
ARTICLE

GOVERNMENT AS THE CRUCIBLE FOR FREE MARKET HEALTH CARE: REGULATION, REIMBURSEMENT, AND REFORM

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Political debates over economic policy commonly pit the virtues of the free market against those of government oversight. Regulatory policy then becomes an ongoing contest between the public and private sectors, infusing policy debates with a sense that it is necessary to choose between them. On closer examination, this duality is false. On a fundamental level, free-market entrepreneurs and government regulators are not opponents, but are, on the contrary, partners in a common enterprise. Across a range of major industries, one party could not exist without the other.

In no industry is this interplay more important than in health care. A series of government programs, most initiated during the latter half of the twentieth century, literally created the health care system as it exists in the United States today. Hospitals grew to their present size and technological complexity because of funding provided by the Hill-Burton Act and Medicare. Medicare also funds physician training, as well as reimbursement for many physician-provided services. Pharmaceutical manufacturers rely on the National Institutes of Health to support basic biomedical research that leads to the development of new drugs. A huge tax subsidy for employer-sponsored coverage finances, in large part, the health insurance industry. Without these programs, none of these health care industry segments could have approached its present

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size or vitality. To ignore this dynamic is to ignore the true nature of American health care and to fundamentally misunderstand the opportunities for reform.

The Patient Protection and Affordable Care Act (PPACA) continues and extends this paradigm. It will expand coverage in large part by facilitating broader demand for individual policies, which will revitalize private insurance markets. It will also extend Medicaid, a program that in most states is administered by private managed care plans, to millions more beneficiaries. Far from representing a government takeover or novel incursion into the health care system, PPACA extends the underlying arrangement that has built and sustains the structure of American health care as it exists today. In the American health care system, private innovation and government intervention represent not opposing forces, but rather partners in a common enterprise.

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INTRODUCTION

It is often taken as a truism that America's health care system is rooted in the free market. No other industrialized country looks to private enterprise to drive the provision and financing of care to the

same extent.¹ Entrepreneurs devise new products and services, investor-owned insurance companies reimburse for services, and independent practitioners offer services. With the tremendous growth of the health sector in the United States over the past several decades and the ever-expanding array of medical advances it offers, it would be easy to hold out American health care as an example of the fruits of an unfettered market-based system.

However, this assessment would miss a central, indispensable player that makes the market-based system possible. That player is the government, which funds, guides, and nurtures American health care on a fundamental level. In fact, the role of the public sector in American health care is so pervasive and of such longstanding importance that government can be credited with creating and sustaining health care as it exists today.

While the health care system in the United States claims the largest share of private sector involvement of any in the industrialized world, this market-based structure emerged from a series of government programs that launched its key sectors and that continue to shape it. In fact, virtually every major aspect of this system grew out of a government initiative. Moreover, governments at both the federal and the state levels continue to inject more money, directly and indirectly, into the system than all private players combined.²

This Article will describe how the government created the private health care sector, how the government continues to sustain it, and

¹ See WORLD HEALTH ORG., THE WORLD HEALTH REPORT 2000, HEALTH SYSTEMS: IMPROVING PERFORMANCE 192-95 annex tbl.8 (2000), available at http://www.who.int/whr/2000/en/whr00_en.pdf (noting that 55.9% of U.S. health care expenditures are private, compared with, for example, 3.1% in the United Kingdom and 19.9% in Japan). The portion of health care spending attributable to various sectors is broken down as follows: businesses (21%), households (28%), governments (44%), and other private sponsors (7%). CTRS. FOR MEDICARE & MEDICAID SERVS., NATIONAL HEALTH EXPENDITURES 2009 HIGHLIGHTS 2 (2009), available at <http://www.cms.gov/NationalHealthExpendData/downloads/highlights.pdf>.

² Direct government spending on health care accounted for 46.5% of total national expenditures in 2008. NAT'L CTR. FOR HEALTH STATISTICS, HEALTH, UNITED STATES, 2010, at 371 tbl.126 (2010), available at <http://www.cdc.gov/nchs/data/hus/hus10.pdf>. However, indirect government spending through tax subsidies and other means brings this figure closer to 60%. Steffie Woolhandler & David U. Himmelstein, *Paying for National Health Insurance—and Not Getting It*, HEALTH AFF., July–Aug. 2002, at 88, 91-92. Moreover, direct government spending alone is expected to account for more than half of all health expenditures within the next few years. Christopher J. Truffer et al., *Health Spending Projections Through 2019: The Recession's Impact Continues*, 29 HEALTH AFF. 522, 525 (2010). Government's share of health care spending alone accounted for an estimated 8.4% of gross domestic product (GDP) in 2009. Peter Landers, *Public Share of Health Tab to Top 50%*, WALL ST. J., Feb. 4, 2010, at A1.

how the Patient Protection and Affordable Care Act (PPACA)³ fits into this historical pattern. Part I describes the paradigm of public-private partnership that characterizes American health care and sets the context for PPACA's structure. Part II describes the paradigm of public-private partnership as it applies in four key industries outside of health care to demonstrate how pervasive this mechanism is in the American economy. Part III applies the paradigm to the creation and growth of four significant health care sectors—hospitals, the medical profession, the pharmaceutical industry, and health insurance. Part IV extends this analysis to PPACA to place its reform approach into perspective. The overall conclusion is that rather than preempting the private health care sector, PPACA will invigorate and expand it.

I. GOVERNMENT UNDERPINNINGS OF AMERICAN HEALTH CARE

A. *The Size and Nature of the Public-Private Partnership in Health Care*

Direct government funding of health care totaled almost \$1 trillion in 2008 through programs such as Medicare, Medicaid, and veterans' health.⁴ In that year, the overall system cost was slightly over \$2.3 trillion.⁵ However, these government expenditures represent only *direct* spending, the appropriations that appear in formal government budgets. Substantial additional funding is provided indirectly, in ways that are less apparent but no less forceful in their effect.⁶

The bulk of indirect government funding of health care is accomplished through tax exemptions that permit large portions of the industry and its customers to avoid assessments on a range of activities. The most substantial of these is the exemption from income tax for health insurance premiums when the coverage is obtained through an employer. That benefit alone was worth over \$200 billion in 2006

³ Pub. L. No. 111-148, 124 Stat. 119 (2010) (to be codified as amended in scattered sections of 21, 25, 26, 29, and 42 U.S.C.).

⁴ The 2008 budget for Medicare was \$468.1 billion, for Medicaid was \$294 billion, and for health care programs of the Department of Veterans Affairs was \$38.3 billion. NAT'L CTR. FOR HEALTH STATISTICS, *supra* note 2, at 402 tbl.140, 407 tbl.143, 409 tbl.145.

⁵ Eric Kimbunde et al., *U.S. Health Care Costs: Background Brief*, KAISEREDU.ORG (Mar. 2010), <http://www.kaiseredu.org/Issue-Modules/US-Health-Care-Costs/Background-Brief.aspx>. In 2009, total health care spending in the United States rose 4%, to \$2.49 trillion. Peter Landers, *Health Spending Eats Up Record Chunk of GDP*, WALL ST. J., Jan. 6, 2011, at A6.

⁶ See Woolhandler & Himmelstein, *supra* note 2, at 89-90 (providing an example of tax-financing of insurance premiums).

when both federal and state revenue is considered,⁷ and the value rose to \$240 billion in 2010.⁸ The government also grants exemptions from various forms of taxation to the majority of hospitals and other health care institutions that operate on a nonprofit basis. That benefit was worth over \$12 billion in 2002 alone.⁹ Indirect government funding of health care also includes the premiums that the federal and state governments pay for the more than two million workers in their employment and those workers' dependents.¹⁰ When combined, direct and indirect government payments cover the cost of almost 60% of the American health care system.¹¹

The most direct beneficiaries of government health care funding are the millions of patients whose care is financed through programs such as Medicare and Medicaid.¹² However, the effects extend much more broadly. A huge swath of the American economy—over one-sixth—is related to health care and therefore benefits from an injection of revenues through government health care programs.¹³ Within this economic sector are hospitals, outpatient clinics, physicians, allied health professionals, insurance companies, and pharmaceutical firms—to name only the larger participants. In addition to those components that directly contribute to the actual provision of care, thousands of researchers receive funding to conduct studies in biomedical science, many of which lead to advances in knowledge that benefit private health care entities.

⁷ Thomas M. Selden & Bradley M. Gray, *Tax Subsidies for Employment-Related Health Insurance: Estimates for 2006*, 25 HEALTH AFF. 1568, 1571 (2006).

⁸ LEN BURMAN ET AL., ROBERT WOOD JOHNSON FOUND., TAX SUBSIDIES FOR PRIVATE HEALTH INSURANCE: WHO BENEFITS AND AT WHAT COST? 1 (2009), available at <http://www.rwjf.org/files/research/synthesistaxsub072009.pdf>.

⁹ CONG. BUDGET OFFICE, PUB. NO. 2707, NONPROFIT HOSPITALS AND THE PROVISION OF COMMUNITY BENEFITS 3 (2006), available at <http://www.cbo.gov/ftpdocs/76xx/doc7695/12-06-Nonprofit.pdf>.

¹⁰ In 2007, the Federal Employee Health Benefit Plan covered about eight million federal employees, retirees, and their dependents. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-07-873T, FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM: PREMIUMS CONTINUE TO RISE, BUT RATE OF GROWTH HAS RECENTLY SLOWED 4 (2007), available at <http://www.gao.gov/new.items/d07873t.pdf>.

¹¹ Woolhandler & Himmelstein, *supra* note 2, at 91.

¹² Key elements of the Medicare program are presented in *Medicare Program—General Information, Overview*, CENTERS FOR MEDICARE & MEDICAID SERVICES, <http://www.cms.gov/MedicareGenInfo> (last visited Mar. 15, 2011). The Medicaid program is described in *Medicaid Program—General Information, Overview*, CENTERS FOR MEDICARE & MEDICAID SERVICES, <http://www.cms.gov/MedicaidGenInfo> (last visited Mar. 15, 2011).

¹³ In 2008, health care accounted for 16.2%, or slightly under one-sixth of GDP. Truffer et al., *supra* note 2, at 524 exhibit 1.

Each of these players owes a significant portion of its income to government programs. For some, that portion is well over half.¹⁴ What appears on the surface to be a market-based system is actually a huge public-private partnership in which the two sides form a symbiotic pair.¹⁵ Private health care organizations and professionals could not function as they do without government-imposed structure and funding. In the absence of government involvement, the industry would be significantly smaller overall, and the range of medical services available to Americans would be much more limited.¹⁶

This is not to say that the United States actually has a government-run system. Even with this large public infrastructure, it is unlikely that the government could maintain the health care system alone. Within the government-crafted structure, private players often take the lead, providing and financing care and manufacturing health care products. Private firms lend energy and vitality to the health care enterprise, along with competition that drives innovation. However, this private component did not arise on its own, and it does not endure based on traditional market principles.

B. *Government-Created Health Care and PPACA*

Failure to understand the government's role in creating and sustaining American health care has warped public debates over the massive health reform legislation enacted in 2010. Opponents have called PPACA a "government takeover" of health care and an attempt at "socializ[ation]" of the health care system.¹⁷ The clear implication of these charges is that the system in its present form is based in the

¹⁴ Sixty percent of the financing for long-term care in the United States comes from Medicare and Medicaid. Penny Hollander Feldman et al., *Long-Term Care, in HEALTH CARE DELIVERY IN THE UNITED STATES* 239, 243-44 (Anthony R. Kovner & James R. Knickman, eds., 2008).

¹⁵ Richard Epstein puts forth an example of the contrary view that government oversight and private enterprise represent an opposing dichotomy. See RICHARD A. EPSTEIN, *OVERDOSE: HOW EXCESSIVE GOVERNMENT REGULATION STIFLES PHARMACEUTICAL INNOVATION*, at x (2006) (asserting that overregulation hinders innovation).

¹⁶ Michael Cannon of the Cato Institute presents the view that government intervention is a force external to the market that holds back the health care industry. See, e.g., MICHAEL F. CANNON & MICHAEL D. TANNER, *HEALTHY COMPETITION: WHAT'S HOLDING BACK HEALTH CARE AND HOW TO FREE IT* 14 (2007) (arguing that "special involvement" of the government in health care limits competition and therefore reduces overall quality).

¹⁷ See, e.g., Jung Lee, *NObama, No Socialism, No Healthcare Reform*, EXAMINER.COM (June 11, 2009, 7:15 PM), <http://www.examiner.com/alexandria-political-buzz-in-washington-dc/nobama-no-socialism-no-health-care-reform>.

private sector and that new government programs represent an intrusion by an external force. This is a significant mischaracterization.

Rather than constituting a novel incursion into a free-market domain, PPACA is consistent with a long series of major public initiatives. Active government regulation of health care dates to the first state-based licensure laws for physicians enacted over 150 years ago.¹⁸ Proposals to guarantee universal financial coverage for medical services date back almost as far. The first such proposal by a major public figure came in the 1912 presidential campaign of Bull Moose Party candidate Theodore Roosevelt.¹⁹ The size and complexity of these proposed programs and initiatives have increased as the complexity of health care itself has grown.

At the end of World War II, health care did not rank as a major American industry.²⁰ Most hospitals were small, the number of physicians was limited, the pharmaceutical industry was just emerging from its roots in chemical manufacturing, and health insurance was a rela-

¹⁸ PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* 44-45, 58, 102-07 (1982).

¹⁹ Robert Myers writes,

Possibly the first national advocacy of government health insurance in the United States was a plank in the platform of the Socialist Party in the early 1900's. Subsequently, when former President Theodore Roosevelt founded the Progressive Party before the 1912 elections, a plank supporting national health insurance was included in its platform.

ROBERT J. MYERS, *MEDICARE* 3 (1970).

²⁰ The number of people covered by hospitalization insurance rose from 12 million to 77 million between 1940 and 1950. Douglas M. Mancino, *Income Tax Exemption of the Contemporary Nonprofit Hospital*, 32 *ST. LOUIS U. L.J.* 1015, 1023-24 n.30 (1988) (citing Steven Golub, *The Role of Medicare Reimbursement in Contemporary Hospital Finance*, 11 *AM. J.L. & MED.* 501, 503-04 (1986)) ("During the 1940's, as health insurance coverage increased in availability and scope, there was a concomitant rise in the development and use of new medical technology. As a result, both the demand for and cost of health care services accelerated."). Additionally, in 1940, health spending accounted for only 4.5% of GDP. OFFICE OF THE ASSISTANT SEC'Y FOR PLANNING & EVALUATION, *FINAL REPORT FOR TASK ORDER NO. HP-06-12, THE EFFECT OF HEALTH CARE COST GROWTH ON THE U.S. ECONOMY* 3 (2008), available at <http://aspe.hhs.gov/health/reports/08/healthcarecost/report.pdf>.

Significant changes in the health care industry in the wake of World War II led to expansion of the health care sector. The most important changes were the introduction of effective antibiotics in 1943, the growing prevalence of health insurance to cover costs, and passage of the Hill-Burton Act to fund hospital construction. Marc N. Gourevitch et al., *Acute Care*, in *HEALTH CARE DELIVERY IN THE UNITED STATES*, *supra* note 14, at 191, 193.

tively recent invention.²¹ During of the latter half of the twentieth century, each of these health care sectors changed dramatically, due almost entirely to public initiatives. Each of them would, of course, still exist in the absence of government actions. All predated government intervention, in some cases by thousands of years.²² However, instead of the vibrant and robust private industry of today, health care would almost certainly be much smaller, less profitable, and less innovative.

While government programs enacted over the years have addressed many aspects of the industry, the policy goal of guaranteeing universal access to the system had remained elusive. Almost every president since Franklin Roosevelt has developed a proposal to achieve universal, or at least dramatically expanded, coverage.²³ Over time, the proposals moved further away from a purely government-run model that had characterized the reform initiatives of Presidents such as Theodore Roosevelt and Harry Truman, to one based on encouragement and facilitation of private market mechanisms.²⁴ PPACA relies largely on this approach by encouraging private insurance companies to cover many of those who had been excluded from the current system.²⁵ In this regard, it reflects a natural continu-

²¹ In 1950, health care accounted for 4.6% of gross domestic product, and private health insurance covered only 8% of personal health expenditures. Dorothy P. Rice & Barbara S. Cooper, *National Health Expenditures, 1929-70*, SOC. SECURITY BULL., JAN. 1971, at 3, 4 chart 1, 15 tbl.5, available at <http://www.ssa.gov/policy/docs/ssb/v34n1/v34n1p3.pdf>.

²² Early hospitals date back to the Byzantine Empire. GUENTER B. RISSE, *MENDING BODIES, SAVING SOULS: A HISTORY OF HOSPITALS* 7 (1999). Physicians were active in ancient Greece. James E. Bailey, *Ashlepios: Ancient Hero of Medical Caring*, 124 ANNALS INTERNAL MED. 257 (1996). Pharmaceutical products were used and traded in ancient Egypt. Renate Germer, *Ancient Egyptian Pharmaceutical Plants and the Eastern Mediterranean*, in *THE HEALTH PAST: PHARMACEUTICALS IN THE BIBLICAL AND RABBINIC WORLD* 69, 69-71 (Irene Jacob & Walter Jacob eds., 1993).

²³ See CATHERINE HOFFMAN, *THE HENRY J. KAISER FAMILY FOUND., PUB. NO. 7871, NATIONAL HEALTH INSURANCE—A BRIEF HISTORY OF REFORM EFFORTS IN THE U.S.* 1 (2009), available at <http://www.kff.org/healthreform/upload/7871.pdf> (summarizing U.S. health reforms undertaken during the twentieth century).

²⁴ See, e.g., MYERS, *supra* note 19, at 19-26, 87 (providing a history of Medicare from its conceptual origins in the New Deal to later market-based proposals and reforms).

²⁵ As discussed in Part IV *infra*, PPACA expands access to health insurance in large part by creating exchanges through which consumers can purchase policies from private companies without regard to their health status. PPACA § 1311(c), 42 U.S.C.A. § 18031 (West Supp. 1B 2010). The exchanges' operation is described in CHRIS L. PETERSON & BERNADETTE FERNANDEZ, *CONG. RESEARCH SERV., R41269, PPACA REQUIREMENTS FOR OFFERING HEALTH INSURANCE INSIDE VERSUS OUTSIDE AN EXCHANGE* 6-9 (2010), available at http://www.nahu.org/legislative/resources/CRS_PPACA%20Requirements%20for%20Offering%20Health%20Ins%20Inside%20V%20Outside%20Exchanges_June%2010.pdf.

ation of the trend of the last half-century to create and sustain private markets to meet policy goals in the context of significant government regulation and financing.

This is the context in which PPACA was enacted and in which it will be implemented. Whatever the law's shortcomings, it does not reflect a new paradigm in industry structure or in the government's underlying role. Only by taking this perspective into account can PPACA be accurately understood.

II. THE PUBLIC-PRIVATE PARADIGM IN THE LARGER ECONOMY

To put the government's health care role in perspective, it is helpful to see how a mix of government and market forces drives elements of the broader economy. Four industries illustrate this dynamic. The computer industry owes much of its vitality to the Internet, a creation of the United States military that was expanded for commercial applications in the 1990s. The automobile industry grew significantly in response to the creation of the interstate highway system. The telecommunications industry relies on the space program's satellites. And the residential construction industry depends on federally financed programs that ease the process of obtaining home mortgages.

All of these industries would, of course, still exist without supportive government initiatives. However, they would unquestionably be much smaller, less diverse, and less innovative. They would also face dramatically fewer opportunities to devise products and services.

A. *Information Technology and the Internet*

Personal computers first became commonplace in the early 1980s, with machines that could fit on the top of a desk or rest on a user's lap.²⁶ Industry sales grew steadily for both computer hardware and software. However, a transformation began in 1994, when the first web browser—the initial version of Netscape—was introduced to the public, allowing the average computer user to access thousands of computers around the globe connected through a worldwide network.²⁷

²⁶ Various websites present the history of the Internet as a timeline. See, e.g., Dave Kristula, *The History of the Internet*, DAVESITE, <http://www.davesite.com/webstation/net-history.shtml> (last visited Mar. 15, 2011) (providing a brief overview of the Internet's history from 1957 to 2001).

²⁷ John Weisman, *The Making of E-Commerce: 10 Key Moments*, E-COM. TIMES (Aug. 22, 2000), http://ecnow.com/media/PDF_files/mlevy008.pdf.

The Internet had, in fact, existed for decades before Netscape was introduced in 1994.²⁸ Initially, it linked the computers of several government agencies, primarily in the military, and those of a few universities and research centers. The military developed the concept of a network linking multiple remote computers in the 1960s as a means of maintaining control of missiles and bombers after a nuclear attack.²⁹ The Department of Defense (DOD) launched the first network in 1968, with four computer hosts collectively creating the Advanced Research Projects Agency Network (ARPANET).³⁰ Over the next twenty years, university researchers with funding from DOD and from the National Science Foundation (NSF) developed enhancements such as e-mail, domain names to replace numerical identifiers for websites, and the first graphical user interface.³¹

Once available to the public, the Internet expanded the range of uses of personal computers to a tremendous degree and greatly increased the demand for these machines. In doing so, it reshaped the nature and size of the industry that manufactures them.³² In the decade from 1990 to 2000, the dollar value of personal computer sales rose by a factor of almost seventy. The growth of the personal computer market also increased demand for computer software, peripheral equipment like printers and modems, and a large range of related products. Countless allied industries have also arisen and grown as offshoots.³³

²⁸ *Id.*

²⁹ See JANET ABBATE, *INVENTING THE INTERNET* 8-17 (1999).

³⁰ The network's capabilities expanded with the creation of the first e-mail program in 1972. *Id.* at 106-07. The name "Internet" was first applied to the system in 1974. *Id.* at 149-52. After numerous enhancements over the next several years, largely funded by the DOD and the National Science Foundation (NSF), researchers at the University of Wisconsin developed the domain name system in 1983, which allowed users to access servers on the network with words, rather than more-difficult-to-remember numbers. *Id.* at 183. In 1991, the NSF funded the creation of a nonmilitary National Research and Education Network, which expanded the Internet's scope. *Id.* at 196. In 1993, researchers at the University of Illinois created a graphical user interface for the web, which was the step that opened the network to a vast audience of computer users worldwide. *Id.* at 216.

³¹ *Id.*

³² In December 1995, there were an estimated 16 million Internet users, representing only 0.4% of the world's population. Miniwatts Mktg. Grp, *Internet Growth Statistics*, INTERNET WORLD STATS, <http://www.internetworldstats.com/emarketing.htm> (last visited Mar. 15, 2011). By July 2000, that number had grown by over twentyfold to 359 million, representing 5.9% of the people on the globe. *Id.* As of June 2008, almost 1.5 billion people, representing over 20% of the world's population, were online. *Id.*

³³ The Internet's dramatic growth since its commercialization reshaped the nature and size of the computer industry. Between 1986 and 1990, 28.1 million personal com-

B. *Automobiles and Interstate Highways*

Automobiles have been popular since their invention in 1885.³⁴ By the early 1950s, they had become entrenched in the American economy but not yet entirely ingrained in the American way of life.³⁵ Commuting and intercity travel still relied to a large extent on public transit.³⁶ As early as the 1930s, the federal government considered the value of facilitating easier automobile travel through the creation of “super highways.”³⁷ These highways were to be limited-access roads that spanned the country on either a north-south or east-west axis.³⁸ In 1938, Congress passed the Federal Highway Act,³⁹ which directed the Bureau of Public Roads to investigate the feasibility of building three such highways along each axis.⁴⁰ In 1944, Congress added legislation designating a “National System of Interstate Highways” to contain up to 40,000 miles of roads.⁴¹ Funding was approved in 1952, and in 1956 President Dwight Eisenhower signed legislation that created

puters with an aggregate value of \$76.4 billion were sold in the United States. See Press Release, Computer Indus. Almanac Inc., 25-Year PC Anniversary Statistics: IBM-Compatible PC Sales Have Topped 1.5B Units Worth \$B 3,100 (Aug. 14, 2006), available at <http://www.c-i-a.com/pr0806.htm> (detailing sales of personal computers from 1981 to 2006). During the next five years, sales jumped to 64.3 million units, bringing in \$153 billion. *Id.* Between 2001 and 2006, 267 million units were sold for an aggregate \$424 billion. *Id.* Overall sales for the entire period between 1981 and 2006 were nearly \$1 trillion. *Id.* From 1990 through 2000, consumer spending on software rose from \$500 million to \$17.8 billion, while spending on personal computers rose from \$1.6 billion to \$108.8 billion. *Id.*; see also Betty W. Su, *The U.S. Economy to 2010*, MONTHLY LAB. REV., Nov. 2001, at 3, 6 tbl.3, available at <http://www.bls.gov/opub/mlr/2001/11/art1full.pdf> (projecting domestic growth from 2000–2010).

³⁴ See *Automobile Popularity: Crowds View the Horseless Vehicles in the Big Garden*, N.Y. TIMES, Jan. 21, 1903, at 10 (reporting on the tremendous and growing public interest in automobiles).

³⁵ See JAMES J. FLINK, *THE CAR CULTURE 191-94* (1975) (describing a cultural push-back against the automobile industry in the late 1950s).

³⁶ See Philip Weinberg, *Public Transportation and Clean Air: Natural Allies*, 21 ENVTL. L. 1527, 1533 (1991) (discussing the importance of rail systems in late 1950s America).

³⁷ See NAT’L COOP. HIGHWAY RESEARCH PROGRAM, TECHNICAL MEMORANDUM TASK 1: THE INTERSTATE AND NATIONAL HIGHWAY SYSTEM—A BRIEF HISTORY AND LESSONS LEARNED 17 (2006), available at <http://www.interstate50th.org/docs/techmemo1.pdf> (explaining the development of the federal highway system).

³⁸ *Id.* at 17-18.

³⁹ Federal Aid Highway Act of 1938, ch. 328, 52 Stat. 633 (repealed 1958). This was one of several laws to encourage and facilitate highway construction. The first was enacted in 1916. Federal Aid Road Act of 1916, ch. 241, 39 Stat. 355 (repealed 1958). Legislation relating to federal highways is codified in scattered sections of Title 23 of the United States Code.

⁴⁰ *Id.*

⁴¹ *Id.* at 36.

the Highway Trust Fund, which used the federal gas tax and other motor vehicle fees as a dedicated source of revenue for maintaining interstate highways.⁴²

With the opening of interstate highways, automobiles became significantly more valuable to travelers as a means of commuting and traversing long distances. Growth in automobile use in the United States over the next several decades far outstripped expansion of the population.⁴³ The number of registered vehicles grew from 65 million in 1956 to over 201 million in 1995, and the number of registered trucks, which are particularly heavy users of interstate highways, grew from just under 10.7 million to 72 million.⁴⁴ The number of buses, which are also major users of the interstate system, grew from 259,000 to almost 686,000 over the same period.⁴⁵

Even with recent setbacks, the automobile industry is still a major force in the economy. It would undoubtedly be so even without the interstate highway system. However, it is unlikely that the industry would have approached its present size and importance without the sizeable boost it received from the federal government's massive infrastructure plan.

C. Telecommunications and Satellites

In the 1960s, the telecommunications industry was flourishing, but long-distance communication was still expensive and cumbersome.⁴⁶ Cables carrying electronic signals spanned the country and reached across oceans, but their capacity was limited, particularly in the case of large, information-heavy signals, like television transmis-

⁴² *Id.* at 25-26.

⁴³ Between 1956 and 2006, the number of U.S. citizens increased from 169 million to over 298 million, a slightly less than twofold increase. U.S. ENERGY INFO. ADMIN., REPORT NO. DOE/EIA-0384, ANNUAL ENERGY REVIEW 2009, at 383 tbl.D1 (2010), available at <http://www.eia.doe.gov/totalenergy/data/annual/pdf/aer.pdf>. Over the same period, the number of vehicle miles driven grew from 814 billion to almost 3 trillion, a rise of almost fourfold. See NAT'L COOP. HIGHWAY RESEARCH PROGRAM, *supra* note 37, at 28.

⁴⁴ FED. HIGHWAY ADMIN., HIGHWAY STATISTICS SUMMARY TO 1995 tbl.MV-200 (1997), available at <http://www.fhwa.dot.gov/ohim/summary95/mv200.pdf>.

⁴⁵ See BUREAU OF TRANSP. STATISTICS, U.S. DEP'T OF TRANSP., BTS01-01, NATIONAL TRANSPORTATION STATISTICS 2000, at 13 tbl.1-9 (2000), available at http://www.bts.gov/publications/national_transportation_statistics/2000/html/1-9.htm (providing detailed statistics on vehicle usage in the United States over the latter half of the twentieth century).

⁴⁶ See HELEN GAVAGHAN, SOMETHING NEW UNDER THE SUN: SATELLITES AND THE BEGINNING OF THE SPACE AGE 171 (1998).

sions.⁴⁷ Pioneering the space program in the 1950s, the government was in a position to eliminate this limitation. The first active communications satellite, Telstar, was launched in 1962 as a collaboration between two private companies—AT&T and Bell Telephone Laboratories—and a variety of government agencies in different countries.⁴⁸ In the United States, the lead agency was the National Aeronautics and Space Administration, and it was joined by the General Post Offices of Great Britain and France.⁴⁹ A series of additional satellites entered geosynchronous orbits over the next ten years.⁵⁰

Following the advent of satellite transmission, growth in the broadcasting industry was dramatic. Revenue in the television industry rose from \$3.6 billion in 1970 to \$16.1 billion in 1983.⁵¹ For cable television, which relies heavily on satellites to transmit content, the growth in revenue over this period was from \$300 million to \$6 billion, a twentyfold increase.⁵² During the period between 1975 and 1983, the satellite carriers' revenue grew by 350%, while that of the television industry grew by 204% and that of the cable television industry by 650%.⁵³ Satellites did not create the television industry, but

⁴⁷ *See id.*

⁴⁸ *See id.* at 188-90.

⁴⁹ Fed. Comm'n Comm'n, *Wired, Zapped, and Beamed, 1960's Through 1980's*, REBOOT.FCC.GOV, <http://www.fcc.gov/omd/history/tv/1960-1989.html> (last visited Mar. 15, 2011).

⁵⁰ Placing satellites in geosynchronous orbit stationed them above key locations on the globe from which they could transmit a steady stream of communications between fixed points. *The Room-Size World*, TIME (May 14, 1965), <http://www.time.com/time/magazine/article/0,9171,898835,00.html>. Syncom 3 was placed above the Pacific Ocean in 1964, and Intelsat 1 hovered above the Atlantic starting in 1965. Syncom 3, NASA, <http://nssdc.gsfc.nasa.gov/nmc/spacecraftDisplay.do?id=1964-047A> (last visited Mar. 15, 2011). Satcom 1, launched in 1975 and placed over the United States, served as the conduit for the initial development of national cable television networks. Michael Hahn, *Satcom Communications Satellite*, GRIN, <http://grin.hq.nasa.gov/ABSTRACTS/GPN-2003-00010.html> (last visited Mar. 15, 2011).

⁵¹ *See* Benjamin M. Compaine, *Size and Growth Trends of the Information Industry, 1970-1983*, at 2 tbl.1, 6 tbl.3 (Harvard Univ. Program on Info. Res. Policy, Incidental Paper No. I-86-2, 1986), available at http://pirp.harvard.edu/pubs_pdf/compain/complain-86-2.pdf (summarizing financial information related to the information industry).

⁵² *Id.*

⁵³ *Id.* at 6 tbl.3. Rapid growth of television revenues continued after 1983, although at a somewhat slower pace. Between 1991 and 1998, total revenue for television grew from \$21.9 billion to \$32.8 billion and for cable from \$24.9 billion to \$49.3 billion. U.S. CENSUS BUREAU, ANNUAL SURVEY OF COMMUNICATION SERVICES 13 tbl.9, 21 tbl.16 (1999), available at <http://www.census.gov/prod/2000pubs/bc98.pdf>. The prevalence of television and radio in daily life also continued to expand during this time. Television sets were found in 59 million American households in 1970 and in 97 million in 1997. U.S. CENSUS BUREAU, STATISTICAL ABSTRACT OF THE UNITED STATES:

they reshaped its potential and greatly expanded its boundaries and profitability.

D. *Homebuilding and Federal Mortgage Support*

The vitality of the homebuilding industry depends on the ability and willingness of consumers to purchase new houses. All but the wealthiest need mortgages to afford the cost. Painful experience has demonstrated that without a free flow of credit for housing, the entire real estate sector of the economy fails to function effectively.⁵⁴

Several government programs have implemented an explicit policy to encourage home ownership. The Federal Housing Administration was established in the 1930s to insure loans, making banks more willing to offer them to a larger range of borrowers.⁵⁵ The Federal National Mortgage Association, commonly known as Fannie Mae, was created in 1938 as part of the New Deal, and it encourages home ownership by purchasing mortgages for resale to other financial institutions.⁵⁶ As of the end of 2007, the organization held over \$723 billion in mortgages.⁵⁷ When combined with over \$2.4 trillion in loans and other guarantees, its book of business totaled nearly \$3 trillion in 2007.⁵⁸

In 1970, Congress created the Federal Home Loan Mortgage Corporation, commonly known as Freddie Mac, to serve a similar function.⁵⁹ Between 1997 and 2007, this organization injected \$4.6 trillion into the housing market through loans and other investments that served over 30 million homeowners.⁶⁰

1999, at 581 tbl.921 (1999). Cable's presence grew from 4 million households to 64 million during the same time. *Id.*

⁵⁴ Cf. Paul J. Lim, *Housing Bubble Correction Could Be Severe*, U.S. NEWS & WORLD REP. (June 13, 2006), http://www.usnews.com/usnews/biztech/articles/060613/13housing_bubble.htm (reporting on rapid increases in housing prices nationwide).

⁵⁵ *The Federal Housing Administration*, U.S. DEPARTMENT HOUSING & URB. DEV., <http://www.hud.gov/offices/hsg/fhahistory.cfm> (last visited Mar. 15, 2011).

⁵⁶ *See About Fannie Mae*, FANNIE MAE, <http://www.fanniemae.com/kb/index?page=home&c=aboutus> (last visited Mar. 15, 2011).

⁵⁷ FANNIE MAE, DECEMBER 2008 MONTHLY SUMMARY 2 tbl.5 (2009), *available at* <http://www.fanniemae.com/ir/pdf/monthly/2008/122908.pdf>.

⁵⁸ *Id.* at 1 tbl.1.

⁵⁹ *See Company Profile*, FREDDIE MAC, http://www.freddiemac.com/corporate/company_profile/ (last visited Mar. 15, 2011) (describing Freddie Mac's mission as "stabiliz[ing] the nation's residential mortgage markets and expand[ing] opportunities for homeownership").

⁶⁰ FREDDIE MAC, MAKING HOME POSSIBLE IN UNITED STATES 1 (2008), *available at* http://www.freddiemac.com/corporate/about/pdf/United_States.pdf (noting that the investment also served four million renters).

The federal tax code also subsidizes home purchasers in the form of a tax deduction for the interest paid on mortgages.⁶¹ For some, the tax break means the difference between owning and renting a home, and for others it is the difference between owning an entry-level house or a more luxurious one. The cost to the federal government in lost revenues from this subsidy reached an estimated \$76 billion in 2005.⁶²

With more Americans able to afford homes, and with more of those who can afford homes able to purchase larger ones, demand for houses has grown steadily over the years.⁶³ Well over a million new private homes have been built every year since 1980, and in many years, the number has been closer to 2 million.⁶⁴ The total number of housing units in the country grew from just under 88 million in 1980 to nearly 128 million in 2007.⁶⁵ Notwithstanding setbacks during the Great Recession, the market for homes has fed a vibrant construction industry that has become an important engine for economic growth.⁶⁶

E. *Government Initiative and Private Innovation*

The reality in these four industries, as in a variety of others, is that government initiatives and private enterprise have not been opposing

⁶¹ Congress never crafted the tax deduction for mortgage interest as an explicit policy. Instead, the deduction grew out of the structure of the federal income tax, which dates to 1913. See Roger Lowenstein, *Who Needs the Mortgage-Interest Deduction?*, N.Y. TIMES MAG., Mar. 5, 2006, at E79. Interest on loans was considered a legitimate business expense that could be deducted from earnings, and this principle was applied to interest paid by individuals as well. *Id.* at E81. At the time, few Americans owned homes and interest on consumer loans was rare, so the deduction was worth very little to most people. *Id.* However, as home ownership and mortgage borrowing grew over the subsequent decades, the deduction became an important, and expensive, economic incentive program. *Id.*

⁶² *Id.* at E80.

⁶³ There were over 75 million owner-occupied housing units in the United States in 2008, of which 49.4% had a value of \$200,000 or more. U.S. CENSUS BUREAU, STATISTICAL ABSTRACT OF THE UNITED STATES: 2011, at 621 tbl.991 (2011), available at <http://www.census.gov/compendia/statab/2011/tables/11s0991.pdf>. There were approximately 52 million such units in 1980 and 59 million in 1990. U.S. CENSUS BUREAU, STATISTICAL ABSTRACT OF THE UNITED STATES: 1995, at 733 tbl.1226 (1995), available at <http://www.census.gov/prod/1/gen/95statab/construc.pdf>.

⁶⁴ U.S. CENSUS BUREAU, STATISTICAL ABSTRACT OF THE UNITED STATES: 2009, at 592 tbl.927 (2008), available at <http://www.census.gov/compendia/statab/2009/tables/09s0927.pdf>.

⁶⁵ *Id.* at 598 tbl.940, available at <http://www.census.gov/compendia/statab/2009/tables/09s0940.pdf>.

⁶⁶ The value of residential construction in the United States grew from \$247 million in 1995 to \$525 million in 2007, while the value of all construction rose from \$428 million to \$875 million during the same period. *Id.* at 589 tbl.922, available at <http://www.census.gov/compendia/statab/2009/tables/09s0922.pdf>.

forces; nor have the two sectors competed with each other in the sense that the success of one diminishes the wellbeing of the other. Instead, they have both served as essential partners in the same endeavor. In essence, a government-facilitated, market-based engine for economic growth has emerged.

The government is the only entity possessing both the resources and the legal authority necessary to create the infrastructure that robust free markets need to achieve their potential. Computers need networks, cars need highways, communication devices need long-range links, and construction needs housing markets to maintain consumer demand. No single private industry, or even combination of industries, could create these elements on a national scale.

The issue for public policy is not whether government-regulated or private markets are better at achieving economic goals, but rather how to use the power of government initiative to create the infrastructure that most effectively enables private innovation to flourish. In large portions of the economy, government promotes vibrant private markets not by avoiding interaction with them, but rather by crafting active policies to promote them.⁶⁷ Understanding the complex interplay of the public and private sectors is a much more productive guide to appreciating industry dynamics and to charting future public policy than is reducing their underlying roles to those of hypothetical contestants.

III. THE PUBLIC-PRIVATE PARADIGM IN HEALTH CARE

There is no sector of the American economy in which collaboration between public initiative and private enterprise is more fundamental than health care. The government created and shaped every

⁶⁷ To point to government's role in promoting private markets is not to say that all public programs are successful or well planned. Government agencies often act in ways that are contrary to the short-term interests of the individual enterprises they regulate. In fact, the relationships between regulated industries and the agencies that oversee them are often hostile. However, disagreements over practical matters do not necessarily translate into differences in long-term goals. For example, the Center for Biologics Evaluation and Research within the Food and Drug Administration, which regulates biological products such as vaccines and gene therapies has, in part, a mission to "[f]acilitate the development, approval of, and access to safe and effective products and promising new technologies." *CBER Vision & Mission*, FDA, <http://www.fda.gov/AboutFDA/CentersOffices/CBER/ucm122878.htm> (last visited Mar. 15, 2011). The goal of facilitating product development echoes the underlying imperative of industry.

core element of the system, yet each operates in large part through the private sector. A market-based industry drives day-to-day functioning, while a government foundation supports the overall enterprise.

Four core elements of health care demonstrate this structural dynamic: hospitals, the key institutions for providing health care services; medical professionals, who are the key practitioners providing medical services; drug and device manufacturers, which create the products that form the armamentarium used for care; and private insurance companies, which are the central conduits for the financing of health care services. In each case, a government program or combination of programs not only created the industry sector, but also continues to impose structure through regulation and to serve as an indispensable source of ongoing funding.

A. *The Government and the Hospital Industry*

American hospitals trace their origins to the middle of the eighteenth century. At that time, patients with financial means received most of their medical care at home from private physicians. Those who could not afford care at home needed a place of rest where their basic needs could be met. In 1751, Benjamin Franklin and Dr. Thomas Bond helped found the first hospital in North America, Pennsylvania Hospital in Philadelphia,⁶⁸ as a successor to the almshouses that housed many of the poor.⁶⁹ In 1791, New York Hospital began operations along the same model,⁷⁰ and in 1821, Massachusetts General Hospital opened in Boston.⁷¹

Hospitals today are centers of advanced, high-technology treatment that bear little resemblance to their forebears of two hundred years ago. Many factors helped foster this transformation, including the growth of the medical profession in the late nineteenth and early twentieth centuries and a series of medical advances that occurred at about the same time, including anesthesia, antisepsis, and x-ray imag-

⁶⁸ *About Pennsylvania Hospital: History & Overview*, PENN MED., <http://www.pennmedicine.org/pahosp/about> (last visited Mar. 15, 2011).

⁶⁹ See STARR, *supra* note 18, at 150 (describing almshouses as providing very minimal care so as to deter the use of public assistance).

⁷⁰ King George III chartered New York Hospital in 1771, but the Revolutionary War delayed the hospital's opening until 1791. Fabrizio Michelassi & Thomas J. Fahey III, *The Department of Surgery at New York-Presbyterian Hospital/Weill Cornell Medical Center: At the Forefront of Surgical Innovation*, 75 AM. SURGEON 643, 643 (2009).

⁷¹ STARR, *supra* note 18, at 150.

ing.⁷² These developments expanded both the boundaries of hospital care and the capacity of these institutions to render treatment and diagnosis beyond simple custodial care.⁷³

The technological and structural transformation of hospitals significantly accelerated during the latter part of the twentieth century, when the industry experienced a particularly dramatic growth spurt.⁷⁴ Access to hospital services improved in many previously underserved regions, the capabilities of institutions expanded, and facilities were upgraded. These changes, which transformed and modernized the industry, were financed primarily by major government programs that injected huge amounts of funding and new forms of regulatory oversight.

The first program was the Hill-Burton Act,⁷⁵ which Congress passed in 1946 to fund construction of new hospitals and expansion of existing facilities on a large scale.⁷⁶ The law's primary purpose was to improve access to hospital services in regions of the country where such access had been limited, with a focus on rural areas.⁷⁷ Over the next twenty-five years, over \$3.7 billion was appropriated under this law, representing grants to almost one-third of the hospitals in the country.⁷⁸ By 1997, Hill-Burton had injected \$4.6 billion in grants and \$1.5 billion in loans to 6800 health care facilities in 4000 communities.⁷⁹

⁷² *Id.* at 155-56.

⁷³ See STARR, *supra* note 18, at 147-62 (describing the transformation of U.S. hospitals from institutions of social welfare to cutting-edge medical science institutions).

⁷⁴ Between 1960 and 2008, national spending on hospital care increased from \$23.3 million to \$1.952 billion. NAT'L CTR. FOR HEALTH STATISTICS, *supra* note 2, at 369 tbl.125. During the 1970s, employment in hospitals in the United States increased by 37.6%. Edward S. Sekscenski, *The Health Services Industry: A Decade of Expansion*, MONTHLY LAB. REV., May 1981, at 9, 10.

⁷⁵ 42 U.S.C. § 291 (2006).

⁷⁶ The law's formal name is the Hospital Survey and Construction Act of 1946. Pub. L. No. 79-725, 60 Stat. 1040.

⁷⁷ *Id.* § 601, 60 Stat. at 1041.

⁷⁸ STARR, *supra* note 18, at 350. By 1968, the Hill-Burton Act had contributed to the financing of 416,000 hospital beds and 9200 new medical facilities. Roger K. Newman, *Hill-Burton Act (1946)*, in 2 MAJOR ACTS OF CONGRESS 166, 166-67 (Brian K. Landsberg ed., 2004). By 1975, it had contributed to almost one-third of all hospital construction projects in the country and had funded close to 10% of the costs of all hospital construction. *Id.*

⁷⁹ *Hill-Burton Facilities Compliance & Recovery*, HRSA U.S. HEALTH RES. & SERVICES ADMIN., <http://www.hrsa.gov/gethealthcare/affordable/hillburton/compliance.html> (last visited Mar. 15, 2011). For a discussion of the role of federal funding in facilitating the growth of rural health facilities in the United States, see Mary K. Zimmerman & Rodney McAdams, *Public Support for Rural Health Care: Federal Programs and Local Hospital Subsidies*, in CHRONIC CARE, HEALTH SYSTEMS AND SERVICES INTEGRATION 25, 27-29 (Jennie Jacobs Kronenfeld ed., 2004).

Hill-Burton funding offered a lifeline for many rural hospitals and the regions that they served, but it came with many regulatory strings attached. Among them, the law required hospitals receiving funds to provide minimum amounts of indigent care and emergency care without regard to ability to pay, and to refrain from discriminating⁸⁰ among patients based on race.⁸¹ Participation in Medicare and Medicaid was added as a retroactive requirement in the 1970s.⁸² The law also implemented a system of state-level planning to allocate funding. This system laid the groundwork for a more comprehensive, state-based planning process that was implemented in the 1960s to determine which clinical services and facility improvements could be added at which hospitals.⁸³

Hill-Burton's combination of funding and regulation formed a blueprint for the structure of the American hospital industry. Through state health planning boards, the government determined where hospitals would be located, enforcing a business model that required care to be rendered to broad segments of the population. At the same time, the government fostered a tremendous expansion in the size and scope of the nation's overall hospital enterprise.

The second and even more substantial finance program that fostered the growth of the American hospital industry was Medicare,

⁸⁰ *Medical Treatment in Hill-Burton Funded Healthcare Facilities*, U.S. DEPARTMENT HEALTH & HUM. SERVICES, <http://www.hhs.gov/ocr/civilrights/understanding/Medical%20Treatment%20at%20Hill%20Burton%20Funded%20Medical%20Facilities/index.html> (last visited Mar. 15, 2011). These requirements are embodied in regulations published at 42 C.F.R. § 124 (2010). The indigent-care obligation varied with the nature of the funding received, lasting either for twenty years, until federal loans were repaid, or in perpetuity. SHARON KEARNEY COLEMAN, CONG. RES. SERV., 98-968, THE HILL-BURTON UNCOMPENSATED SERVICES PROGRAM 2 (2005), available at <http://www.policyarchive.org/handle/10207/bitstreams/719.pdf>.

⁸¹ While the Hill-Burton Act outlawed racial discrimination by hospitals that received funds, until 1963 hospitals were permitted to provide racially segregated services that were of equal quality. STARR, *supra* note 18, at 350.

⁸² The requirements are contained in regulations of the Department of Health and Human Services (HHS). See 42 C.F.R. § 124 (2010).

⁸³ Implementation of the planning process occurred through certificate-of-need programs. See ROBERT I. FIELD, HEALTH CARE REGULATION IN AMERICA: COMPLEXITY, CONFRONTATION AND COMPROMISE 57-58 (2007). The programs divide states into planning regions and develop a health care needs assessment for each one. *Id.* New facilities and services must obtain a certificate-of-need in order to be implemented, and certificates are issued based on whether a proposed facility or service satisfies an unmet need under the plan for its region. *Id.* All states adopted these programs in response to a federal mandate in 1966 under the Comprehensive Health Planning and Services Act, 42 U.S.C. § 246 (2006), but the mandate was permitted to expire in 1986, and only about half of the states retain programs today. FIELD, *supra*, at 57-58.

which today covers the cost of care for nearly 47 million elderly and disabled beneficiaries.⁸⁴ This reimbursement mechanism has grown relentlessly since its enactment in 1965. Its total budget in 2010 was over \$510 billion, and it has been rising steadily at about 5% annually.⁸⁵ Of the 2010 total, \$186 billion was allocated for Part A of the program, which covers hospital and other inpatient services, while \$140 billion was earmarked for Part B, which covers physician and other professional services.⁸⁶ Its companion program Medicaid, through coverage for several categories of the poor, injects slightly over \$400 billion into the system when both state and federal contributions are considered.⁸⁷

Of particular importance to the growth of the hospital industry is the mechanism Medicare used in its early years to reimburse hospitals for the cost of capital expansion. Until 1983, Medicare paid hospitals based on the actual cost of providing care. Expenses related to the provision of care were calculated and then multiplied by the percentage of patients covered by Medicare. Allowable costs for calculation included not only operating expenses for treatment, but also capital expenditures for expanding and improving facilities.⁸⁸ Because of the large Medicare population served by many hospitals, this system covered a significant portion of the total hospital costs, including the cost of many expansions and facilities upgrades.⁸⁹ It is not surprising that the years immediately following implementation of the Medicare program corresponded with a period of substantial growth in hospital construction.⁹⁰

⁸⁴ As of May 2010, the total number of Medicare beneficiaries was nearly 46.6 million. The Henry J. Kaiser Family Found., *Total Number of Medicare Beneficiaries, 2010*, STATEHEALTHFACTS.ORG, <http://www.statehealthfacts.org/comparamtable.jsp?ind=290&cat=6> (last visited Mar. 15, 2011).

⁸⁵ *Fiscal Year 2010 Budget in Brief: Medicare*, U.S. DEPARTMENT HEALTH & HUM. SERVICES., <http://dhhs.gov/asfr/ob/docbudget/2010budgetinbrief.html> (last visited Mar. 15, 2011).

⁸⁶ *Id.*

⁸⁷ *Fiscal Year 2010 Budget in Brief: Medicaid*, U.S. DEPARTMENT HEALTH & HUM. SERVICES., <http://dhhs.gov/asfr/ob/docbudget/2010budgetinbriefm.html> (last visited Mar. 15, 2011).

⁸⁸ See generally Rick Mayes, *The Origins, Development, and Passage of Medicare's Revolutionary Prospective Payment System*, 62 J. HIST. MED. & ALLIED SCI. 21 (2007) (detailing the development of the Medicare reimbursement system).

⁸⁹ In 2008, Medicare covered just under 30% of overall hospital expenditures. NAT'L CTR. FOR HEALTH STATISTICS, *supra* note 2, at 371 tbl.126. All government sources of payment combined covered almost 57%. *Id.*

⁹⁰ Brian Kinkead explains that "[f]rom 1968 to 1971 the constant dollar value of medical facility construction increased at an average annual rate of 13.1%, a rate of

The advent of Medicare and Medicaid, however, did not coincide with an increase in the total number of hospitals or hospital beds. These remained fairly constant from the late 1960s onward.⁹¹ Instead these programs provided funding to improve hospital facilities and equipment.⁹²

Medicare brought about another major change in hospital operations in 1983 when Congress modified its reimbursement mechanism to become a prospective payment system. The program began to base reimbursement not on actual costs but on a set fee, determined in advance, based on the patient's principal diagnosis. With limited exceptions, hospitals received the same amount regardless of the actual expenses incurred for each patient. This new payment structure dramatically altered the nature of hospital-physician relations.⁹³ Hospitals found that some diagnoses could be treated efficiently, and therefore the corresponding services could be quite profitable. Other diagnoses required resources that were disproportionate to the economic reward and could thus be a monetary drain. Many hospitals responded by structuring their medical staffs to include more practitioners of profitable procedures and fewer of those whose work was less remunerative.⁹⁴

increase not seen since the establishment of the Hill-Burton program twenty years before." Brian M. Kinkead, *Medicare Payment and Hospital Capital: The Evolution of Policy*, HEALTH AFF., Aug. 1984, at 49, 60-61.

⁹¹ In fact, the number of hospital beds decreased slightly between 1975 and 2004. NAT'L CTR. FOR HEALTH STATISTICS, HEALTH, UNITED STATES, 2006, at 392 tbl.130 (2006), available at <http://www.cdc.gov/nchs/data/hus/hus06.pdf>.

⁹² See OFFICE OF TECH. ASSESSMENT, OTA-H-227, MEDICAL TECHNOLOGY AND COSTS OF THE MEDICARE PROGRAM 38 (1984), available at <http://www.fas.org/ota/reports/8419.pdf>. ("Medicare payment policies generally have assured hospitals that they would be paid for the cost of new technologies. This assurance has had a direct effect on hospitals' decisions to adopt new technologies."); see also James C. Robinson, *The Changing Boundaries of the American Hospital*, 72 MILBANK Q. 259, 260 (1994) ("Between 1972 and 1990, acute care facilities diversified rapidly, but significant areas of health care remain outside the boundaries of the hospital organization.").

⁹³ The diagnosis-related group (DRG) system of payment was predicted to affect hospital-physician relations soon after its implementation. See Bruce C. Vladeck, *Medicare Hospital Payment by Diagnosis-Related Groups*, 100 ANNALS INTERNAL MED. 576, 585-90 (1984) (noting that it would be nearly impossible for hospitals and physicians to act autonomously and independently).

⁹⁴ Hospitals' selection of staff physicians based on the profitability of their specialty is known as "economic credentialing." Several courts have upheld this practice. See, e.g., *Mahan v. Avera St. Luke's*, 621 N.W.2d 150, 160 (S.D. 2001) (holding that Avera St. Luke's decision to close its facility for certain procedures was "reasonable" because the hospital had established that "the closures were necessary to insure the continued viability of the hospital," which provided "comprehensive medical services to the . . . community"); see also John D. Blum, *Beyond the Bylaws: Hospital-Physician Relationships, Economics,*

Hospitals also pushed some kinds of procedures to outpatient clinics where Medicare reimbursement could still be obtained on a fee-for-service basis. Work in outpatient surgery and radiology clinics can be attractive to physicians because clinics often offer higher income potential.⁹⁵ This change in the location of treatment altered the nature of care, fostered the growth of ambulatory surgery and other outpatient treatment centers, and changed the relative attractiveness of different specialties to physicians.⁹⁶

As a third government financial boost, those hospitals operating on a nonprofit basis receive an indirect government subsidy through a tax exemption. This confers several financial advantages. It allows hospitals to avoid tax on income earned, on real estate holdings, which can be substantial, and on sales of goods and services.⁹⁷ Non-

and Conflicting Agendas, 53 BUFF. L. REV. 459, 470-74 (2005) (detailing the emergence of economic credentialing, the legal response, and its potential consequences).

⁹⁵ The higher income potential for physicians who practice in ambulatory surgery centers can result from the opportunity for ownership interests, which permit physicians to share in the facility fees for services that hospitals would otherwise obtain, the chance for a return on equity for their investments, and the potential to receive higher reimbursement rates for their professional services from some insurers. See Tracy K. Johnson et al., *Ambulatory Surgery: Next-Generation Strategies for Physicians and Hospitals*, HEALTHCARE FIN. MGMT., Jan. 2000, at 48, 48, available at <http://healthstrategiesandsolutions.com/pdfs/pdfs-3-22-05/Article53.pdf>. In addition, orthopedic surgery and diagnostic radiology, specialties that are often practiced in outpatient settings, are among the most lucrative. See CTRS. FOR MEDICARE & MEDICAID SERVS., AMERICAN MEDICAL ASSOCIATION COMPENSATION SURVEY DATA 2009 REPORT (2009) (citing AM. MED. GRP. ASS'N, 2009 MEDICAL GROUP COMPENSATION AND FINANCIAL SURVEY (2009)), available at http://www.cms.gov/AcuteInpatientPPS/Downloads/AMGA_08_template_to_09.pdf (estimating the median salary for physicians in orthopedic surgery and diagnostic radiology to be approximately \$500,000, varying upward for subspecialties).

⁹⁶ “A number of legislative changes have altered the environment for Medicare beneficiaries, underscoring and strengthening the incentives for a shift from inpatient hospital care to outpatient sites such as hospital outpatient departments, ambulatory surgery centers, and physicians’ offices.” Shelah Leader & Marilyn Moon, *Medicare Trends in Ambulatory Surgery*, HEALTH AFF., Spring 1989, at 158, 158. Between 1983 and 1985, just after Medicare changed the reimbursement system for hospitals to DRGs, the portion of surgery performed in ambulatory surgery centers (ASCs) grew from 1% to 3%, and total reimbursement grew from \$9 million to \$71 million. *Id.* at 162 exhibit 1, 165 exhibit 4. The total number of physician and surgeon bills for services rendered at ASCs grew by 825.7% during this time period, compared to 111.1% for hospitals. *Id.* at 163 exhibit 2. Ophthalmology is one example of a specialty that saw increased opportunities at ASCs. The percentage of Medicare bills for physicians practicing this specialty for services rendered at ASCs grew from 7% to 12% between 1983 and 1985. *Id.* at 167 exhibit 6.

⁹⁷ In some states, such as Pennsylvania and Utah, extension of the federal tax exemption to state and local taxes, such as real estate and sales taxes, is not automatic. Hospitals must prove that they actually serve a charitable function in their communi-

profit status also permits investors who purchase the hospitals' bonds to earn tax-free interest. The foregone tax revenue represents a government subsidy that allows hospitals to pay lower interest rates on their debt, further encouraging capital expansion.⁹⁸

In return for receiving a tax exemption, nonprofit hospitals must abide by a set of rigorous regulatory requirements. They must ensure that no part of their earnings benefits private individuals, that they do not engage in lobbying concerning legislation, and that they do not participate in political campaigns.⁹⁹ To avoid benefiting private parties, any financial dealings between the hospital and its physicians must meet various regulatory restrictions so that favored staff members are not overcompensated.¹⁰⁰ Hospitals must also demonstrate on a continuing basis that they provide special benefits to their communities, for example, by maintaining open emergency rooms that treat indigent patients without charge, participating in Medicare and Medicaid, and including community representatives on their boards.¹⁰¹

As hospital operations expanded during the decades following World War II, so too did the value of this subsidy. In 2002, the federal government lost about \$6 billion in taxes that nonprofit hospitals would otherwise have paid, and state and local governments lost an equivalent amount for a total annual subsidy of over \$12 billion.¹⁰² In

ties. However, most nonprofit hospitals continue to qualify for tax-exempt status. *See, e.g.,* Institutions of Purely Public Charity Act, 10 PA. CONS. STAT. ANN. §§ 371–385 (West 2010) (laying out specific criteria for determining whether an institution is a “purely public charity” and therefore exempt from state taxation).

⁹⁸ I.R.C. § 145(a) (2006). Tax-exempt bonds represent an important government subsidy that reduces borrowing costs for hospitals. *See Tax Exempt Bonds*, AM. HEALTH LAW. ASS'N (July 14, 2010), <http://www.healthlawyers.org/Resources/Health%20Law%20Wiki/Tax%20Exempt%20Bonds.aspx>.

⁹⁹ I.R.C. § 501(c)(3) (2006); *see also Exemption Requirements—Section 501(c)(3) Organizations*, IRS.GOV (Nov. 15, 2010), <http://www.irs.gov/charities/charitable/article/0,,id=96099,00.html> (providing an overview of exemption requirements); FIELD, *supra* note 83, at 189–94 (outlining the regulation of tax-exempt status, including the process of gaining and maintaining it, and penalties for violating its restrictions).

¹⁰⁰ *See* I.R.S. Gen. Couns. Mem. 39,862 (Nov. 21, 1991) (concluding that a hospital can lose its section 501(c)(3) tax-exempt status if it enters into certain hospital-physician joint ventures that involve the sale of part of the hospital's net revenue stream).

¹⁰¹ The IRS first articulated the community-benefit standard for assessing the charitable operations of hospitals in 1969. *See* Rev. Rul. 69-545, 1969-2 C.B. 117 (using examples to illustrate under what circumstances a nonprofit hospital would meet the public-interest standard required to receive tax-exempt status); *see also* John D. Colombo, *The Role of Tax Exemption in a Competitive Health Care Market*, 31 J. HEALTH POL. POL'Y & L. 623, 629–35 (2006) (analyzing whether the community-benefit requirement leads to better performance according to several identified criteria).

¹⁰² CONG. BUDGET OFFICE, *supra* note 9, at 3.

this way, the government injects additional funding into the industry while using the leverage that comes with it to shape the underlying business model of the recipients through regulations requiring open access and community services.

The Emergency Treatment and Labor Act (EMTALA) imposes an additional significant community-benefit obligation on hospitals receiving Medicare funds.¹⁰³ Under this law, hospitals that participate in Medicare must assess and stabilize all patients who present themselves in the emergency room before inquiring about payment arrangements.¹⁰⁴ Consequently, hospitals often provide care to patients without the means to pay. Aware of this obligation, many indigent patients have turned to emergency rooms as a source of routine care. As a result, many hospitals, particularly in inner-city areas, have come to serve some of the same functions as community health centers. These de facto clinics define health care in many communities and place a substantial burden on hospital finances.¹⁰⁵ Hospitals recoup much of the lost revenue from this policy through cost shifting to privately insured patients, which places upward pressure on premiums. In essence, through EMTALA, Medicare has altered important elements of hospital-community and hospital-insurer relations.

As these various government programs grew, so did the financial fortunes of the hospital industry. Total spending on hospital care in the United States rose from almost \$9.2 billion in 1960 to almost \$571 billion in 2004, an increase of just under sixtyfold.¹⁰⁶ Hospital construction, in constant 1972 dollars, grew from \$3.1 billion during the years between 1945 and 1949 to \$16.6 billion between 1975 and 1979.¹⁰⁷ Hospitals' share of total nonresidential construction during the same time period rose from 10% to 19%.¹⁰⁸ With this greater economic presence, the hospital industry has evolved into a major economic force.

¹⁰³ See 42 U.S.C. § 1395dd(a)–(c) (2006).

¹⁰⁴ *Id.*

¹⁰⁵ See Laurence C. Baker & Linda Schuurman Baker, *Excess Cost of Emergency Department Visits for Nonurgent Care*, HEALTH AFF., Winter 1994, at 162, 170 (finding “significant excess expenditures associated with the use of emergency departments for nonurgent care”).

¹⁰⁶ See NAT'L CTR. FOR HEALTH STATISTICS, *supra* note 91, at 377 tbl.123.

¹⁰⁷ See Kinkead, *supra* note 90, at 56.

¹⁰⁸ *Id.*

B. *The Government and the Medical Profession*

Until just over a hundred years ago, the medical profession was an occasionally disreputable, often low-paid vocation.¹⁰⁹ Physicians were as likely to be trained through apprenticeships as through formal education.¹¹⁰ Few of them worked in, or even had contact with, hospitals.¹¹¹ Many earned more of their income selling potions and patent medicines than rendering services.¹¹²

Members of the profession initiated their own standardization to reverse their uneven social and economic standing. The American Medical Association (AMA) was founded in 1847 to systematize the education that physicians received.¹¹³ Its efforts led to the passage of licensure laws in every state between 1874 and 1915 and the establishment of a private accreditation process for medical schools.¹¹⁴ By 1920, medicine had emerged as a respected science-based enterprise with rigorous standards for new entrants.¹¹⁵

The seminal step in the process of modernization was a survey of medical schools initiated in 1904 by the AMA's Council on Medical Education and conducted by the Carnegie Foundation.¹¹⁶ Under the foundation's auspices, a young educator named Abraham Flexner visited every school in the country to evaluate the quality of instruction and the adequacy of resources.¹¹⁷ The outcome was a report issued in 1910 that recommended closing about half of the medical schools in the United States.¹¹⁸ The report produced its intended effect, as the number of medical schools declined substantially in its wake.¹¹⁹ Those that remained emphasized rigorous scientific training coupled with intensive, hands-on clinical experience in hospitals.¹²⁰

¹⁰⁹ See STARR, *supra* note 18, at 141-44 (discussing the evolution of the status of the medical profession).

¹¹⁰ *Id.* at 40.

¹¹¹ *Id.* at 63.

¹¹² *Id.* at 128.

¹¹³ FIELD, *supra* note, 83 at 20-21.

¹¹⁴ *Id.* at 104.

¹¹⁵ *Id.*

¹¹⁶ *Id.* at 117-18.

¹¹⁷ *Id.* at 118.

¹¹⁸ ABRAHAM FLEXNER, *MEDICAL EDUCATION IN THE UNITED STATES AND CANADA: A REPORT TO THE CARNEGIE FOUNDATION FOR THE ADVANCEMENT OF TEACHING* 143 (1910) (arguing for the "necessity of a reconstruction that will at once reduce the number and improve the output of medical schools").

¹¹⁹ STARR, *supra* note 18, at 119-21.

¹²⁰ *Id.*

The centerpiece of the regulatory structure that emerged to oversee the medical profession was the process of licensing physicians in each state.¹²¹ The profession retained a role for itself in accrediting medical schools and administering competency examinations. In the decades that followed, new sets of regulatory programs enabled the profession to bolster its credibility further. In the 1930s, the AMA first recognized specialties within medicine. It fostered the creation of boards to certify practitioners who meet additional standards as specialists and to permit them to claim particular expertise.¹²² Today, twenty-four boards recognize skill and training in areas that range from cardiology to neurology to nuclear medicine.¹²³

Further regulatory requirements for medical practice followed. Starting with its inception in 1965, the Medicare program mandated that physicians meet eligibility criteria to participate.¹²⁴ In the 1980s, managed care grew in prominence as a reimbursement mechanism and imposed new requirements on physician members.¹²⁵ Throughout all these changes, physicians have always needed permission from hospitals to admit patients and to render clinical services.

All of these regulatory efforts shaped the profession and enhanced public respect for it. They also restricted entry, thereby limiting the supply of practitioners—facilitating a concomitant rise in physician income.¹²⁶ With this arrangement in place, a government infusion of funding for physician services, beginning in the mid-1960s with Medicare and Medicaid, accelerated the profession's expansion and its financial strength.

In 1965, policy attention focused on a predicted looming shortage and maldistribution of physicians, which was perceived as a threat that

¹²¹ See *id.* at 102-12 (discussing the gradual extension towards licensing control of medical services).

¹²² See FIELD, *supra* note 83, at 76-77 (discussing the increasingly important role of specialty boards in granting certifications).

¹²³ See *What Board Certification Means*, AM. BOARD MED. SPECIALTIES, http://www.abms.org/about_board_certification/means.aspx (last visited Mar. 15, 2011) (discussing the certification process the American Board of Medical Specialities' twenty-four member boards use).

¹²⁴ See generally CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE GENERAL INFORMATION, ELIGIBILITY (2007), available at <http://www.cms.gov/manuals/downloads/ge101c04.pdf> (outlining eligibility criteria for physicians participating in Medicare).

¹²⁵ See FIELD, *supra* note 83, at 28-30 (summarizing how managed care entities actually oversee medical services).

¹²⁶ See STARR, *supra* note 18, at 385-87 (explaining how systemic features have altered physicians' income incentives).

could limit access to care.¹²⁷ Wealthy suburbs and upscale urban neighborhoods had a surplus of qualified practitioners, while shortages were the rule in many rural and inner-city areas.¹²⁸ To address this perceived shortfall, Congress allocated significant funding to the creation of new medical schools and the expansion of existing ones.¹²⁹ This funding caused substantial growth in the number of medical schools—from 88 when the program was first implemented to 126 in 1980—and a corresponding rise in the number of graduates from 7409 to 15,135.¹³⁰ The ratio of physicians to population increased from 148 to 202 per 100,000 between 1960 and 1980.¹³¹ By 2004, the United States had about 780,000 physicians in active practice, approximately two-thirds of whom were specialists.¹³²

¹²⁷ In the late 1950s the Office of the Surgeon General predicted a shortfall in physicians; the predictions led to passage of the Health Professions Education Act of 1963, Pub. L. No. 88-129, 77 Stat. 164, which allocated funds for medical school construction and loans for students. Amendments enacted in 1965, the Health Professions Educational Assistance Amendments of 1965 Pub. L. No. 89-290, 79 Stat. 1052, continued the programs and expanded their scope. The legislation, amounts allocated under them, and subsequent health manpower programs, including the Health Manpower Act of 1968, Pub. L. No. 90-490, 82 Stat. 773, and the Comprehensive Health Manpower Training Act of 1971, Pub. L. No. 92-157, 85 Stat. 431, are described in OWEN MACBRIDE, ROBERT WOOD JOHNSON FOUND., AN OVERVIEW OF THE HEALTH PROFESSIONS EDUCATIONAL ASSISTANCE ACT, 1963-1971 (1973), *available at* <http://www.eric.ed.gov/PDFS/ED111245.pdf>. At about the same time, the Association of American Medical Colleges and the AMA committed to promoting medical school growth. Between 1972 and 1982, the number of medical schools increased from 89 to 127 and the number of graduates doubled. MICHAEL J. DILL & EDWARD S. SALSBERG, ASS'N OF AM. MED. COLL., THE COMPLEXITIES OF PHYSICIAN SUPPLY AND DEMAND: PROJECTIONS THROUGH 2025, at 11 (2008), *available at* <http://www.tht.org/education/resources/AAMC.pdf>.

¹²⁸ Physician shortages in rural areas were recognized in the 1950s and 1960s. Today, shortages are attributed, at least in part, to the reluctance of medical students from big cities to relocate to those locations. January W. Payne, *Bringing Better Health to Rural America*, U.S. NEWS & WORLD REP. (Apr. 15, 2010), <http://www.usnews.com/education/articles/2010/04/15/bringing-better-health-to-rural-america>. The maldistribution of physicians, with many gravitating to affluent urban and suburban areas, has been a longstanding policy concern. See COUNCIL ON GRADUATE MED. EDUC., TENTH REPORT: PHYSICIAN DISTRIBUTION AND HEALTH CARE CHALLENGES IN RURAL AND INNER-CITY AREAS, at xii (1998), *available at* <http://www.cogme.gov/10.pdf> (seeking to address the problem of geographic maldistribution).

¹²⁹ The law that initially implemented funding to increase medical school enrollments was the Higher Education Act of 1965, Pub. L. No. 89-329, 79 Stat. 1219 (portions codified at 20 U.S.C. § 1088).

¹³⁰ STARR, *supra* note 18, at 421.

¹³¹ *Id.* at 422.

¹³² Robert I. Phillips et al., *COGME's 16th Report to Congress: Too Many Physicians Could Be Worse Than Wasted*, 3 ANNALS FAM. MED. 268, 269 tbl.1 (2005).

This attempt at management of the physician workforce did not eliminate cost pressures and distribution inequities, but it did help to transform the nature of the profession.¹³³ By the time funding for the expansion boom ended in the 1980s, the United States had twice as many medical school graduates each year.¹³⁴ During this time, medical schools also solidified their standing as research-based institutions,¹³⁵ and research findings, at medical schools and elsewhere, led to advances in technology that helped physicians offer new services.¹³⁶ By funding an expansion in the number of physicians, the government had conferred on the profession new prestige and new revenue-generating opportunities.

However, an even greater force in transforming the medical profession during the late twentieth century was the same initiative that had transformed the hospital industry, the Medicare program. Medicare made available huge amounts of money for patient access to physician services, which permitted demand for these services to grow dramatically. Part B of the program, which reimburses for physician and other professional services, had a budget of \$2.2 billion in 1970; that budget rose to over \$152 billion in 2005.¹³⁷ The pool of beneficiaries grew during that time from 19.5 million to almost 40 million.¹³⁸ In other words, the number of beneficiaries merely doubled while the budget grew by a factor of nearly seventy.

The combination of Medicare reimbursement and government funding for physician training stimulated another tremendous expansion in the size of the medical profession toward the end of the twentieth century. In 1975, the United States had 15.3 physicians for every

¹³³ While funding for medical school expansion has expired, the government continues to influence the size and shape of the physician workforce through grants and loans administered by the Health Resources and Services Administration (HRSA). See *BHPR Grants*, HEALTH RESOURCES & SERVICES ADMIN., <http://bhpr.hrsa.gov/grants/default.htm> (last visited Mar. 15, 2011). Funding programs that the agency administers emphasize help to future practitioners who will enter primary care and practice in underserved regions. *Id.* The effect of this funding on the overall composition of the profession, however, has been fairly limited.

¹³⁴ DILL & SALSBERG, *supra* note 127, at 11, 12.

¹³⁵ See Robert G. Petersdorf, *Medical Schools and Research: Is the Tail Wagging the Dog?*, DAEDALUS, Spring 1986, at 99, 101 (stating that medical schools incorporated sophisticated research departments during the 1950s and 1960s).

¹³⁶ See Elliott S. Fisher & H. Gilbert Welch, *Avoiding the Unintended Consequences of Growth in Medical Care*, 281 JAMA 446, 450 (1999) (opining that “physicians have more to do” because of the rapid increase in treatment and testing options).

¹³⁷ NAT’L CTR. FOR HEALTH STATISTICS, *supra* note 91, at 404.

¹³⁸ *Id.*

10,000 people.¹³⁹ By 2004, that number had grown to 26.3.¹⁴⁰ The expanded physician workforce tended to cluster in the most lucrative aspect of the profession, specialty practice. During the thirty-year period beginning in 1975, ten years after Medicare's enactment, the number of physicians in general and family practice increased from 46,347 to 74,999, for an expansion rate of about 60%, while the number of office-based specialists increased from 126,112 to 329,344 for an expansion rate almost three times as great.¹⁴¹ Specialties that focus on conditions primarily afflicting the elderly, who comprise the bulk of Medicare beneficiaries, experienced some of the highest rates of growth, with the number of cardiologists more than tripling from 5046 to 17,519, the number of neurologists growing almost fivefold from 1862 to 10,400, and the number treating pulmonary diseases growing almost sevenfold from 1166 to 7321.¹⁴²

Beyond these large financial outlays, the Medicare program took two more significant steps during the late twentieth century to shape the expanding physician workforce. The first was through payments for the clinical training of new physicians. After completing medical school, new doctors usually spend the next three to five years as residents and fellows in hospitals, where they hone their skills as apprentices in a particular specialty.¹⁴³ These physicians-in-training play an important role in the clinical care that their hospitals provide, but they require considerable supervision, which detracts from the hospital's overall productivity.¹⁴⁴ To compensate for this cost, Medicare

¹³⁹ *Id.* at 354.

¹⁴⁰ *Id.*

¹⁴¹ NAT'L CTR. FOR HEALTH STATISTICS, *supra* note 2, at 347 tbl.107. The number of office-based specialists is derived from the chart by subtracting the number of physicians in general and family practice, internal medicine, and pediatrics, which are the major primary care specialties, from the total number in office-based practice.

¹⁴² *Id.*

¹⁴³ *Requirements for Becoming a Physician*, AM. MED. ASS'N, <http://www.ama-assn.org/ama/pub/education-careers/becoming-physician.page> (last visited Mar. 15, 2011).

¹⁴⁴ Several tasks involved in supervising residents and fellows at teaching hospitals reduce the efficiency of physicians involved their education, including direct supervision, didactic training, and administrative tasks such as completing evaluation forms. Robert Mechanic et al., *Teaching Hospital Costs: Implications for Academic Mission in a Competitive Market*, 280 JAMA 1015, 1017 (1998). Additional Medicare payments account for the added expenses. CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE POLICY CLARIFICATIONS ON GRADUATE MEDICAL EDUCATION PAYMENTS FOR RESIDENTS TRAINING IN NON-HOSPITAL SETTINGS 3 (2005), *available at* <https://www.cms.gov/AcuteInpatientPPS/Downloads/nonhospQA.pdf>. These expenses, which have been estimated to add as much as 83% to the cost of care, are in part responsible for the higher costs of treating patients in teaching hospitals. Mechanic et al., *supra*, at 1017.

supplements the amount paid for patient care to teaching hospitals that administer training programs for residents.¹⁴⁵ The government actively manages the size and kinds of training programs eligible for these “graduate medical education” (GME) payments by designating a predetermined amount for training in each specialty.¹⁴⁶ The result is that Medicare’s allocation of training payments among specialties sets limits on the number of new physicians who can enter each field.¹⁴⁷

The second way Medicare crafts the composition of the medical profession is through the structure of its payment mechanism. When the program began operation in 1966, physician services were reimbursed according to the prevailing rates in each community, while hospital services were reimbursed based on the actual cost of providing care.¹⁴⁸ By the late 1970s, it had become evident that this system encouraged overuse of services and excessive costs.¹⁴⁹ While the hospital payment process was changed in 1983 to base reimbursement rates on a patient’s diagnosis, the physician payment scheme was changed to a fee schedule in 1992.¹⁵⁰ That schedule bases reimburse-

¹⁴⁵ See CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 144, at 1 (noting that Medicare makes both direct and indirect payments to support medical education at teaching hospitals).

¹⁴⁶ See 42 C.F.R. § 413.78 (2010) (containing general requirements for GME payments, including the determination of the number of residencies that are funded).

¹⁴⁷ The Balanced Budget Act of 1997 implemented substantial cuts to Medicare reimbursement, some of which targeted the size of GME payments to hospitals. See Pub. L. No. 105-33, § 4621(a)–(b), 111 Stat. 251, 475-76 (decreasing reimbursement percentages for GME payments, providing that payments are dependent on resident ratios, and limiting allopathic and osteopathic residency spots). These cuts created a significant financial challenge for many teaching hospitals, which depend on these payments to maintain physician training programs. See *The Balanced Budget Act of 1997: A Current Look at Its Impact on Patients and Providers: Hearing Before the H. Subcomm. on Health and Env’t of the H. Comm. on Commerce*, 106th Cong. 6 (2000) (statement of Gail R. Wilensky, Chair, Medicare Payment Advisory Comm’n), available at <http://pages.stern.nyu.edu/~jasker/BBA1.pdf> (“Hospitals’ financial status deteriorated significantly in 1998 and 1999.”).

¹⁴⁸ See John K. Iglehart, *Medicare Begins Prospective Payment of Hospitals*, 308 NEW ENG. J. MED. 1428, 1428 (1983) (describing the change from the prior Medicare policy of reimbursing all “reasonable costs”); Lauren A. McCormack & Russel T. Burge, *Diffusion of Medicare’s RBRVS and Related Physician Payment Policies*, HEALTH CARE FIN. REV., Winter 1994, at 159, 159 (referencing Medicare’s prior “customary, prevailing, and reasonable” (CPR) payment methodology for physician reimbursement).

¹⁴⁹ See OFFICE OF INSPECTOR GEN., OEI-09-00-00200, MEDICARE HOSPITAL PROSPECTIVE PAYMENT SYSTEM: HOW DRG RATES ARE CALCULATED AND UPDATED I (2001), available at <http://oig.hhs.gov/oei/reports/oei-09-00-00200.pdf> (“Medicare’s hospital costs under this payment system increased dramatically; between 1967 and 1983, costs rose from \$3 billion to \$37 billion annually.” (citations omitted)).

¹⁵⁰ See William C. Hsiao et al., *Overview of the Development and Refinement of the Resource-Based Relative Value Scale: The Foundation for Reform of U.S. Physician Payment*, 30

ment on the training and practice expense involved in rendering each service, regardless of the prevailing rate in the market.¹⁵¹

The physician fee schedule, officially known as the Resource-Based Relative Value Scale (RBRVS), initially set its payment rates to be more rewarding for primary care specialties, and less so for surgery and other procedure-oriented fields, than the market rates in most communities had been.¹⁵² However, more recently, the pendulum has swung the other way, with Medicare offering higher relative payments for performance of procedures.¹⁵³ The result once again has been a reshaping of economic incentives in medicine due to government policy.¹⁵⁴

The medical profession has existed for thousands of years, at least since the time of Hippocrates. Physicians would still be rendering care, regardless of these government programs. However, the size and shape of the profession in the United States would be quite different without them.

C. *The Government and the Pharmaceutical Industry*

The pharmaceutical industry is often held out as a prime example of the private market's success in enhancing health while reaping investor rewards. It is perennially among the most profitable of all

MED. CARE NSI, NSI (Supp. 1992) (providing a brief history of the implementation of the change to Medicare physician reimbursement).

¹⁵¹ *Id.*

¹⁵² See F. Kenneth Ackerman, III, *The Movement Toward Vertically Integrated Regional Health Systems*, HEALTH CARE MGMT. REV., Summer 1992, at 81, 85 (stating that the system's goal was to reward primary care physicians at the expense of specialists).

¹⁵³ John D. Rowson, *Unintended Consequences of Resource-Based Relative Value Scale Reimbursement*, 298 JAMA 2308, 2309 (2007) ("Current reimbursement incentives substantially favor procedures and technical interventions and offer financial advantages for expensive care, thereby encouraging specialty services." (citation omitted)).

¹⁵⁴ Physician incomes have historically followed Medicare's spending growth. During the 1980s, for example, overall incomes for the profession rose by about 25% in constant dollars. See Gregory C. Pope & John E. Schneider, *Trends in Physician Income*, HEALTH AFF., Spring 1992, at 181, 183 (noting that average physician income rose from \$125,500 in 1982 to \$155,800 in 1989). Surgeons saw the greatest increase in income, at 33%, while other medical specialists saw a rise of 31%. *Id.* at 183-88. In sharp contrast, salaries of general and family practice physicians, whose practice tends to include a much smaller share of Medicare patients, gained only about 5%. *Id.* Between 1995 and 2003, the largest increase in physician incomes in absolute dollars was for medical specialists, followed by surgical specialists, followed by those in primary care. While incomes actually fell slightly during this period in inflation-adjusted dollars, the relative change for these three kinds of physicians followed the same pattern. HA T. TU & PAUL B. GINSBURG, CTR. FOR STUDYING HEALTH SYS. CHANGE, LOSING GROUND: PHYSICIAN INCOME, 1995-2003, at 2 (2006), available at <http://www.hschange.com/CONTENT/851/851.pdf>.

American industries.¹⁵⁵ It has produced a cascading assortment of products to treat an ever-growing range of illnesses, resulting in major enhancements to life and health. The industry's horizons are poised for a new expansion with the maturation of biotechnology and the growing use of genomics.¹⁵⁶

The industry has traditionally been composed of private for-profit corporations.¹⁵⁷ With rare exceptions, government entities do not manufacture pharmaceuticals, nor do nonprofit organizations.¹⁵⁸ On the surface, this may seem to exemplify purely private enterprise in the service of health care. However, this industry—as much as any other in the health care sector—relies on a base of government initiative.

Pharmaceutical manufacturing is among the most research-intensive industries.¹⁵⁹ Without a huge scientific apparatus, development of new products would be impossible. This apparatus rests on a foundation of basic research that generates discoveries about fundamental elements of biology. This basic research is funded primarily by the federal government through the National Institutes of Health (NIH), the largest biomedical research enterprise in the world.¹⁶⁰

¹⁵⁵ See JANET LUNDY, THE HENRY J. KAISER FAMILY FOUND., PUB. NO. 3057-08, PRESCRIPTION DRUG TRENDS 4 (2010), available at <http://www.kff.org/rxdrugs/upload/3057-08.pdf> (“[F]rom 1995 to 2002, pharmaceutical manufacturers were the nation’s most profitable industry (profits as a percent of revenues).”). The industry’s profits as a percent of revenue were 19.3% in 2008, just over 1% lower than the most profitable industry, which was communications equipment. *Top Industries: Most Profitable*, FORTUNE (May 4, 2009), <http://money.cnn.com/magazines/fortune/fortune500/2009/performers/industries/profits>.

¹⁵⁶ See, e.g., Geoffrey S. Ginsberg & Huntington F. Willard, *Foundations of Genomic and Personalized Medicine* (noting the rapid growth of genomic medicine and predicting future advances), in *ESSENTIALS OF GENOMIC AND PERSONALIZED MEDICINE* 1, 7-8 (Geoffrey S. Ginsberg & Huntington F. Willard eds., 2010).

¹⁵⁷ The concept of structuring pharmaceutical companies on a nonprofit basis has recently been discussed as an alternative to the traditional for-profit model. See generally Victoria G. Hale et al., *Oxymoron No More: The Potential of Nonprofit Drug Companies to Deliver on the Promise of Medicines for the Developing World*, 24 HEALTH AFF. 1057 (2005). It is seen as a radical departure from the basis on which the industry has traditionally rested. See *id.*

¹⁵⁸ *Id.*

¹⁵⁹ See CONG. BUDGET OFFICE, PUB. NO. 2589, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 7-9 (2006), available at <http://www.cbo.gov/ftpdocs/76xx/doc7615/10-02-DrugR-D.pdf> (“The pharmaceutical industry spends more on research and development relative to its sales revenue, than almost any other industry in the United States.”).

¹⁶⁰ Peter Suber, *An Open Access Mandate for the National Institutes of Health*, 2 OPEN MED. 39, 39 (2008), available at <http://www.openmedicine.ca/article/viewArticle/213/135>.

NIH's 2009 annual budget stood at more than \$29 billion.¹⁶¹ This figure reflects a doubling of its authorized budget between 1998 and 2003.¹⁶² Congress added an additional \$10 billion for 2009 in the economic stimulus bill enacted that year.¹⁶³

The importance of the NIH to biomedical research today cannot be overstated.¹⁶⁴ It is by far the largest single source of financial support for medical research in any country.¹⁶⁵ Its funding underpins the scientific enterprise not only in the United States but in many other nations as well. Every 1% increase in public research funding is estimated to produce an increase of between 2% and 2.4% in the number of commercially available new compounds.¹⁶⁶ The rate of return from public funding of biomedical research is projected to be as high as 30% per year.¹⁶⁷

Congress created the NIH to fund biomedical investigations across the United States.¹⁶⁸ It was the culmination of a decade-long ef-

¹⁶¹ NAT'L INSTS. OF HEALTH, SUMMARY OF THE FY 2009 PRESIDENT'S BUDGET 2 (2008), available at <http://officeofbudget.od.nih.gov/pdfs/FY09/Summary%20of%20FY%202009%20Budget-Press%20Release.pdf>.

¹⁶² See *The NIH Almanac—Appropriations*, NAT'L INSTS. HEALTH, <http://www.nih.gov/about/almanac/appropriations/part2.htm> (last visited Mar. 15, 2011) (reporting that the NIH budget was nearly \$14 billion in 1998, but over \$27 billion in 2003).

¹⁶³ See Letter from Douglas W. Elmendorf, Dir., Cong. Budget Office, to Nancy Pelosi, Speaker, U.S. House of Representatives 2 tbl.2 (Feb. 13, 2009), available at <http://www.cbo.gov/ftpdocs/99xx/doc9989/hr1conference.pdf>.

¹⁶⁴ The rise of the NIH over the second half of the twentieth century paralleled significant advances in medical science. See *Chronology of Events*, NAT'L INSTS. HEALTH, http://www.nih.gov/about/almanac/historical/chronology_of_events.htm (last visited Mar. 15, 2011) (describing past NIH achievements and current research).

¹⁶⁵ NIH boasts that it is the largest source of funding for medical research in the world. *About the National Institutes of Health*, NAT'L INSTS. HEALTH (Oct. 27, 2010), <http://www.nih.gov/about>.

¹⁶⁶ Andrew A. Toole, *The Impact of Public Basic Research on Industrial Innovation: Evidence from the Pharmaceutical Industry* 5 (Stan. Inst. for Econ. Policy Research, Discussion Paper No. 00-07, 2000), available at <http://www.stanford.edu/group/siepr/cgi-bin/siepr/?q=system/files/shared/pubs/papers/pdf/00-07.pdf> (concluding that "publicly funded basic research contributes to product innovation in the pharmaceutical industry").

¹⁶⁷ See Iain M. Cockburn & Rebecca M. Henderson, *Publicly Funded Science and the Productivity of the Pharmaceutical Industry* (concluding that even the seemingly high 30% per year return on investment may be an underestimate, as the number may "fail to fully capture the wider impact of pharmaceutical innovation on health and well-being"), in 1 INNOVATION POLICY AND ECONOMY 1, 1 (Adam B. Jaffe et al. eds., 2000).

¹⁶⁸ *A Short History of the National Institutes of Health—WWI and the Ransdell Act of 1930*, NAT'L INSTS. HEALTH, http://history.nih.gov/exhibits/history/docs/page_04.html (last visited Mar. 15, 2011).

fort to increase the money available for scientific research, as medical breakthroughs in the early part of the twentieth century demonstrated the significance of the results that could be achieved.¹⁶⁹ In 1937, Congress established the National Cancer Institute, which was later incorporated into the NIH, the first distinct institute to focus on a single kind of disease or physiological system.¹⁷⁰ Additional institutes were added to the NIH in the years immediately following World War II, along with substantial budget increases.¹⁷¹ Today, the agency operates through twenty-seven such component agencies.¹⁷² In the 1950s, the NIH acquired new capabilities to conduct intramural research—experiments within its own walls by its employed scientists—with the opening of its sprawling campus in Bethesda, Maryland.¹⁷³ The agency now employs 6000 scientists to conduct these studies.¹⁷⁴

The majority of the NIH budget is awarded to researchers outside of the agency through a process of competitive grants.¹⁷⁵ Over 300,000 investigators at more than 3000 universities and private research institutes receive this funding.¹⁷⁶ The remainder of the budget supports the 6000 scientists who conduct intramural research in the agency's own facilities.¹⁷⁷ Beyond the hundreds of thousands of established researchers whose careers NIH funding sustains, NIH training grants support the entry of thousands of future researchers into the world of science, and thousands of graduate students who work in the laboratories of professors who receive NIH funding.¹⁷⁸

¹⁶⁹ *Id.*

¹⁷⁰ *A Short History of the National Institutes of Health—NCI*, NAT'L INSTS. HEALTH, http://history.nih.gov/exhibits/history/docs/page_05.html (last visited Mar. 15, 2011).

¹⁷¹ *A Short History of the National Institutes of Health—New Institutes*, NAT'L INSTS. HEALTH, http://history.nih.gov/exhibits/history/docs/page_07.html (last visited Mar. 15, 2011).

¹⁷² *See Chronology of Events*, *supra* note 164.

¹⁷³ *See A Short History of the National Institutes of Health—The Clinical Center*, NAT'L INSTS. HEALTH, http://history.nih.gov/exhibits/history/docs/page_08.html (last visited Mar. 15, 2011).

¹⁷⁴ *About the National Institutes of Health*, *supra* note 165.

¹⁷⁵ *See Chronology of Events*, *supra* note 164.

¹⁷⁶ *Id.*

¹⁷⁷ *About the National Institutes of Health*, *supra* note 165. More than 80% of the NIH budget funds over 300,000 researchers at over 3000 universities and research institutions. *Id.*

¹⁷⁸ The NIH provides training grants that support approximately 3000 graduate students in over 250 training programs. *For Students: NIGMS Support for Graduate Training*, NAT'L INSTS. HEALTH, <http://www.nigms.nih.gov/Training/Overview.htm> (last visited Mar. 15, 2011).

In addition to funding, the NIH also administers a regulatory apparatus that governs much of the biomedical research conducted in the United States. Most prominently, the Government Patent Policy Act of 1980, commonly known as the Bayh-Dole Act, provides patent protection for products developed by private companies that succeed in commercializing the fruits of NIH-funded discoveries.¹⁷⁹ Under the National Research Act of 1974, institutional review boards (IRBs) housed in each institution receiving funding, review, with NIH oversight, research involving human subjects.¹⁸⁰

A mechanism known as a cooperative research and development agreement (CRADA) explicitly encourages commercialization of NIH-sponsored findings. CRADAs are partnership arrangements that facilitate joint development of drugs and other technologies between private companies and the government.¹⁸¹ The foundation for CRADAs is a series of laws enacted in the 1980s to encourage technology transfer from government laboratories to private firms. The most significant was the Stevenson-Wydler Technology Innovation Act of 1980, which established a set of federal offices to coordinate technology transfer for each federal research agency.¹⁸² The Act was amended by the Federal Technology Transfer Act of 1986, which mandated that the federal government actively seek opportunities to transfer tech-

¹⁷⁹ 35 U.S.C. §§ 202, 210 (2006).

¹⁸⁰ 42 U.S.C. § 289 (2006).

¹⁸¹ “A CRADA is a formal research and development agreement of limited duration and scope between PHS [Public Health Service] Agencies and one or more non-Federal collaborator(s) such as a pharmaceutical or biotechnology company. Research can cover basic, preclinical, or clinical areas, a combination of any, or even a nontraditional project such as developing software.” *Glossary of Terms*, NAT’L CANCER INST.: TECH. TRANSFER CTR., <http://ttc.nci.nih.gov/glossary.php> (last visited Mar. 15, 2011). CRADAs allow government agencies, such as NIH, to pool resources with private industry to pursue promising avenues of research. Bruce Goldstein, *Overview of Technology Transfer, Part IV*, NAT’L CANCER INST.: TECH. TRANSFER CTR., <http://ttc.nci.nih.gov/resources/brochures/sec7c.php> (last visited Mar. 15, 2011). These may include therapies for rare diseases, uses of drugs for new indications, and development of new vaccines. *Id.* Often, private companies consider such ventures too risky to pursue on their own. *Id.* They may also lack sufficient expertise. *Id.* For its part, NIH can access manufacturing channels and research materials that might otherwise be prohibitively expensive. *Id.* CRADAs are authorized and subject to requirements set forth in 15 U.S.C. § 3710.

¹⁸² Pub. L. No. 96-480, 94 Stat. 2311 (codified as amended at 15 U.S.C. §§ 3701–3717 (2006)). In the NIH, this is the Office of Technology Transfer. A description of the Office’s function can be found on the website of the NIH Office of Technology Transfer. See *Licensing & Royalties*, NIH OFF. TECH. TRANSFER, http://www.ott.nih.gov/licensing_royalties/royalties_administration.aspx (last visited Mar. 15, 2011).

nology to industry, academia, and state and local governments.¹⁸³ Private firms receive strong encouragement to enter into CRADAs through the opportunity, conferred by the Bayh-Dole Act,¹⁸⁴ to retain patent rights to the partnership's products.¹⁸⁵

NIH-funded research represents, in large part, basic science—fundamental knowledge that advances overall understanding of biological processes. Applied research turns basic knowledge into actual therapies. Traditionally, private companies, which rely on NIH research findings as their intellectual building blocks, have taken the lead in conducting these investigations.¹⁸⁶ As a reflection of this implicit partnership, as NIH budgets have grown, research and development spending by the pharmaceutical industry has, as well. Between 1993 and 2004, NIH's budget more than doubled,¹⁸⁷ yet in 1987, industry spending surpassed NIH's budget.¹⁸⁸

There is some overlap between NIH research and that of the pharmaceutical industry. A portion of the industry's efforts involve basic research into underlying biological mechanisms with no relation to a specific product. A portion of NIH funds go towards clinical trials

¹⁸³ Pub. L. No. 99-502, 100 Stat. 1785 (codified as amended at 15 U.S.C. §§ 3701-3717 (2006)).

¹⁸⁴ Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified as amended at 35 U.S.C. §§ 202, 210 (2006)).

¹⁸⁵ An example of a successful CRADA is the development of the drug Taxol, which is now a standard treatment for ovarian and breast cancer. See Frank Stephenson, *A Tale of Taxol*, FLA. ST. UNIV. RES. REV. (Fall 2002), <http://www.rinr.fsu.edu/fall2002/taxol.html> (telling the story of Taxol's development over a forty-year period beginning with the collection of plant specimen in a Washington State National Forest in 1962). NIH and Bristol-Meyers Squibb jointly developed the drug. *Id.* Sales reached nearly \$1.6 billion in 2000 and produced total revenue of \$11 billion by 2002. *Id.* Subsequently, Taxol was repurposed under a second CRADA as a coating for cardiac stents to discourage the growth of scar tissue in arteries. See NIH OFFICE OF TECH. TRANSFER, NIH PACLITAXEL-COATED STENTS: A WAY TO BYPASS BY-PASS SURGERY (2005), available at <http://www.ott.nih.gov/pdfs/TaxusCS.pdf>. Boston Scientific manufactures this products. *Id.* Boston Scientific's Taxus stent "is believed to be the most successful launch of a medical device in the history of medical devices, with sales approximating \$3 billion in the first year of commercialization." *Company Overview*, INNOVIA, <http://www.innovia-llc.com/0909/company-overview.html> (last visited Mar. 15, 2001).

¹⁸⁶ Ashley J. Stevens et al, *The Role of Public-Sector Research in the Discovery of Drugs and Vaccines*, 364 NEW ENG. J. MED. 535, 536 (2011).

¹⁸⁷ See U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-07-49, NEW DRUG DEVELOPMENT: SCIENCE, BUSINESS, REGULATORY, AND INTELLECTUAL PROPERTY ISSUES CITED AS HAMPERING DRUG DEVELOPMENT EFFORTS 4 (2006), available at <http://www.gao.gov/new.items/d0749.pdf> (reporting that industry's research spending increased from nearly \$16 billion to almost \$40 billion during that eleven-year time span).

¹⁸⁸ CONG. BUDGET OFFICE, *supra* note 159, at 28 fig.4-1 (juxtaposing spending of private drug companies and spending of the NIH over a twenty-five-year period).

for drugs. However, most of the \$40 billion in private funding supports applied investigations related to products in development, and most of the NIH budget supports basic studies that expand overall knowledge.¹⁸⁹ These two funding sources, in effect, work in tandem to foster medical innovation. The government carries the front end that generates conceptual support for new product ideas, and industry carries the back end by putting new concepts to work. In this way, the two halves of the research enterprise depend on one another.

As impressive as these achievements are, an NIH initiative transforming the foundations of medical science and clinical practice is poised to dwarf them. In 1988, Congress allocated initial funding for the Human Genome Project (HGP) as a joint effort of the NIH and the Department of Energy.¹⁹⁰ The goal was to produce a complete map of the human genome, the sequence of genes that directs all biological processes.¹⁹¹ The Project's work resulted in the completion of an initial sequence in 2000.¹⁹² That sequence was the fruition of work both of the HGP and of a competing private effort that built on publicly accessible HGP data.¹⁹³ A complete map of the human genome was published in 2001.¹⁹⁴

The HGP's accomplishment in mapping the biochemical structure of human existence has been called "one of the remarkable

¹⁸⁹ See *id.* at 3 ("In general, the government tends to focus on basic research, whereas private firms focus much more on applied research and development."). The agency classified 54.6% of its 2006 budget as basic research. Jonathan Fishburn, *National Institutes of Health in the FY 2006 Budget*, in AAAS REPORTS XXX: RESEARCH AND DEVELOPMENT FY 2006, at 81, 84 (2005), available at <http://www.aaas.org/spp/rd/06pch8.pdf>.

¹⁹⁰ The HGP's initial 1988 budget allocated \$10.7 million to the Department of Energy and \$17.2 million to the NIH. *Human Genome Project Budget*, HUMAN GENOME PROJECT INFO., http://www.ornl.gov/sci/techresources/Human_Genome/project/budget.shtml (last visited Mar. 15, 2011).

¹⁹¹ See NAT'L INSTS. OF HEALTH, HUMAN GENOME PROJECT 1 (2010), available at [http://report.nih.gov/NIHfactsheets/Pdfs/HumanGenomeProject\(NHGRI\).pdf](http://report.nih.gov/NIHfactsheets/Pdfs/HumanGenomeProject(NHGRI).pdf) (providing an overview of the history and future of the Human Genome Project).

¹⁹² The results of the HGP announced in 2000 were described as a "working draft" of the human genome. *Major Events in the U.S. Human Genome Project and Related Projects*, HUMAN GENOME PROJECT INFO., http://www.ornl.gov/sci/techresources/Human_Genome/project/timeline.shtml (last visited Mar. 15, 2011).

¹⁹³ The role of the private company Celera and its success in creating a sequence of the human genome is described in J. Craig Venter et al., *The Sequence of the Human Genome*, 291 SCIENCE 1304, 1306 (2001).

¹⁹⁴ A press conference to announce the publication of a working draft of the human genome was held on February 12, 2001. See *Major Events in the U.S. Human Genome Project*, *supra* note 192.

achievements in the history of science.”¹⁹⁵ Starting in 1993, well before the HGP was finalized, NIH scientists began to investigate the function of each gene and its role in human health and disease.¹⁹⁶ Within ten years, several hundred diagnostic tests had been developed to probe for sensitivity to a range of genetically based disorders.¹⁹⁷

Genomic research has also begun to transform the process of developing new drugs. Tests can determine individual variations in susceptibility to both therapeutic and adverse effects.¹⁹⁸ A new era of “tailored” medicine, with drug regimens customized according to a patient’s genetic makeup, lies on the horizon.¹⁹⁹

Beyond the apparatus of NIH funding, government initiatives support the private pharmaceutical industry in other ways. The Orphan Drug Act, passed by Congress in 1983, implemented a set of targeted incentives to induce companies to develop drugs for rare conditions, commonly referred to as “orphan diseases.”²⁰⁰ These diseases—including Huntington’s disease, myoclonus, Lou Gehrig’s disease, Tourette’s syndrome, and muscular dystrophy²⁰¹—are often debilitating and even life-threatening, but because they strike relatively few patients, there is a limited market for treatments.²⁰² The Act provides financial and regulatory incentives to encourage private companies to

¹⁹⁵ *International Consortium Completes Human Genome Project*, NIH: NAT’L HUM. GENOME RES. INST. (Apr. 14, 2003), <http://www.genome.gov/11006929>.

¹⁹⁶ See Francis S. Collins, Shattuck Lecture, *Medical and Societal Consequences of the Human Genome Project*, 341 NEW ENG. J. MED. 28, 30-34 (1999) (discussing implications of the Human Genome Project for diagnosing and treating genetic disorders).

¹⁹⁷ *Id.*

¹⁹⁸ Andrew Smart et al., *Tailored Medicine: Whom Will It Fit? The Ethics of Patient and Disease Stratification*, 18 BIOETHICS 322, 323 (2004).

¹⁹⁹ Tailored medicine permits clinicians to customize treatment to each patient’s genetic makeup. By analyzing a patient’s genome, it may be possible to predict the diseases a patient will be susceptible to and the drugs and other therapies that will be most effective and least harmful. See *id.* at 337-40 (2004) (weighing the ethical issues pharmacogenetics poses).

²⁰⁰ 21 U.S.C. §§ 360aa–360ee (2006).

²⁰¹ *Id.* § 360aa.

²⁰² The Orphan Drug Act authorized grants, tax credits, and seven years of additional market exclusivity beyond a patent’s expiration for drugs that are developed for rare conditions. See John Henkel, *Orphan Products: New Hope for People with Rare Disorders*, FDA CONSUMER, June 1994, at 17, 20 (detailing the Act’s incentives to drug companies). Rare disorders are defined as ailments afflicting 200,000 people or fewer. Over 7,000 rare disorders have been identified affecting over 25 million people in total. FDA CONSUMER HEALTH INFO., DEVELOPING ORPHAN PRODUCTS: FDA AND RARE DISEASE DAY 1-2 (2009), available at <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/ucm107301.pdf>.

take the risk of entering these markets.²⁰³ In the twenty-five years following the law's enactment, more than 300 treatments for orphan diseases received Food and Drug Administration (FDA) approval, compared with only ten in the previous decade.²⁰⁴

The private pharmaceutical industry has also benefited from a regulatory apparatus that reassures the public about the products that it sells.²⁰⁵ FDA oversight of drug safety enhances consumer trust.²⁰⁶ Years of preclinical and clinical testing conducted under FDA guidance, reduce promising new products down to a tiny percentage that actually make it to market. While hazardous drugs can slip through, public confidence in the industry hinges on this process.

These government programs have made the pharmaceutical industry one of the most profitable in the United States. According to the most widely used measures, drug companies earned three times the median of all Fortune 500 companies in 2004.²⁰⁷ Between 1995 and 2002, pharmaceutical manufacturing was the most profitable industry in the United States, and since then it has remained in the top three.²⁰⁸ Sales of prescription drugs in the United States now exceed \$300 billion a year.²⁰⁹ Even during the recession year of 2009, domes-

²⁰³ *Developing Products for Rare Diseases & Conditions*, FOOD & DRUG ADMIN., <http://www.fda.gov/forindustry/developingproductsforrare diseasesconditions/default.htm> (last visited Mar. 15, 2011).

²⁰⁴ FDA CONSUMER HEALTH INFO., *supra* note 202, at 1-2.

²⁰⁵ Congress granted the FDA authority to oversee the safety and efficacy of drugs and devices in a series of steps over the course of the past 100 years. The Pure Food and Drug Act, passed by Congress in 1906, created the FDA. Pub. L. No. 59-384, 34 Stat. 768 (1906) (codified at 21 U.S.C. §§ 1-15 (1934)) (*repealed by* Food, Drug and Cosmetic Act, 21 U.S.C. § 392(a)). Congress expanded government authority to regulate medical products in 1938 under the Food, Drug and Cosmetic Act, which mandated premarket approval of safety. Pub. L. No. 75-717, 52 Stat. 1040 (1938) ((codified as amended in scattered sections of 21 U.S.C.)). The Kefauver-Harris amendments of 1962 added efficacy as a criterion in the review process. Pub. L. No. 87-781, 76 Stat. 780 (1962) (codified as amended in scattered sections of 21 U.S.C.). The Food and Drug Amendments Act of 2007 enhanced postmarket safety oversight. Pub. L. No. 110-85, 121 Stat. 823 (codified as amended in scattered sections of 21 U.S.C.). Congress enacted each of these laws to reassure the public in the wake of a scandal over food or drug safety.

²⁰⁶ 2004 polling data indicate that 70% of Americans have a great deal or a moderate amount of confidence in the FDA to ensure prescription drug safety, although 37% said their confidence had diminished in the previous few years. Julie Appleby, *Poll: Confidence in FDA Still Strong Despite Blunders*, USA TODAY, Nov. 24, 2004, at 2A.

²⁰⁷ See LUNDY, *supra* note 155, at 4 (noting the enormous profitability of the pharmaceutical industry).

²⁰⁸ *Id.*

²⁰⁹ Press Release, IMS Health, IMS Health Reports U.S. Prescription Sales Grew 5.1 Percent in 2009, to \$300.3 Billion (Apr. 1, 2010), *available at* <http://www.imshealth.com>.

tic sales remained robust, growing at a rate of 5.1%.²¹⁰ Global sales for 2009 stood at \$837 billion, having risen 7% from a year earlier.²¹¹ The fastest-growing component, biotechnology, owes its existence to NIH-funded research, as does the dawning era of genomic medicine.²¹² The government research infrastructure has created an industrial powerhouse.

D. *The Government and Private Health Insurance*

The United States is the only industrialized country without a universal health insurance system that guarantees coverage to all citizens.²¹³ The result is that over 50.7 million Americans were uninsured in 2009.²¹⁴ The uninsured face considerable difficulty in obtaining even routine care, as well as the prospect of financial ruin in the event of a medical emergency. This situation was the major impetus behind the passage of PPACA.

Nevertheless, the lack of a coordinated national coverage system does not mean that the government is absent from the health insurance market. In fact, the government directly funds coverage for almost 30% of the population and indirectly funds coverage for another

com/portal/site/imshealth/menuitem.a46c6d4df3db4b3d88f611019418c22a/?vgnextoid=d690a27e9d5b7210VgnVCM100000ed152ca2RCRD&cpsexcurrchannel=1.

²¹⁰ *Id.* The appropriate accounting for pharmaceutical profitability is somewhat controversial. Some analysts believe that the treatment of research and development costs in standard assessments is incorrect, contending that it should be treated as an investment subject to depreciation rather than as an expense. This approach generates much lower rates of profits in comparison to assets. Nevertheless, the resulting profitability is still consistently higher than the average for all American industries. See F.M. Scherer, *The Pharmaceutical Industry—Prices and Progress*, 351 NEW ENG. J. MED., 927, 929 (2004) (explaining some common misconceptions associated with the computation of profits in the pharmaceutical industry).

²¹¹ Press Release, IMS, IMS Forecasts Global Pharmaceutical Market Growth of 5-8% Annually Through 2014; Maintains Expectations of 4-6% Growth in 2010 (Apr. 20, 2010), available at <http://www.imshealth.com/portal/site/imshealth/menuitem.a46c6d4df3db4b3d88f611019418c22a/?vgnextoid=4b8c410b6c718210VgnVCM100000ed152ca2RCRD&vgnnextchannel=b5e57900b55a5110VgnVCM10000071812ca2RCRD&vgnnextfmt=default>.

²¹² *Biotechnology Pharmaceutical Market in US 2009–2013*, EZINEMARK.COM (Sept. 20, 2010), <http://health.ezinemark.com/biotechnology-pharmaceutical-market-in-us-2009-2013-168677c53d9.html>.

²¹³ See Bruce Vladeck, Editorial, *Universal Health Insurance in the United States: Reflections on the Past, the Present, and the Future*, 93 AM. J. PUB. HEALTH 16, 16 (2003) (proposing explanations for the United States' lack of a universal health care system).

²¹⁴ CARMEN DENAVAS-WALT ET AL., U.S. CENSUS BUREAU, INCOME, POVERTY, AND HEALTH INSURANCE COVERAGE IN THE UNITED STATES: 2009, at 24 fig.7 (2010), available at <http://www.census.gov/prod/2010pubs/p60-238.pdf>.

50%.²¹⁵ The government's most visible role is to directly cover segments of the population that are the most difficult for private companies to insure: the elderly and disabled under Medicare, and the poor under Medicaid. However, the government shapes, oversees, and indirectly funds the private market for employer-provided coverage, the mainstay for the remainder of the country. Private health insurance in its present form would not exist in the United States were it not for a sustained government role that started around the middle of the twentieth century and has steadily grown ever since.

1. The Creation of Private Employer-Based Coverage

The first general private health insurance plans were created during the early years of the Great Depression.²¹⁶ Subsequently they evolved into the dominant force in health care finance.²¹⁷ Baylor University Hospital in Houston launched the first one in 1929, offering a group of schoolteachers up to twenty-one days of hospital care each year for six dollars per person.²¹⁸ The concept proved popular and soon spread to other states. In the early 1930s, plans were developed in California and New Jersey to provide care at multiple institutions.²¹⁹ This model was formalized on a national basis under the name "Blue Cross."²²⁰ The plans in each state operated on a nonprofit basis, serving as financing mechanisms for hospitals rather than as profit centers in their own right.²²¹ In 1939, a similar concept was applied to physician services for low-income families in California.²²² The force behind this system was again the providers—in this case physicians—seeking a

²¹⁵ In 2009, Medicare, Medicaid, the Veterans Administration, the DOD health care system, and other federal health care programs together provided coverage for over 83 million Americans out of a total population of about 300 million. See John Holahan, *The 2007–09 Recession and Health Insurance Coverage*, 30 HEALTH AFF. 145, 148 (2011) (providing data on coverage and sources of insurance for the nonelderly population). Employment-based insurance, supported by a tax subsidy, covered over 155 million people. *Id.* For data on coverage of the elderly under Medicare, see JULIETTE CUBANSKI ET AL., THE HENRY J. KAISER FAMILY FOUND., MEDICARE CHARTBOOK 10 (4th ed. 2010), available at <http://www.kff.org/medicare/upload/8103.pdf>.

²¹⁶ See STARR, *supra* note 18, at 294-306 (offering an account of the rise of the private insurance industry).

²¹⁷ *Id.*

²¹⁸ *Id.* at 295.

²¹⁹ *Id.* at 296.

²²⁰ *Id.* at 296-98.

²²¹ *Id.* at 296.

²²² *Id.* at 307.

steady source of payment.²²³ This mechanism also proved to be popular and spread from state to state under the name “Blue Shield.”²²⁴

For these newcomers to the world of finance, operating under the same structure as established for-profit insurance companies presented challenges. In particular, they could not raise and maintain the same level of financial reserves that state regulators generally required to guarantee the ability to pay claims.²²⁵ New York was the first state to address this imbalance in 1934, when it enacted an enabling statute that conferred special regulatory status on the new health insurance mechanisms.²²⁶ Under this legislation, if Blue Cross plans agreed to maintain their nonprofit status and remain under the control of member hospitals, they would be exempted from the reserve requirements that applied to the rest of the insurance industry.²²⁷ Twenty-five states enacted similar statutes over the next five years.²²⁸ Blue Shield plans later received similar favorable treatment.²²⁹

Through this regulatory leniency, state governments had enabled the first health insurance plans to take shape. With their structure in place, the major catalyst for their widespread expansion arose about ten years later through the intercession of another government regulatory action. As the country ramped up production of war supplies during World War II and millions of young men headed overseas to fight, the economy faced the threat of rampant inflation from a constricted supply of goods and of workers available to make them.²³⁰ In response, the federal government imposed a freeze on prices and

²²³ *Id.* at 306-07.

²²⁴ *Id.*

²²⁵ *Id.* at 296.

²²⁶ *Id.* at 297.

²²⁷ *Id.* The legislation was based on the reasoning that the new plans did not need the same level of financial backing because they could honor claims by providing services directly. *Id.* at 296.

²²⁸ *Id.* at 298.

²²⁹ In the 1930s, many private insurance companies considered medical expenses too risky to insure, leaving Blue Cross and Blue Shield plans as the only source of coverage. See Robert D. Eilers, *The Fundamental Nature of Blue Cross and Blue Shield*, 29 J. INS. 385, 385 (1962) (detailing the history of insurance coverage for medical expenses and state attempts to protect the coverage that Blue Cross and Blue Shield offered). To ease the regulatory burden on these new entities in order to encourage their growth, many states passed enabling statutes to exempt them from some provisions of their insurance codes. *Id.*

²³⁰ See *id.* at 398 (describing how World War II modified aspects of the competitive market).

wages, outlawing any increases unless approved by a federal board.²³¹ In 1943, to accommodate the needs of employers having difficulty attracting workers, the War Labor Board exempted fringe benefits, such as health insurance, from the definition of wages, thereby permitting employers to add such compensation without violating the freeze.²³² Enrollment in Blue Cross plans, which were widely offered through employment as a result of this ruling, increased almost fourfold during the War from seven to twenty-six million.²³³

This regulatory action led to an even more influential government step in the postwar years. The War Labor Board's decision treated sums paid for health insurance as distinct from worker's pay.²³⁴ In keeping with this reasoning, the Internal Revenue Service took the position that these sums were not subject to income tax.²³⁵ In 1954, as part of a comprehensive overhaul of the Internal Revenue Code, Congress ratified this position in legislation.²³⁶ Since then, employers have been able to fund their workers' health insurance premiums on a tax-free basis.

While employment-based health insurance enjoyed this substantial financial boost, coverage that individuals obtained directly from insurance companies did not. With limited exceptions, dollars used to pay

²³¹ See Thomas Bodenheimer & Kip Sullivan, *How Large Employers Are Shaping the Health Care Marketplace: First of Two Parts*, 338 NEW ENG. J. MED. 1003, 1003 (1998) (describing how the wage freeze incentivized employers to offer a variety of benefits, such as health insurance).

²³² STARR, *supra* note 18, at 311.

²³³ *Id.*

²³⁴ David A. Hyman & Mark Hall, *Two Cheers for Employment-Based Health Insurance*, 2 YALE J. HEALTH POL'Y & ETHICS 23, 25 (2001).

²³⁵ The IRS first took the position that employer-paid premiums for group insurance plans were excludable from taxable income in 1943. See I.R.S. Priv. Ltr. Rul. ¶ 6587 (Oct. 26, 1943) ("If corporations . . . purchased insurance for the purpose of furnishing such employees and members of their families group medical care and hospitalization, the premiums paid therefor [sic] constitute ordinary and necessary expenses . . ."). It was incorporated into the 1954 revision of the Internal Revenue Code as I.R.C. § 106 (1958), which states, "Gross income does not include contributions by the employer to accident or health plans for compensation (through insurance or otherwise) to his employees for personal injuries or sickness." The Code had not previously provided for this exclusion. Amounts received as benefits paid out by employer-sponsored health insurance plans had been considered tax-exempt since the income tax was first instituted, and this policy was also continued in the 1954 revision. See I.R.C. §§ 104, 105 (1958). See also BOB LYKE, CONG. RESEARCH SERV., RL34767, THE TAX EXCLUSION FOR EMPLOYER-PROVIDED HEALTH INSURANCE: POLICY ISSUES REGARDING THE REPEAL DEBATE 3, 7-9 (2008) (outlining the scope, coverage, and benefits of the exclusion of employer-provided health coverage from employee income).

²³⁶ I.R.C. § 3121(a)(2)(b) (2006).

premiums for these policies come from income that is subject to taxation.²³⁷ This dynamic has led the market to gravitate toward employer-sponsored plans. Those without access to this form of coverage—including those who are unemployed, are self-employed, or work for firms that do not offer health benefits—often have tremendous difficulty finding insurance and comprise a large portion of the uninsured.²³⁸ Policies sold directly to individuals have come to represent a tiny portion of the market, in the range of about six percent.²³⁹

The amounts government coffers forgo by exempting employer-paid health insurance from taxation represent a subsidy for those able to take advantage of this form of insurance. Over the years, this subsidy has grown to a significant size.²⁴⁰ By exempting employer-paid health insurance premiums from income tax, federal and state governments lost a total of over \$200 billion in 2006.²⁴¹ This amount was projected to be almost \$250 billion in 2010.²⁴² This means that the tax subsidy for private insurance is the third most expensive government health care financing program, behind Medicare and Medicaid.²⁴³ It represents over one-third of the aggregate amount Americans pay for private employer-sponsored coverage each year.²⁴⁴

The magnitude of government financial support for private health insurance means that this product is not offered through a truly private mechanism. Rather, the government heavily shapes and funds

²³⁷ The premiums for individual insurance policies are tax deductible to the extent that, when combined with other medical expenses, they exceed 7.5% of adjusted gross income. See BURMAN ET AL., *supra* note 8, at 1.

²³⁸ See JENNIFER TOLBERT ET AL., KAISER COMM'N ON MEDICAID & THE UNINSURED, APPROACHES TO COVERING THE UNINSURED: A GUIDE 4-7 (2008), available at <http://www.kff.org/uninsured/upload/7795.pdf> (describing the various sources of insurance and offering solutions to reduce the number of uninsured).

²³⁹ See KAISER FAMILY FOUND. & EHEALTH INSURANCE, UPDATE ON INDIVIDUAL HEALTH INS. 1 (2004), available at <http://www.kff.org/insurance/upload/Update-on-Individual-Health-Insurance.pdf> ("In 2002, about 6.6% of the nonelderly population (16.5 million people) purchased individual health insurance . . .").

²⁴⁰ See Woolhandler & Himmelstein, *supra* note 2, at 88 (discussing the significance of the tax subsidy for employment-based insurance in overall health care finance).

²⁴¹ See Selden & Gray, *supra* note 7, at 157 (providing a distribution of tax subsidies).

²⁴² See BURMAN ET AL., *supra* note 8, at 1 ("The exclusion . . . will provide \$240 billion in income and payroll subsidies in 2010.").

²⁴³ In 2008, the most expensive government health care program was Medicare, which spent \$468.1 billion; the second-most expensive was Medicaid, which spent \$294 billion. NAT'L CTR. FOR HEALTH STATISTICS, *supra* note 2, tbls.140 & 143. The tax subsidy for private employer-sponsored health insurance was valued at approximately \$240 billion in 2010, making it the third-most expensive. BURMAN ET AL., *supra* note 8, at 1.

²⁴⁴ See Selden & Gray, *supra* note 7, at 1571 (noting that the tax subsidy accounts for 35.8% of premiums paid to private establishments).

the private health insurance market. By indirectly paying Americans almost \$250 billion a year to obtain health coverage at work, the public-private partnership that began with special regulatory treatment for the first Blue Cross plans has promoted an employer-based system that rests on coverage through private firms.

The federal role in this partnership grew substantially in 1974 when Congress granted employer-sponsored health insurance a set of additional regulatory exemptions with the Employee Retirement Income Security Act (ERISA), which upended the regulatory structure for employment benefits.²⁴⁵ The regulatory scheme that ERISA implements is extremely complex, but in essence, it exempts employer-sponsored health plans from the reach of many state laws.²⁴⁶ This includes statutes that limit unfair insurance practices and case law that permits aggrieved beneficiaries to sue insurance companies for damages in state courts.²⁴⁷

Beyond these provisions, ERISA is particularly kind to plans that employers fund themselves without the use of insurance companies.²⁴⁸ In these self-funded plans, the employer pays claims directly, rather than purchasing coverage for its workers. ERISA placed these arrangements beyond the reach of almost all state insurance regulation, including rules that prescribe the extent of coverage, the rates that are charged, and the reserves that must be maintained to guaran-

²⁴⁵ 29 U.S.C. § 1144 (2006).

²⁴⁶ A complex and voluminous case law has developed concerning the interplay of state and federal jurisdiction over health insurance under ERISA's preemption scheme, but a common theme throughout is that state authority is severely limited. See Robert F. Rich et al., *Judicial Interpretation of Managed Care Policy*, 13 ELDER L.J. 85, 108 (2005) ("[T]he core of ERISA's preemptive scope still acts to restrict any state seeking to effectuate wholesale health care reform.")

²⁴⁷ In *Pilot Life Insurance Co. v. Dedeaux*, the Supreme Court held that ERISA preempted a Mississippi statute permitting suits against insurance companies for denying claims in bad faith as the statute applied to workers covered by employer-sponsored plans. 481 U.S. 41, 48-51 (1987). In *Aetna Health Inc. v. Davila*, the Court held that ERISA preempted suits against an HMO for failing to exercise ordinary care in handling coverage decisions under employer-sponsored plans. 542 U.S. 200, 207-09 (2004). After decades of case law, ERISA preemption of state law concerning employee health benefit plans remains broad. See WILLIAM PIERRON & PAUL FRONSTIN, EMP. BENEFIT RESEARCH INST., ISSUE BRIEF NO. 314, ERISA PRE-EMPTION: IMPLICATIONS FOR HEALTH REFORM AND COVERAGE 9 (2008), available at http://www.ebri.org/pdf/briefspdf/EBRI_IB_02a-20082.pdf (concluding that ERISA preemption of state law remains broad despite some Supreme Court decisions rejecting preemption).

²⁴⁸ See Matt Leming, *More Employers Weigh Self-Funded Health Plans*, SOC'Y FOR HUM. RESOURCE MGMT. (Aug. 14, 2009), <http://www.shrm.org/hrdisciplines/benefits/Articles/Pages/SelfFunded.aspx> (weighing the risks, responsibilities, and benefits to employers who opt for self-funded employee health coverage).

tee claims payment.²⁴⁹ No other form of insurance receives such favorable regulatory treatment, and ERISA does not apply to health coverage obtained outside of employment.²⁵⁰

By easing state regulatory strictures, ERISA added another inducement for companies to offer coverage, and for insurance companies to market policies through employers rather than to individuals. Policies sold directly to the public must comply with more rigorous state regulatory oversight, and the companies that sell them are more vulnerable to lawsuits for their administration of coverage.²⁵¹ With ERISA's particularly lenient treatment of self-insured plans, these coverage vehicles proliferated in the years after the law's passage.²⁵² By inducing this market change, the government, through ERISA, took yet another step in sculpting the financial environment of health care.

Without the tax subsidy and regulatory leniency, health care coverage would almost certainly be provided directly to individuals to a much greater extent than it is currently. Moreover, absent this support from the government, most people would likely purchase less coverage than they presently do.²⁵³ There would consequently be a smaller pool of money available for reimbursing providers, causing reimbursement rates to fall. This reduction, in turn, would reduce the incomes of many physicians and the revenues of hospitals—likely resulting in there being fewer of each. In other words, by subsidizing private health insurance, the government plays a substantial role in determining not only the financial strength, stability, size, and structure of health care's financing mechanism, but also the shape of the entire health care industry.

²⁴⁹ See 29 U.S.C. § 1144(b) (2006) (delineating the kind of state laws that are saved from preemption).

²⁵⁰ For a discussion of the favorable treatment that ERISA provides for employer-sponsored managed care plans, see Rich et al., *supra* note 246, at 109.

²⁵¹ Hyman & Hall, *supra* note 234, at 29.

²⁵² As of 2000, the proportion of firms using self-insurance to provide employee health coverage was almost 21%, and the proportion of employees working in firms that offered this kind of coverage was just over 49%. Christina H. Park, *Prevalence of Employer Self-Insured Health Benefits: National and State Variation*, 57 MED. CARE RES. & REV. 340, 348 tbl.1 (2000), available at <http://www.shrm.org/publications/hrmagazine/editorialcontent/documents/prevalence.pdf>.

²⁵³ "One criticism of the exclusion for employer-provided health insurance is that it reduces the after-tax cost of insurance to workers in ways that are not transparent, likely resulting in their obtaining more coverage than they otherwise would." LYKE, *supra* note 235, at 14.

2. The Creation of Managed Care

In addition to structuring and funding private health insurance, the government created an important subindustry within private health insurance. Managed care initially took the form of the health maintenance organization (HMO), a system that combines the provision of and payment for care in the same entity.²⁵⁴ The concept originated in the late 1960s in a proposal by Paul Elwood, a Minneapolis family physician, based on the model of what were then known as prepaid plans.²⁵⁵ These plans collected premiums in return for direct access to services.²⁵⁶

Dr. Elwood saw in these plans a way to finance the full range of care while keeping a tight rein on costs.²⁵⁷ By directly employing physicians and owning or managing the facilities in which they worked, prepaid plans had strong tools with which to control costs.²⁵⁸ The HMO concept uses the prepaid-plan model without the bricks and mortar of actual clinics. Physicians remain in their own practices and

²⁵⁴ “HMOs assume both the financial risks associated with providing comprehensive medical services and the responsibility for delivering health care in a particular geographic area, usually in return for a fixed, prepaid fee from members.” BUREAU OF LABOR STATISTICS, NATIONAL COMPENSATION SURVEY: GLOSSARY OF EMPLOYEE BENEFIT TERMS 11 (2009), available at http://www.bls.gov/ncs/ebs/detailedprovisions/2008/glossary_2008_2009.pdf.

²⁵⁵ Paul Elwood is credited with developing the concept of HMOs and inventing the term “health maintenance organization.” Mike Mitka, *A Quarter Century of Health Maintenance*, 260 JAMA 2059, 2060 (1998). He based the idea on the model of prepaid health plans. See Thomas R. Mayer & Gloria Gilbert Mayer, *HMOs: Origins and Development*, 312 NEW ENG. J. MED. 590, 593 (1985) (crediting Dr. Elwood with being “single-handedly responsible for the rapid growth in HMOs”).

²⁵⁶ See Kelly A. Hunt & James R. Knickman, *Financing Health Care*, in HEALTH CARE DELIVERY IN THE UNITED STATES 57, 58-80 (Anthony R. Kovner & James R. Knickman eds., 9th ed. 2008).

²⁵⁷ Prepaid health plans originated in the 1930s and 1940s under the auspices of large employers and labor unions. Mayer & Mayer, *supra* note 255, at 592. Kaiser Aluminum launched the Kaiser-Permanente plan in the 1940s to cover its steel mill workers on the West Coast during World War II. *Id.* Its success led to the spin-off of the health plan after the War into an independent nonprofit organization open to employees of other companies. *Id.* After the War, the City of New York opened the Health Insurance Plan to cover municipal workers. *Id.* Similar plans based on a clinic model founded during this time included the Group Health Insurance Plan in Washington, D.C., and the Health Cooperative of Puget Sound in Seattle, Washington. *Id.* at 291-92.

²⁵⁸ Of particular interest in this regard is the incentive structure prepaid plans used. They paid physicians a salary that remained largely fixed regardless of the number of services they provided or procedures they performed. This eliminated the financial incentive to overtreat, since treatment no longer necessarily generated additional payments. *Id.* at 593.

continue to render services in their own offices, but do so under a new payment structure.²⁵⁹

The concept appealed to the Nixon Administration, which was receptive to a market-based approach to health reform.²⁶⁰ It sought an initial push to introduce HMOs into the market, which took the form of the federal Health Maintenance Organization Act (HMO Act), enacted by Congress in 1973.²⁶¹ This law allowed HMOs to force their way into local markets by requiring employers to offer their products as an option in employee health plans.²⁶² It also implemented a regulatory structure that determined the shape of this new segment of the industry. The HMO Act defined the role and structure of HMOs as they grew to become a major private health care financing paradigm.²⁶³

²⁵⁹ Primary care physicians in HMOs are paid based on “capitation.” See Hunt & Knickman, *supra* note 256, at 68-69 (explaining the financing of managed care). Under this mechanism, a physician is responsible for a panel of patients who can see her as often as necessary. *Id.* at 69. In return, the physician is paid a set monthly fee for each patient, regardless of how often the physician actually sees the patient or the number of services actually provided. *Id.* Beyond capitation, HMOs use a set of other tools to constrain spending. All patients must see their designated primary care physician first for any ailment and receive a referral from her before consulting a specialist. *Id.* Procedures and tests specialists perform or order are reviewed for necessity before payment is authorized. *Id.* Hospitalizations must be preapproved, and the maximum length of stay that is eligible for payment is determined in advance. *Id.* Specialists, hospitals, and ancillary services providers such as laboratories are paid only if they have entered into a contract with the HMO in advance under terms that reimburse at discounted fees. *Id.* This structure represents an attempt to coordinate care to control costs and improve quality with dispersed networks of providers, rather than centralized clinics. See generally PETER R. KONGSTVEDT, *MANAGED CARE: WHAT IT IS AND HOW IT WORKS* (3d ed. 2009).

²⁶⁰ See STARR, *supra* note 18, at 393-405 (providing an overview of the adoption of the HMO concept).

²⁶¹ Pub. L. No. 93-222, 87 Stat. 914 (1973) (codified as amended at 42 U.S.C. §§ 300e-1 to e-17 (2006)).

²⁶² *Id.* sec. 2, § 1301, 87 Stat. at 930-31.

²⁶³ The HMO Act gave these new financing vehicles the right to demand inclusion in employer benefit offerings. If an employer provided health coverage, the law required that it include an HMO as one of the options if the HMO requested the employer to do so. *Id.* To request inclusion, the HMO had to meet a set of standards to be deemed “federally qualified.” The standards included minimum numbers of network providers, implementation of an appeals mechanism for claims denials, and use of community ratings in setting premiums. *Id.* sec. 2, § 1301, 87 Stat. at 914-17. As further encouragement, the Act also provided loans and grants to new HMOs to help with start-up costs. *Id.* sec. 2, § 1305, 87 Stat. at 924-25. Once established, HMOs were regulated by each state, with most states putting them under the jurisdiction of both the health and insurance departments. See generally Joseph L. Dorsey, *The Health Maintenance Organization Act of 1973 (P.L. 93-222) and Prepaid Group Practice Plans*, 13 MED. CARE 1, 3-7 (1975) (detailing the major features of the law).

Congress let the funding provisions of the HMO Act expire in 1981, after HMOs had become entrenched in the health care landscape.²⁶⁴ However, building on this solid start, a set of additional government programs implemented over the next twenty years gave managed care added momentum. ERISA, passed the year after the HMO Act, was the first of these programs. It substantially limited the scope of state regulatory oversight for managed care plans that were offered through employers.²⁶⁵

Starting about ten years later, a public market for HMOs emerged to supplement the private market as the government began to purchase their services directly.²⁶⁶ In the 1980s, a few states experimented with the use of private HMOs to provide services under their Medicaid programs with an eye to harnessing their cost-control techniques.²⁶⁷ The experience was considered favorable, and by the end of the 1990s, most states were using managed care for a substantial portion of their Medicaid populations.²⁶⁸ With this model in mind, the Medicare program began to experiment with managed care at about the same time.²⁶⁹ After promising initial trials, managed care arrangements were formally integrated into the program as a beneficiary option under the Balanced Budget Act of 1997 as a new Part C of the Medicare program.²⁷⁰ Originally named “Medicare + Choice,” it was

²⁶⁴ See Omnibus Budget Reconciliation Act of 1981, Pub. L. No. 97-35, § 2174(a), 95 Stat. 809 (codified at 42 U.S.C. § 1396a(a)(30)(A) (1976 & Supp 1984)). This law also permitted Medicare to begin contracting with HMOs to provide services to beneficiaries. See *id.* § 2178, 95 Stat. 813-15.

²⁶⁵ See *supra* notes 245-50 and accompanying text (detailing ERISA and its impact on managed care).

²⁶⁶ See Allen Dobson et al., *The Role of Federal Waivers in the Health Policy Process*, HEALTH AFF., Winter 1992, at 72, 75-76 (describing how certain government waivers allow policymakers to experiment with innovative Medicare and Medicaid programs).

²⁶⁷ See *id.* at 76 (describing the legislation that authorized states to explore alternative health care delivery systems, such as HMOs, for Medicaid recipients).

²⁶⁸ Managed care is used in administering benefits to over half of enrollees in the Medicaid programs of forty-six states, and in 2010 it covered seventy percent of Medicaid beneficiaries nationwide. THE HENRY J. KASIER FAMILY FOUND., NO. 8046, MEDICAID AND MANAGED CARE: KEY DATA, TRENDS, AND ISSUES 1, 2 fig.2 (2010).

²⁶⁹ See CONG. BUDGET OFFICE, CBO STAFF MEMORANDUM, MANAGED CARE AND THE MEDICARE PROGRAM: BACKGROUND AND EVIDENCE 10-11 (1990), available at <http://www.cbo.gov/doc.cfm?index=7754> (“Between the time the original Medicare legislation was enacted and the present, Medicare has offered a number of different contracting options to HMOs wishing to participate in the Medicare program.”).

²⁷⁰ Pub. L. No. 105-33, 111 Stat. 251 (codified in scattered sections of 42 U.S.C.).

expanded and renamed "Medicare Advantage" by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.²⁷¹

Opening these two huge public markets enabled many managed care organizations to significantly expand their scope of operations. The horizons of established companies expanded well beyond their original expectations.²⁷² Many smaller companies sprang up throughout the country, often to be acquired by larger ones seeking to meet the growing market demand.²⁷³ What had been a largely local industry in the 1970s expanded to include many national players, growing through mergers, consolidations, and acquisitions.²⁷⁴

As markets and companies expanded, managed care companies began to innovate. They modified the original HMO model of stringent oversight of all aspects of care with variations that permitted more patient choice. These took the form of Preferred Provider Organizations (PPOs) and Point-of-Service Plans (POs) that retained many elements of the management-of-care model while also permitting patients to obtain some services outside of predetermined provider networks.²⁷⁵ With these changes, employers could select from a range of insurance products to offer their workers with different levels of restriction and corresponding variations in premiums, all under the paradigm of integrating the financing with the provision of health care.²⁷⁶

The growth of managed care since the government first catalyzed the market has been tremendous. In January 1970, three years before passage of the HMO Act, twenty-six HMO plans operated in the United States.²⁷⁷ This number grew to seventy-two plans by 1973, and almost doubled to 142 in 1974, the year after the Act was passed.²⁷⁸ By

²⁷¹ Pub. L. No. 108-173, 117 Stat. 2066 (codified in scattered sections of 42 U.S.C.).

²⁷² See Jo Ann Lamphere et al., *The Surge in Medicare Managed Care: An Update*, HEALTH AFF., May-June 1997, at 128, 128 exhibit 1 (showing a rapid expansion in Medicare managed care risk-plan enrollment between 1987 and 1996 and projecting continued growth).

²⁷³ See Jon B. Christianson et al., *The HMO Industry: Evolution in Population Demographics and Market Structures*, 48 MED. CARE REV. 3, 15-21 (1991) (identifying changes in the HMO market via mergers, acquisitions, and entries to the market and explaining how the changes altered HMO organizational structures).

²⁷⁴ *Id.*

²⁷⁵ See Elizabeth W. Hoy et al., *Change and Growth in Managed Care*, HEALTH AFF., Winter 1991, at 18, 22-25 (reviewing various HMO models and the characteristics of different managed care approaches).

²⁷⁶ See *id.* at 19-22 (describing enrollment in different types of plans).

²⁷⁷ Alvin R. Tarlov, *HMO Enrollment Growth and Physicians: The Third Compartment*, HEALTH AFF., Spring 1986, at 23, 30 exhibit 2.

²⁷⁸ *Id.*

December 1984, the country had 337 plans.²⁷⁹ By June 1987, that number had reached 662.²⁸⁰ Enrollment grew from six million to over twenty-nine million subscribers between 1976 and 1987.²⁸¹ As an option under Medicare, HMO enrollment grew from just over 1.3 million beneficiaries, representing 3.8% of the total Medicare population, in 1990 to 6.9 million, representing 18.3% of Medicare recipients in 1998.²⁸² By 2008, 8.8 million people were enrolled in private managed care plans through Medicare Advantage.²⁸³

Today, managed care is the dominant form of health insurance coverage in the United States. Its growth has continued in recent decades. In 1988, it covered 27% of insured Americans.²⁸⁴ The proportion reached 54% in 1993, 73% in 1996, and 92% in 2000.²⁸⁵ By 2007, over 97% of insured workers were covered under a managed care arrangement of some sort, with 21% in traditional HMOs.²⁸⁶ Many Americans today have never experienced health insurance in any other form.

During the 1990s, as large, national managed care companies swallowed smaller local ones, their bargaining clout drove down fees paid to hospitals and physicians in many markets.²⁸⁷ This, in turn, led many providers to consolidate into health systems, hospital chains, and large physician-group practices to try to gain a better negotiating position.²⁸⁸ By the end of the 1990s, much of American health care had become a more centralized enterprise.²⁸⁹ In effect, the rise of managed care

²⁷⁹ *Id.*

²⁸⁰ Lynn R. Gruber et al., *From Movement to Industry: The Growth of HMOs*, HEALTH AFF., Summer 1988, at 197, 199 exhibit 2.

²⁸¹ *Id.* at 198 exhibit 1.

²⁸² Robert Weech-Maldonado & Dennis Shea, Dept. Health Policy & Admin., Pa. State Univ., Market Factors Influencing Medicare Managed Care Growth, Presentation to the Academy for Health Services Research and Health Policy (June 2000) (on file with the author).

²⁸³ MARK MERLIS, THE HENRY J. KAISER FAMILY FOUND., PUB. NO. 7744, THE VALUE OF EXTRA BENEFITS OFFERED BY MEDICARE ADVANTAGE PLANS IN 2006, at 1 (2008), available at <http://www.kff.org/medicare/upload/7744.pdf>.

²⁸⁴ Gary Claxton et al., *Health Benefits in 2007: Premium Increases Fall to an Eight-Year Low, While Offer Rates and Enrollment Remain Stable*, 26 HEALTH AFF. 1407, 1413 exhibit 4 (2007).

²⁸⁵ *Id.*

²⁸⁶ *Id.*

²⁸⁷ See Martin Gaynor & Deborah Haas-Wilson, *Change, Consolidation, and Competition in Health Care Markets*, J. ECON. PERSP., Winter 1999, at 141, 142-44 (describing the 1990s horizontal consolidation of health care organizations via mergers and acquisitions).

²⁸⁸ *Id.*

²⁸⁹ *Id.* at 141-42.

revised the organizational structure of health care provision overall—a result with origins in a series of pushes by the government.

E. *Government-Created Health Care and the Larger Economy*

These examples of government-created health care industry sectors are by no means exhaustive. The Medicare program has sustained, for example, home health care, hospice care, many allied health professions such as physical therapy and occupational therapy, and the prescription drug plans that administer its prescription benefits—all heavily dependent on government financing.²⁹⁰

In creating American health care as it exists today, the government established not just a vibrant industry but a pillar of the larger economy. The health care industry represents over sixteen percent of America's gross domestic product, meaning that it absorbs one out of every six dollars that Americans spend.²⁹¹ That portion is projected to reach one-fifth over the next ten years.²⁹²

In occupying such a central economic role, health care has also become one of the country's most important engines for jobs, accounting for almost one out of every ten nonfarm jobs nationwide.²⁹³ In some regions, the proportion is even larger. Several major cities rely on health care as a critical economic pillar, including Boston, Philadelphia, San Francisco, and Nashville.²⁹⁴ Cities such as these, and

²⁹⁰ From 1980 to 2006, the number of home health agencies increased from 2924 to 8618, outpatient physical therapy providers from 419 to 3009, and portable x-ray providers from 216 to 549. NAT'L CTR. FOR HEALTH STATISTICS, *supra* note 2, at tbl.118. Between 1985 and 2004, the number of ambulatory surgery centers certified to provide services under Medicare grew from 336 to 4136, of home health agencies from 5679 to 7519, of outpatient physical therapy providers from 854 to 2971, of portable x-ray services from 308 to 608, and of hospice providers from 164 to 2645. *Id.*

²⁹¹ Andrea Sisko et al., *Health Spending Projections Through 2018: Recession Effects Add Uncertainty to the Outlook*, 28 HEALTH AFF. w346, w347 exhibit 1 (2009), <http://content.healthaffairs.org/content/28/2/w346.full.pdf+html>.

²⁹² *Id.*

²⁹³ See KAISER FAM. FOUND., PUB. NO. 7031, TRENDS AND INDICATORS IN THE CHANGING HEALTH CARE MARKETPLACE, exhibit 5.1 (2006), *available at* <http://www.kff.org/insurance/7031/print-sec5.cfm> (showing growth in health care employment compared to other nonfarm employment).

²⁹⁴ A report released in 2010 by the Nashville Health Care Council found that the health care industry was the region's largest employer and the fastest growing in terms of adding jobs, with a 36% increase between 2004 and 2008. April Wortham, *Study: Health Care Industry Has \$30 Billion Impact on Nashville*, NASHVILLE BUS. J. (July 7, 2010, 1:33 PM), <http://www.bizjournals.com/nashville/stories/2010/07/05/daily14.html>. It is home to the headquarters of several of the nation's largest for-profit hospital chains and average wages in health care were more than 50% higher than the regional

the states in which they are located, are home to major teaching hospitals, medical schools, and pharmaceutical companies that employ significant fractions of their workforces. In each case, government funding provides crucial ongoing support. In 2005, for example, Massachusetts received over \$2 billion in NIH grants, Pennsylvania almost \$1.5 billion, and California over \$3 billion.²⁹⁵

Health care is also a job-creating engine, accounting for the creation of 1.7 million new jobs between 2001 and 2006, a period of otherwise slow economic growth.²⁹⁶ No other industry came close.²⁹⁷ Without health care, national employment during this time would have contracted.²⁹⁸ More recently, health care has been one of the only industries that continued to thrive during the period of peak unemployment during the “Great Recession.”²⁹⁹ Looking ahead to the next 25 years, health care could account for over 30% of all new jobs.³⁰⁰

IV. PPACA AND MARKET-BASED HEALTH CARE

The major government health care programs of the latter part of the twentieth century extended health care access to large portions of the population. They did this by financing health care services, both directly through Medicare, Medicaid, and other programs, and indirectly through tax-subsidized private health insurance and by increasing the supply of providers through programs that funded hospital expansion and physician training. In each case, government involvement brought about dramatic growth in the private sector, including the creation and maintenance of new industry segments.

average for all industries. *Id.* The health care industry accounted for almost \$30 billion in annual revenue. *Id.*

²⁹⁵ *NIH Awards by State of Recipient Institution, Fiscal Year 2005*, NAT'L INSTS. OF HEALTH, <http://report.nih.gov/award/trends/states05.htm> (last visited Mar. 15, 2011).

²⁹⁶ Michael Mandel, *What's Really Propping Up the Economy*, BUS. WK., Sept. 25, 2006, at 55, 55, 62.

²⁹⁷ *See id.* at 56 (stating that the construction sector, the next greatest job-creating industry after health care, created less than half as many new jobs during the period between 2001 and 2006).

²⁹⁸ *See id.* at 55 (“Without [the health care industry] the nation’s labor market would be in a deep coma.”).

²⁹⁹ *See* Michael E. Kanell, *During a Recession, Some Jobs Survive—and Thrive*, ATLANTA J. CONST., Dec. 12, 2010, at D1 (observing that jobs in health care, like those in the federal government and universities, continue to materialize even during the recession).

³⁰⁰ Mandel, *supra* note 296, at 58.

PPACA is the first program to guarantee access to the system for every American.³⁰¹ The law does so largely through private-sector mechanisms. The ramifications of this step for the private health care industry are likely to follow the same path as prior programs.

PPACA relies primarily on two mechanisms to extend coverage, which together are projected to cost about \$800 billion over the next ten years.³⁰² The first is an expansion of Medicaid eligibility. The Act requires that states set their income thresholds at no less than 133% of the federal poverty level and to include all adults as eligible beneficiaries.³⁰³ Under present rules, many states cut off eligibility at much lower income levels and cover only adults if they are disabled, elderly, or have dependent children.³⁰⁴ The extension of Medicaid is projected to account for about half of PPACA's overall coverage expansion.³⁰⁵

The second mechanism is an expansion of the private market for individual policies. Using a three-pronged approach, PPACA prohibits underwriting restrictions on the basis of health status,³⁰⁶ offers subsidies to those with low incomes,³⁰⁷ and mandates that every American maintain coverage.³⁰⁸ Individual policies are to be sold through exchanges in each state that standardize policy terms, facilitate comparison shopping, and effectuate insurance-purchasing transactions.³⁰⁹ PPACA

³⁰¹ See PPACA § 2704(a), 42 U.S.C.A. § 300gg-3(a) (West Supp. 1A 2010) (barring insurance companies from refusing coverage to individuals because of a preexisting medical condition).

³⁰² The Congressional Budget Office has estimated that PPACA's insurance coverage provisions will cost the federal government \$788 billion over the next ten years. This will be offset by cuts to Medicare and new taxes to reduce federal deficits by \$143 billion over that time period. See Douglas W. Elmendorf, Dir., Cong. Budget Office, Presentation to the World Health Congress: The Effects of Health Reform on the Federal Budget 3 (Apr. 12, 2010), available at http://www.cbo.gov/ftpdocs/114xx/doc11439/WHCC_Presentation-4-12-10.pdf.

³⁰³ PPACA sec. 2001(a)(1)(C), § 1902(a)(10)(A)(i)(VIII), 42 U.S.C.A. § 1396a(a)(10)(A)(i)(VIII) (West Supp. 1B 2010)

³⁰⁴ The Henry J. Kaiser Family Found., *Income Eligibility Limits for Working Adults at Application as a Percent of the Federal Poverty Level (FPL) by Scope of Benefit Package*, STATE-HEALTHFACTS.ORG, <http://www.statehealthfacts.org/comparereport.jsp?rep=54&cat=4&gsa=2> (last visited Mar. 15, 2011).

³⁰⁵ See THE HENRY J. KAISER FAMILY FOUND., PUB. NO. 7920-02, EXPLAINING HEALTH CARE REFORM: QUESTIONS ABOUT MEDICAID'S ROLE 4 (2010), available at <http://www.kff.org/healthreform/upload/7920-02.pdf> ("The program is expected to cover another 16 million people by 2019, half of the reduction in the uninsured by that time.")

³⁰⁶ PPACA § 2705(a), 42 U.S.C.A. § 300gg-4(a) (West Supp. 1A 2010).

³⁰⁷ *Id.* § 1402, 26 U.S.C.A. § 36(B) (reduced cost); *id.* § 1401, 26 U.S.C.A. § 36 (tax credits); *id.* § 1413, 42 U.S.C.A. § 18083 (West Supp. 1B 2010) (health subsidy programs).

³⁰⁸ *Id.* § 1501, 26 U.S.C.A. § 5000A (West Supp. 1A 2010).

³⁰⁹ *Id.* § 1311, 42 U.S.C.A. § 18031 (West Supp. 1B 2010).

envisions that many of the exchanges will include new nonprofit cooperative insurers, however it is expected that existing private companies will offer the bulk of the policies. This revitalized individual market is projected to cover the other half of the coverage expansion.³¹⁰

This second mechanism represents a deliberate attempt to expand private insurance availability. In contrast to calls for a single government payer to extend coverage, PPACA's individual market reforms rely on multiple private companies in a newly invigorated market. With PPACA mandating that everyone have health insurance, these companies stand to enjoy substantial new business. Moreover, many of the new customers will receive government subsidies to help defray the cost.³¹¹

In return for this business opportunity, insurers will be subject to substantial new regulatory restrictions. Most significantly, individual policies are subject to "guaranteed issue," meaning that they may not be denied to any willing customer.³¹² Health status, including preexisting medical conditions, does not determine insurability and may not be used as a factor in setting rates.³¹³ Policies are also subject to minimum coverage standards. For all policies—both those sold directly to individuals and those sold to employer groups—medical-loss ratios, the proportion of premiums used for actual medical expenses, must meet minimum levels.³¹⁴ Insurers must justify premium increases

³¹⁰ PPACA is not projected to provide coverage to everyone who is presently uninsured. It is expected to extend insurance to about 32 million of the approximately 50 million who presently lack coverage. See Letter from Douglas W. Elmendorf, Dir., Cong. Budget Office, to Nancy Pelosi, Speaker of the U.S. House of Representatives 9 tbl.2 (Mar. 18, 2010), available at www.cbo.gov/ftpdocs/113xx/doc11355/hr4872.pdf (estimating revenue and spending effects of the health care reconciliation bill). The Medicaid expansion and individual market reforms will each add about half of that number to coverage roles. *Id.*

³¹¹ The applicable provisions of the Act are PPACA § 1401, 42 U.S.C.A. § 36 (West Supp. 1B 2010) (granting tax credits to eligible individuals); *id.* § 1402, 42 U.S.C.A. § 18071 (reducing cost sharing); *id.* § 1421, 26 U.S.C.A. § 45R (West Supp. 1A 2010) (providing tax credits to small businesses providing employee health insurance); *id.* § 1513, 26 U.S.C.A. 4980H (amending tax provisions for large employers providing coverage).

³¹² See *id.* sec. 1201(4), § 2702(a)–(b)(1), 42 U.S.C.A. § 300gg-1(a)–(b)(1) (requiring that health insurance issuers accept all applicants).

³¹³ Insurers may only use four factors in setting rates: age, tobacco use, geographic region, and whether the coverage is for an individual or a family. *Id.* sec. 1201, § 2701(a)(1)(A), 42 U.S.C.A. § 300gg(a)(1)(A). The ratio of the highest to the lowest rates based on age may not exceed a factor of three to one, and for tobacco use the ratio may not exceed one-and-a-half to one. *Id.*

³¹⁴ These levels are eighty percent for individual and small-group policies and eighty-five percent for large employer groups. *Id.* § 2718(b), 42 U.S.C.A. § 300gg-18.

above a predetermined level to state regulators.³¹⁵ Numerous other consumer protections also apply to all policies, including prohibitions on annual and lifetime coverage limits and on copayments for designated preventive services.³¹⁶

PPACA's extension of a market-based model of health reform continues the pattern that has defined other government health care programs over the past half-century. While the government has been actively involved in shaping and financing the health care system, rarely has that involvement commanded exclusive control of the relevant industry sectors. Even in Medicare, the most costly government program, private companies play major administrative roles, such as administering claims and making many coverage determinations.³¹⁷

The Medicaid expansion will also create opportunities for private businesses, as most states rely predominantly on private plans to administer their Medicaid programs.³¹⁸ The combination of new Medicaid business and an expanded individual market will cause private health care sectors that handle the financing of the system to experience yet another burst of growth. As in the past, the growth will be due to the largess and intervention of the government.

The public-private paradigm has survived in large part because of its importance to the private sector. With annual total health care spending of almost \$2.5 trillion and public programs directly and indirectly (through favorable tax treatment of employer-provided health insurance) funding about 60% of that amount, the government

³¹⁵ See Rate Increase Disclosure and Review, 75 Fed. Reg. 81,004-01 (Dec. 23, 2010) (to be codified at 45 C.F.R. pt. 154) (regulating premium increases).

³¹⁶ The prohibition of annual and lifetime coverage limits is set forth at PPACA § 1001(5), 42 U.S.C.A. § 300gg-11 (West Supp. 1A 2010). The prohibition of copayments for designated preventive health services is set forth at *id.* § 1001(5), 42 U.S.C.A. § 300gg-13.

³¹⁷ Claims are administered under Part A of Medicare, which covers hospital and other institutional services, under contract with private insurance companies known as "intermediaries," and under Part B, which covers physician and other professional services, by contracted insurance companies known as "carriers." See PATRICIA A. DAVIS, CONG. RESEARCH SERV., RS20946, MEDICARE: HISTORY OF PART A TRUST FUND INSOLVENCY PROJECTIONS I (2009) (mentioning the different parts of Medicare in explaining projections for their insolvency). In this role, the companies also make some coverage determinations concerning new treatments and technologies. *Id.* Under Part C of the program, beneficiaries can opt to have all of their coverage handled through private insurance plans, known as "Medicare Advantage" plans, in lieu of Parts A and B. *Id.*

³¹⁸ See Avery Johnson, *Insurers Bid for State Medicaid Plans*, WALL ST. J., Dec. 29, 2010, at B1 (noting that private plans expect up to \$40 billion in new business opportunities in the next three years from administering benefits under state Medicaid programs for new enrollees under PPACA).

injects close to \$1.5 trillion into American health care each year.³¹⁹ Most of that sum supports private providers and insurance companies, who rely on this funding to maintain their business models.³²⁰

Once in place, government-induced market expansions can prove difficult to reverse. Health care businesses have proven to be extremely adept at lobbying to maintain the programs that sustain them.³²¹ If the insurance exchanges succeed in facilitating a robust market for individual policies, then a large segment of the health insurance industry will increasingly come to depend on them. With such a significant vested interest, they are likely to play an active role in fostering political support for maintaining this structure.

The government programs that underlie private markets in health care and in the broader economy have become so ingrained in the economic infrastructure that it is largely taken for granted that they will continue. Moreover, much of this public support is barely visible outside of the industry. Few patients see the government's hand in building their hospitals, training their physicians, developing their drugs, or shaping their insurance.³²² Government support is woven so tightly into the fabric of America's "free market" that it has become almost imperceptible. However, without it, health care, along with many other major industries, would likely have languished as a more minor enterprise.

If PPACA succeeds, the expanded insurance market and larger Medicaid program will also become ingrained features of American economic life. As with other entitlements, Americans will likely come to take for granted these programs' roles in guaranteeing coverage. Guaranteed access to health insurance may no longer even be commonly recognized as the creation of a government initiative.

³¹⁹ See Anne Martin et al., *Recession Contributes to Slowest Annual Rate of Increase in Health Spending in Five Decades*, 30 HEALTH AFF. 11, 13, 16 (2011).

³²⁰ See JENNIFER JENSON, CONG. RESEARCH SERV., RS22898, GOVERNMENT SPENDING ON HEALTH CARE BENEFITS AND PROGRAMS: A DATA BRIEF 4 (2008), available at <http://aging.senate.gov/crs/medicaid7.pdf> (stating that the largest health related tax expenditure goes to privately administered employer-sponsored health benefits.)

³²¹ See Steven H. Landers & Ashwini R. Sehgal, *Health Care Lobbying in the United States*, 116 AM. J. MED. 474, 474-75 (2004) (noting that lobbying by health care organizations has been estimated to represent fifteen percent of all lobbying expenditures at the federal level, which is the largest amount spent by any industry).

³²² Cf Philip Rucker, *S.C. Senator Is a Voice of Reform Opposition*, WASH. POST, July 28, 2009, at A1 (describing an encounter with a constituent who told his representative to "keep your government hands off my Medicare").

CONCLUSION

America's health care system is built on a series of government programs. Both directly through appropriations and indirectly through tax subsidies, these programs fund about 60% of the system's almost \$2.5 trillion annual cost.³²³ In addition to lending financial support, they implement a regulatory structure that shapes the entire industry.

Without this government base, health care in the United States would take a very different form. The mechanisms that fund hospital operations and construction, physician services and training, pharmaceutical research, and private employer-based insurance would not exist. It is unlikely that the private sector on its own could recreate the massive financial investment needed to support these endeavors or the oversight structure that builds public trust. For better or worse, private-sector health care would constitute a much smaller and less robust enterprise.

PPACA builds on this paradigm. It will inject large amounts of funding and impose new regulatory structures to fill one of the most glaring hole in the present system, the lack of coverage for over one-sixth of the population. With this legislation, private health care in America is poised for another substantial expansion. Along with it, America's distinctive position as the country with the largest private health care sector in the world stands to be solidified.³²⁴

Underlying this market growth will be the engine that drives the private sector throughout the American economy—the government. Different sides in political debates may characterize American health care as a government-run system or as a “free-market” system, but in reality, it contains elements of both. Under the structure that supports health care in the United States, and indeed much of the broader economy, these two forces are part of the same enterprise.

³²³ Martin et al., *supra* note 319, at 13.

³²⁴ See GERARD F. ANDERSON & PATRICIA MARKOVICH, MULTINATIONAL COMPARISONS OF HEALTH SYSTEMS DATA, 2009, at 5 (2009), available at http://www.commonwealthfund.org/~media/Files/Publications/Chartbook/2010/PDF_Anderson_multinational_comparisons_hlt_sys_data_2009_OECD_chartpack.pdf (noting that the private health care sector in the U.S. is over twice the size of the private sector in any other country).