of previously inaccessible information, can give the system the knowledge about effectiveness and the awareness of itself that it has lacked; where paths beyond fee-for-service are clearly visible ahead; where patients, providers, and even politicians are coming to recognize the inevitability and desirability of change; and where, in pockets of innovation around the country, change is proving its mettle.

We don't pretend to be sure where the system is. But we *think* it is in the latter place. And we believe the suggestions in this report can help make it so.

⁸² Paul Starr, *The Social Transformation of American Medicine: The Rise of a Sovereign Profession and the Making of a Vast Industry* (Basic Books, 1984).



TASK FORCE MEMBERS

KENNETH ARROW
Stanford University

KAMRAN BILIR
Stanford University/University of Wisconsin–Madison

SHANNON BROWNLEE
New America Foundation

ROBERT CALIFF
Duke Medical Center

ROBERT COOK-DEEGAN (Task Force Co-Organizer)
Duke University

FRANK DOUGLAS
Austen BioInnovation Institute in Akron

PAULA EHRLICH
Drug Discovery Center of Innovation

STEPHEN FRIEND
Sage Bionetworks

DAVID GRATZER
Manhattan Institute

SCOTT HARRINGTON
Wharton School, University of Pennsylvania

DAVID HYMAN
University of Illinois

BRINK LINDSEY
Ewing Marion Kauffman Foundation

ROBERT E. LITAN (Task Force Co-Organizer)
Ewing Marion Kauffman Foundation

SUSAN LOVE
Dr. Susan Love Research Foundation

ERNEST LUDY
EGL Advisors/The Ludy Family Foundation

LESA MITCHELL (Task Force Co-Organizer)
Ewing Marion Kauffman Foundation

BEN MOULTON
FIMDM

DOMINIQUE PAHUD
Ewing Marion Kauffman Foundation

GEORGE POSTE
Arizona State University, Complex Adaptive Systems
Initiative

FRANKLYN PRENDERGAST
Mayo Clinic

GEORGE PRIEST
Yale Law School

ARTI RAI
Duke Law School

JONATHAN RAUCH (Rapporteur)
National Journal

BARAK RICHMAN
Duke Law School

CARL J. SCHRAMM
Ewing Marion Kauffman Foundation (at the time)

PETER SCHUCK
Yale Law School

GREG SIMON
Pfizer Inc. (at the time)

JOSEPH SMITH
West Wireless Health Institute

DANE STANGLER
Ewing Marion Kauffman Foundation

JOHN TYLER
Ewing Marion Kauffman Foundation

JOHN WILBANKS
Consent to Research / Lybba

Research Assistance:
Jared Konczal
Ewing Marion Kauffman Foundation

Logistics:
Glory Olson
Ewing Marion Kauffman Foundation



EWING MARION KAUFFMAN FOUNDATION
4801 ROCKHILL ROAD, KANSAS CITY, MISSOURI 64110
TEL: 816-932-1000 www.kauffman.org