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Fiercely contested before, during, and since its passage, the 2010 Patient Protection and Affordable Care Act (ACA) will restructure the U.S. healthcare market if fully implemented in coming years. This article describes the institutional and political context in which the ACA was passed, and develops estimates of its likely impact on the biopharmaceutical industry. Universal insurance, either through a government-run system or by mandated purchase of private insurance, has been controversial in the United States since it was first proposed in the mid-1930s. Even in the absence of national health coverage, the United States became the world's largest prescription drug market and emerged as the global leader in new drug research and testing. With health benefits globally from the availability of new drugs, albeit for poorer populations only after patent terms expire, changes to the U.S. healthcare system are also of significance to patients and the pharmaceutical industry internationally. This article evaluates how the ACA will affect the size of the biopharmaceutical market and competitive dynamics within the industry. Estimates are developed for healthcare spending in 2015 and 2020, especially for expenditures on prescription drugs in nominal terms and as a percentage of overall health spending. The article concludes with a discussion of the political economy of insurance and the sustainability of largely free-pricing of pharmaceuticals in the United States.

Keywords: Health policy, pharmaceutical industry, drug prices, health insurance, United States healthcare reform

1. Introduction

Implementation of the Patient Protection and Affordable Care Act ("Affordable Care Act," or ACA) began shortly after its passage in March 2010. Among the first provisions acted upon by the U.S. Department of Health and Human Services were requirements that insurers offer coverage to young adults up to age 26 under family plans and new rules to ensure that patients with preexisting conditions or with diseases whose treatment was especially expensive did not lose coverage. Other major provisions will be phased in by the end of 2014, including the key requirement that every U.S. citizen carry health insurance, either through their employer; through government-run Medicare, Medicaid, or Veteran's Administration programs; or from a private plan. Insurance firms face new regulations, including a ban on annual or lifetime caps on coverage. New private plans, marketed through on-line state-based insurance exchanges, will be subsidized for people unable to obtain coverage by other means. It is expected that these

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changes will result in coverage for most of the 49 million Americans who were uninsured in 2010. For the pharmaceutical industry, the ACA is a mixed blessing. Provisions expanding Medicare drug coverage and encouraging preventive care will likely generate additional sales. At the same time, these will be offset somewhat by mandates for the use of generics and through additional taxes and fees on pharmaceutical firms.

The Act was controversial through a year of Congressional debate, vociferous public demonstrations, and intensive lobbying by insurers and healthcare industries. Only negotiations led by House speaker Nancy Pelosi, Senate majority leader Harry Reid, and president Barack Obama resulted in the legislation's passage after it stalled repeatedly in the face of Republican opposition to coverage mandates and concerns over costs. The law is of historic significance since national healthcare reform, notably the creation of universal coverage, failed to pass under Franklin D. Roosevelt in 1934, Harry S. Truman in 1945, John F. Kennedy in 1962, and William (Bill) J. Clinton in 1993.

Sponsors of the ACA expect that greater coverage will eventually lower total healthcare spending, which exceeded 17 percent of U.S. GDP in 2010. Spending 60 percent more on insurance and patient care than any other developed country in the OECD, the United States has similar or worse outcomes in terms of life expectancy and infant mortality. Lack of insurance contributes to 45,000 Americans dying prematurely every year.¹ Even Americans with insurance can find out-of-pocket costs difficult to pay; over 60 percent of bankruptcies in 2007 stemmed from medical debts.² At the same time, survival rates for many cancers, notably breast cancer in women and prostate cancer in men, are better in the United States than in countries with lower health spending per capita. The United States also maintains a global lead in biomedical research, has greater availability of advanced technology such as CT scanners and MRI units, and invests over twice as much as any other country in medical facilities on a per capita basis.³

¹ A. Wilper, et al., "Health Insurance and Mortality in U.S. Adults," *American Journal of Public Health* 99 (September 17, 2009), 2289-2295.

² D. Himmelstein, et al., "Medical Bankruptcy in the United States, 2007," *The American Journal of Medicine*, 122 (2009), 741-746.

³ Author's analysis, Source: OECD, "OECD Health Data," *OECD Health Statistics (database)*, accessed August 2011.

This article has two ambitions. First, it contributes to scholarship on the political economy of healthcare, specifically concerning healthcare reform.⁴ Research on the U.S. healthcare system has focused on political barriers to universal coverage, with a great deal of emphasis on the policy deadlocks that historically sustained America's exceptionalism in insurance coverage internationally. A historical institutionalist analysis is developed here to understand how healthcare reform came to the top of the policy agenda in 2009 and 2010 and to explain how the ACA achieved passage despite strong opposition to several of its major provisions. Second, the article has a pragmatic goal of advancing estimates for how the ACA will affect the pharmaceutical sector, both quantitatively in terms of the size of the prescription drug market and qualitatively in terms of industry structure and competitive dynamics.

The article begins by putting current reforms to the U.S. healthcare system into historical context, specifically in relation to developments in insurance and pharmaceutical markets. It next details the contentious passage of the ACA, including key arguments for and against expanding coverage and increasing government regulation of insurers. In contrast to previous reform efforts, the ACA passed with support of the pharmaceutical and insurance industries. Building on this study of the institutional setting for healthcare reform in the United States, the article analyzes the probable impacts of the ACA on the pharmaceutical sector. Changes to the U.S. pharmaceutical market are calculated based on total healthcare spending and changing demographics of the insured population. Following this approach, estimates are developed for future expenditure on prescription drugs, on a per capita basis and as a percentage of overall health spending. Since the United States is the largest single pharmaceutical market in the world, the ACA holds significance also to the drug industry internationally. The article concludes with analysis of the political economy of insurance and the sustained power in the United States of neoclassical economic arguments concerning drug price controls.

2. History of the U.S. Healthcare System

In contrast to either state-run or coordinated social insurance systems found in other OECD countries, the United States combines private insurance with public financing of Medicare and

⁴ This literature is quite extensive. For representative works, see: L. Jacobs and T. Skocpol, *Health Care Reform and American Politics: What Everyone Needs to Know* (Oxford: Oxford University Press, 2010); J. Quadagno, *One Nation, Uninsured: Why the US Has No National Health Insurance* (Oxford: Oxford University Press, 2005); A. Garber and J. Skinner, "Is American Health Care Uniquely Inefficient?" *Journal of Economic Perspectives*, 22 (2008), 27-50; E. Connors and L. Gostin, "Health Care Reform: A Historic Moment in U.S. Social Policy," *JAMA* 303 (2010), 2521-2522.

Medicaid. The delivery of care is mostly through privately operated hospitals and physicians working independently or in small groups. Costs are largely unconstrained, though Medicare sets reimbursement levels and private insurers commonly negotiate fee schedules with hospitals and other providers. The product of more than a century of separating public and private, even as coverage was expanded incrementally in both areas, the U.S. system is an exception among developed countries.

Individually, Americans could hedge against unexpected medical costs starting in the mid-19th century by purchasing limited insurance from local hospitals. Group health insurance was established in Dallas, Texas in 1929 when Baylor University Hospital offered schoolteachers a prepaid plan for \$6 per year (\$76, if inflation-adjusted to 2010). The first Blue Cross plan was offered in 1932, based also on a prepayment mechanism, but freeing subscribers to select the site of care. Blue Shield plans also emerged in the 1930s, providing coverage for physician visits. Compulsory health insurance was included in the proposed Social Security Act in 1935, but strong opposition by the American Medical Association (AMA) led President Roosevelt to drop it in favor of unemployment and retirement benefits.⁵

2.1. Private Insurance

During and after World War II, wage controls prevented U.S. employers from offering higher salaries to attract employees. Instead, they began to compete through ever-more-generous benefits, including health insurance through combined Blue Cross and Blue Shield or from other private insurers. Further encouraging this trend, changes to the tax code in 1954 granted exemptions to employers that provided and managed health insurance. It became the norm for large employers to subsidize and manage insurance offerings for their workers.

Physicians and the AMA initially sought to slow the spread of insurance. The AMA favored a business model of physicians in private practice, paid by individual patients, as a way to prevent the consolidation of medical practices into larger businesses.⁶ Yet, when nonprofit Blue Shield plans broadened offerings to cover doctor's visits and prescription drugs, physicians began accepting third-party payments. Private insurers then gradually started to exercise

⁵ P. Starr, *The Social Transformation of American Medicine* (New York: Basic Books, 1982), 235-279.

⁶ J. Burrow, *AMA: Voice of American Medicine* (Baltimore: Johns Hopkins Press, 1963); F. Campion, *The AMA and U.S. Health Policy since 1940* (Chicago: Chicago Review Press, 1984).

control over physicians in the 1950s and 1960s. Specifically, insurance companies set up “utilization review committees” and tracked doctor fee profiles and treatment histories.⁷ These data were then used to set care guidelines that physicians had to follow to receive payments. Physicians nevertheless retained a great deal of autonomy over patient care, and the dominance of fee-for-service over capitation or other payment models limited the power insurers could wield over rising prescription drug use, and costs.

Health maintenance organizations (HMOs) that integrated insurance and delivery grew slowly in the post-war era from their origins in the Kaiser system in California and Oregon. Under the 1973 HMO act, employers were required to offer coverage from at least one federally qualified HMO, providing an impetus to rapid national expansion.⁸ By the 1980s, HMOs had transformed from local healthcare cooperatives to large national corporations, and enrollment grew from 3 million in 1970 to a peak of 80 million in 2000.⁹ HMOs came under attack in the 1990s and 2000s for failing to control costs, while physicians complained of restrictions on patient visit times and rules that interfered with their choice of care, including which drugs to prescribe. Nevertheless, emergence of the broader managed care movement in the 2000s meant that working Americans had to select a primary care physician from a list controlled by their employer-selected insurance, with limits put on access to specialists and diagnostic services.

According to critics of the U.S. system, getting coverage from private insurance firms, often chosen and partly or wholly paid through employer-managed programs, failed to create incentives for optimal care. Between 1996 and 2006, the average annual premium for employer-provided health insurance for a family of four increased by 85 percent from \$6,500 to \$12,000.¹⁰ Patients with chronic illnesses accounted for nearly 80 percent of U.S. healthcare spending and it took a decade for insurers to recoup the costs of effective disease management plans for conditions such as asthma, diabetes, chronic heart failure, or obesity.¹¹ However, due to the vagaries of employer decisions about insurance carriers and job and family changes, between 20

⁷ C. Chapin, “The American Medical Association, Health Insurance Association of America, and Creation of the Corporate Health Care System,” *Studies in American Political Development* 24 (2010), 143-167.

⁸ Starr, *Social Transformation*, 302-306.

⁹ M. Markovich, *The Rise of HMOs* (Santa Monica, CA: RAND, 2003), 2-4.

¹⁰ Council of Economic Advisers, *The Economic Case for Health Care Reform* (Washington, D.C.: 2009), 3.

¹¹ M. Porter and E. Teisberg, *Redefining Healthcare: Creating Value-Based Competition on Results* (Boston, MA: Harvard Business School Press, 2006), 253-258.

and 25 percent of Americans switch coverage annually.¹² The integrated insurance and care HMO model had largely disappeared by the late 1990s, leaving treatment and insurance markets fragmented. Physicians continued to work primarily on a fee-for-service basis, with only modest financial incentives to undertake long-term preventive care.¹³

The private health insurance market in the United States presently comprises a complex mix of national, regional, and local insurers, with some operating for-profit and some as nonprofit corporations. Many Blue Cross and Blue Shield plans have shifted to for-profit status in an effort to compete with smaller competitors that offer customized plans.¹⁴ Remarkably, profitability across the U.S. private health insurance sector is not especially high. In 2008, profits as a percentage of revenues for insurance and managed care firms averaged 2.4 percent, putting the industry in 46th place out of 75 total (pharmaceutical firms ranked 3rd at 11.2 percent profits as a percentage of revenue).¹⁵ Employers and individuals purchasing coverage on their own typically have several choices, though the concentration of insurers in some locations limits options. In 48 percent of metropolitan statistical areas, at least one insurer has a market share of 50 percent or more.¹⁶ In addition, even competing plans lack price transparency and coverage often varies in quite complex and subtle ways. As a Congressional Research Service report recently observed, “comparing competing plans can be difficult even for sophisticated health care consumers.”¹⁷

2.2. Public Insurance

U.S. government involvement in healthcare originated with benefits provided to veterans after the Civil War.¹⁸ Centers providing medical, surgical, and rehabilitative care were consolidated in 1930 under the Veterans Administration (VA). Benefits were expanded after

¹² M. Votruba, et al., “Insurance Turnover as an Impediment to Improving Health Care Quality,” Annual Meeting of the American Society of Health Economists (Madison, WI: June 4, 2006), www.allacademic.com/meta/p93450index.html, accessed August 2011.

¹³ E. Elhauge, “Why We Should Care About Health Care Fragmentation and How to Fix It,” in E. Elhauge (ed), *The Fragmentation of U.S. Health Care* (Oxford: Oxford University Press, 2010), 1-20.

¹⁴ S. Folland, A. Goodman, and M. Stano, *The Economics of Health and Health Care*, 6th edition (Boston, Prentice Hall: 2010), esp. 215-218.

¹⁵ Fortune, “The Largest U.S. Corporations,” *Fortune* 159 (May 4, 2009), 28-29.

¹⁶ American Medical Association, *Competition in Health Insurance: A Comprehensive Study of U.S. Markets, 2010 Update* (Chicago, American Medical Association: 2011).

¹⁷ D. Austin and T. Hungerford, “The Market Structure of the Health Insurance Industry,” Congressional Research Service 7-5700 (November 17, 2009), www.crs.gov (accessed August 2011).

¹⁸ T. Skocpol, *Protecting soldiers and Mothers: The Political Origins of Social Policy in the United States* (Cambridge: Harvard University Press, 1992); Department of Veterans Affairs, “VA History,” www.va.gov, accessed August 2011.

WWII, and again after the Vietnam War. By the mid-1990s, the VA had become the single largest healthcare provider in the United States, handling 1.1 million hospital admissions per year and 24 million outpatient visits. However, VA hospitals were criticized for low quality but expensive care in substandard facilities that were difficult to access. A major transformation initiated in 1995 improved the timeliness and quality of care, upgraded facilities, and introduced electronic patient records, all while slowing the rate of spending growth.¹⁹

2.2.1. Medicare and Medicaid

In the wake of failed health insurance proposals under Truman in 1945 and Kennedy in 1961, liberals turned to coverage for the elderly as a first step toward a broader federal role.²⁰ Following years of failed Congressional debates, president Johnson spearheaded a bill in 1965 that created Medicare and Medicaid. A compromise was forged between Democrats, who supported Medicare Part A (hospital in-patient insurance) and Republicans, who supported Medicare Part B (outpatient coverage).²¹ Initially restricted to citizens 65 or older regardless of income or medical history, Medicare was expanded in 1972 to include Americans under age 65 with disabilities.

Medicaid provided basic medical insurance for low-income Americans, jointly financed by the federal government and the states. From the beginning, each state administered its own Medicaid program, under federal regulatory oversight. Coverage was expanded under the American Recovery and Reinvestment Act of 2009, resulting in Medicaid providing at least some benefits to 60 million citizens.²² Income criteria for Medicaid eligibility vary by state; to qualify in 2010, an individual typically had to earn less than \$9,200 and a family of four less than \$17,420.

When enacted, Medicare and Medicaid reimbursed physicians and hospitals on a “cost plus 2 percent basis,” putting them at or above payments from private insurers.²³ Almost immediately, expenditures began to rise, and both Medicare and employer-sponsored insurance

¹⁹ K. Kizer and R. Dudley, “Extreme Makeover: Transformation of the Veterans Health Care System,” *Annual Review of Public Health* 30 (2009), 313-339.

²⁰ D. Sheri, *With Dignity: The Search for Medicaid and Medicare*. (Westport, CT: Greenwood Press, 1985).

²¹ Starr, *Social Transformation*, 368.

²² The Kaiser Commission on Medicaid, “Medicaid Facts” (Washington DC: Kaiser Family Foundation, September 2009), www.kff.org/medicaid/upload/7235_03-2.pdf, accessed December 2009.

²³ R. Mayes, “The Origins, Development, and Passage of Medicare’s Revolutionary Prospective Payment System,” *Journal of the History of Medicine and Allied Sciences* 62 (2007), 21-55.

premiums increased by 15 to 20 percent per year in the 1960s and 1970s. Whereas the overall consumer price index rose 89 percent between 1966 and 1976, hospital costs grew by 345 percent.²⁴ After president Carter twice failed to gain congressional passage of a plan to cap annual growth in hospital prices, Medicare appeared headed toward insolvency. Starting in the mid-1970s, policymakers developed a more sophisticated prospective payment system with diagnosis-related groups (DRGs). Built around distinct diagnostic categories, the DRG approach bundled various charges for treating a particular medical event into a single payment.

Seeking to cut government spending during a deep recession, the Reagan administration made the DRG approach mandatory in 1983.²⁵ Hospitals soon warned that DRGs failed to capture the difference between serious and moderate conditions. For example, payments for treating a serious stroke were only modestly higher than for a simple stroke, leading hospitals to under-treat patients and shorten the length of stay.²⁶ Hospital participation was voluntary, although by 2010 Medicaid and Medicare enrollees accounted for 56 percent of all hospital care and despite complaints, few hospitals declined to treat patients covered by the government.²⁷

Medicare initially did not include prescription drug coverage, though medicines dispensed in a physician's office or in hospitals (i.e., vaccines, immunosuppressive drugs, and other injections) were covered. Seniors were able to access other sources of drug coverage, including employer-provided insurance, privately purchased supplemental insurance, and managed care plans with restricted formularies. Numerous legislative proposals in the 1970s, 1980s, and 1990s sought to expand pharmaceutical coverage, though always in combination with other reforms that proved stumbling blocks to passage.²⁸ In a significant exception, Congress in 1988 passed the Medicare Catastrophic Coverage Act, which included limited prescription drug benefits, albeit with high deductibles (\$600 in 1991) and cost-sharing for beneficiaries. The Act was repealed less than 18 months later, in the wake of a controversy over additional taxes and fees on the elderly.²⁹ Medicaid programs provide coverage for prescription drugs, though states

²⁴ Executive Office of the President's Council on Wage and Price Stability, "The Rapid Rise of Hospital Costs" (Washington, D.C.: USGPO, 1977), 9-11.

²⁵ Mayes, "Origins, Development, and Passage of Medicare's Revolutionary Prospective Payment System," 21-55.

²⁶ Porter and Teisberg, *Redefining Healthcare*, 74.

²⁷ American Hospital Association, "American Hospital Association Underpayment By Medicare and Medicaid Fact Sheet" AHA: November 2008.

²⁸ T. Oliver, P. Lee, and H. Lipton, "A Political History of Medicare and Prescription Drug Coverage," *The Milbank Quarterly* 82 (2004), 283-354.

²⁹ T. Rice, K. Desmond, and J. Gabel, "The Medicare Catastrophic Coverage Act: A Post-Mortem," *Health Affairs* 9 (1990), 75-87.

differed concerning copayment amounts, the breadth of the formulary, and limits on the number of prescriptions that recipients can fill. Prices paid for drugs under different government programs vary, sometimes significantly, with Medicaid frequently paying the least thanks to a more restricted formulary and long-term fixed contracts with pharmaceutical manufacturers.³⁰

Funded through payroll taxes and operated on a “pay as you go” model, Medicare and Medicaid have significant long-term liabilities. As the Baby Boom generation, a cohort of some 75 million Americans born between 1946 and 1964, now reach retirement age, Medicare is projected to expand at over 7 percent annually for the foreseeable future, well above even very optimistic GDP growth projections.³¹ The anticipated total liability by 2082 is \$106.8 trillion dollars, equal to the entire federal budget under normal growth scenarios.³²

2.2.2. Expanding Coverage at High Cost

In 1985, the Consolidated Omnibus Budget Reconciliation Act (COBRA) gave employees terminated for reasons other than gross misconduct an option to remain in their employer’s group health plan for up to 18 months. COBRA had a bite since employees had to pay the full costs of coverage plus a 2 percent administrative fee. In 2009, monthly premiums averaged 84 percent of government unemployment benefits for a family of four, and 30 percent for individuals.³³

A small provision within the 1985 Omnibus act had significant implications for overall healthcare costs. Enacted in response to reports of “patient dumping”—hospitals transferring or refusing treatment to patients who lacked insurance—the Emergency Medical Treatment and Active Labor Act (EMTALA) turned emergency rooms (ERs) into a primary care site for uninsured Americans. Under the act, hospitals could not transfer, discharge, or refuse to treat patients coming to the ER. By 2006, the uninsured accounted for 20 percent of 120 million ER

³⁰ R. Frank and J. Newhouse, “Mending the Medicare Prescription Drug Benefit: Improving Consumer Choices and Restructuring Purchasing,” Brookings Institution Discussion Paper 2007-03 (April 2007); Department of Health and Human Services, Office of Inspector General, “Higher Rebates for Brand-Name Drugs Result in Lower Costs for Medicaid Compared to Medicare Part D,” <http://oig.hhs.gov/oei/reports/oei-03-10-00320.pdf>, accessed August, 2011.

³¹ S. Keehan, et al., “Health Spending Projections Through 2017: The Baby-Boom Generation is Coming to Medicare,” *Health Affairs* 27 (2008), 145-155.

³² R. Sunshine, “The Budget and Economic Outlook,” Congressional Budget Office, February 2010.

³³ Families USA, *Squeezed: Caught Between Unemployment Benefits and Health Care Costs* (Washington, D.C.: Families USA, 2009).

visits and treatment of conditions such as back pain, flu, and headaches was between four and six times as expensive as in primary care clinics.³⁴ Expenses were borne by Medicare, Medicaid, and private insurers through higher fees for the insured.³⁵

As healthcare costs, especially for prescription drugs, rose at double the rate of consumer price inflation in the 1990s and early 2000s, Congress expanded pharmaceutical coverage for retirees and Medicaid recipients. The 2003 Medicare Part D policy operated through private firms; seniors had to select from among over 1,800 plans with varying coverage and co-payment options. In 2010, Medicare required participants to pay up to the first \$310 of prescription drug costs as a baseline deductible. Plans then covered 75 percent of expenses until total costs reached \$2,830. At that point, beneficiaries entered a so-called “donut hole” and had to pay all drug costs until total out-of-pocket expenses reached \$4,550. Then the coverage gap ended and Medicare covered authorized prescriptions for the remainder of the year. Critics noted that because Medicare was not allowed to negotiate drug prices with manufacturers the government paid up to 58 percent more for the same medicines under Part D than through the VA.³⁶

Table 1. Total Public and Private Healthcare Expenditure (percentage of GDP)

	1970	1980	1990	2000	2009
Canada	6.9	7.0	8.9	8.8	11.4
France	5.4	7.0	8.4	10.1	11.8
Germany	6.0	8.4	8.3	10.3	11.6
Japan	4.6	6.5	6.0	7.7	8.5
Switzerland	5.4	7.3	8.2	10.2	11.4
United Kingdom	4.5	5.6	5.9	7.0	9.8
United States	7.1	9.0	12.2	13.6	17.6

Source: OECD, “OECD Health Data,” *OECD Health Statistics (database)*, accessed August 2011.

Together, the combination of private and public insurance, with few incentives on providers to limit available treatment, led to steady growth in spending in the United States. In contrast to other major OECD countries, whose spending leveled off in the past decade at between 10 and

³⁴ L. Szabo, “Chronic Conditions Crank up Health Cost,” *USA Today* (September 8, 2009), A1.

³⁵ American Academy of Emergency Medicine, “EMTALA,” www.aaem.org/emtala, accessed August 2011; Healthcare Costs and Utilization Project, “Nationwide Emergency Department Sample,” www.hcup-us.ahrq.gov, accessed August 2011; M. Newton, et al., “Uninsured Adults Presenting to U.S. Emergency Departments,” *JAMA* 300 (2008), 1914-1924.

³⁶ M. Steinberg and K. Bailey, *No Bargain: Medicare Drug Plans Deliver High Prices* (Washington, D.C.: FamiliesUSA, 2007).

12% of GDP, the United States experienced continual spending growth since the 1970s (see Table 1).

2.3. The Pharmaceutical Industry and Healthcare Reform

Pharmaceutical prices and the industry's profitability became the subject of public policy starting with a lengthy congressional investigation initiated by the populist Senator Estes Kefauver (D-TN) in 1959.³⁷ Coming on the heels of a Federal Trade Commission study that identified a lack of competition in the antibiotics market, Kefauver announced his intention to protect "captive" consumers and "indigent" patients from companies that colluded to set high drug prices.³⁸ Testimony by pharmaceutical company leaders during Kefauver's Senate hearings would set the tone for the industry position concerning price controls for several decades. CEOs of leading firms and Austin Smith, head of the pharmaceutical industry trade association and a noted physician and former editor of the *Journal of the American Medical Association*, contended that high prices compared to the costs of manufacturing were necessary to recoup the expense of failed research. A three-part argument was put forth: one, that pharmaceuticals cut down on hospital stays and returned ill people to health faster; two, that successful drugs had to pay for failures along a lengthy testing and development pipeline; and three, that it would be a mistake to orient the industry to cost-savings in light of its public health responsibilities.³⁹

In 1961, Kefauver introduced a controversial bill designed to foster competition through additions to existing antitrust laws and compulsory licensing of drug patents to other manufacturers after an initial three-year exclusivity period. Kefauver's bill was shelved after an initial debate on the Senate floor.⁴⁰ However, the proposed legislation gained new life after a scandal erupted concerning birth defects linked to the sedative thalidomide. In what would become the 20th century's most prominent drug disaster, thalidomide's use by pregnant women led to the birth of approximately 10,000 children worldwide with congenital

³⁷ U.S. Senate, Subcommittee on Antitrust and Monopoly, *Administered Prices* 26 vols. (Washington, D.C.: U.S. Government Printing Office, 1957-1960); see also E. Kefauver, *In a Few Hands: Monopoly Power in America* (New York: Pantheon Books, 1965).

³⁸ Federal Trade Commission, *Economic Report on Antibiotics Manufacture* (Washington, D.C.: U.S. Government Printing Office, 1958); for Kefauver's opening statement, see: U.S. Senate, *Administered Prices* v. 14 (1959), 7836-7841.

³⁹ U.S. Senate, *Administered Prices* v. 19 (1960), 10615-10618.

⁴⁰ R. Harris, *The Real Voice* (New York: MacMillan Company, 1964), 157-169.

abnormalities between 1959 and 1963.⁴¹ Kefauver's bill was rewritten to focus on consumer protection; provisions concerning competition policy and drug prices were dropped. Pharmaceutical firms now had to meet regulations governing every stage of new drug testing, from the laboratory to human trials, and officials at the U.S. Food and Drug Administration (FDA) formally had to approve a drug for it to enter commerce. At the same time, the additional safety and efficacy rules helped to provide a long-term justification for minimal interference with drug prices, even as healthcare system costs rose in the 1970s and 1980s.⁴²

Health spending featured prominently in the 1992 presidential campaign that brought Bill Clinton to office. Following discussions with insurers and care providers led by Hillary Clinton, the Health Security Act was introduced in fall 1993.⁴³ The proposed bill would have broadened insurance coverage nationally through a network of new "health alliances" structured as regional purchasing cooperatives. Alliances were to offer insurance to individuals unable to access employer-sponsored coverage. Policymakers planned to control insurance premiums and could cap the annual insurance costs borne by consumers at 3.9 percent of their income. The bill also contained provisions targeted to pharmaceuticals, including coverage through Medicare and the health alliances. Costs were to be offset, in part, through mandated rebates from pharmaceutical firms of up to 17 percent of the average retail price for prescription drugs. In an effort to secure lower prices on new drugs, the bill called for the formation of an advisory council on breakthrough drugs, with representatives from consumer organizations, hospitals, insurers, and the pharmaceutical industry. The council was to publish formal opinions concerning the "reasonableness" of drug prices based on: "prices of other drugs in the same therapeutic class; cost information supplied by the manufacturer ... and projected prescription volume, economies of scale, product stability, special manufacturing requirements and research costs."⁴⁴ By comparing new drugs to others in the same therapeutic class, and by taking into account research and manufacturing costs but not marketing expenditures, the council was intended to reduce drug prices by influencing Medicare, Medicaid, and private insurance formularies.

⁴¹ R. McFadyen, "Thalidomide in America: A Brush with Tragedy," *Clio Medica* 11 (1976), 79-93; A. Daemmrich, "A Tale of Two Experts: Thalidomide and Political Engagement in the United States and West Germany," *Social History of Medicine* 15 (2002), 137-158.

⁴² D. Tobbell, "Allied Against Reform: Pharmaceutical Industry-Academic Physician Relations in the United States, 1945-1970," *Bulletin of the History of Medicine* 82 (2008), 878-912.

⁴³ U.S. Congress, *Health Security Act of 1993*, (Washington, D.C.: U.S. Government Printing Office, 1993).

⁴⁴ U.S. Congress, *Health Security Act*, section 1572.

Pharmaceutical firms responded to the bill with warnings of stifled research and suffering patients. The industry trade association cautioned: "What other industry can provide hope for curing AIDS, Alzheimers, osteoporosis, or cancer?"⁴⁵ A number of companies further argued that pharmaceuticals were cost-effective compared to other approaches to patient care. Merck's CEO explained in 2-page newspaper advertisement: "Good medicines save more money than they cost by keeping people out of hospitals, out of operating rooms, and out of nursing homes."⁴⁶ Pfizer's CEO added, "We are the future of health care cost-containment."⁴⁷ A broader argument combining health, industry economic, and international competition was put forward in an editorial in *Science*: "The major casualties of excessive price pressure on drugs would be the small biotechnology companies, the rate of development of new drugs to relieve human suffering, and global leadership of the United States in creating new pharmaceuticals."⁴⁸

Insurers, threatened by caps on annual increases and by the potential for new competitors in the form of large health alliances, also fought the proposed bill. Notably, the Health Insurance Association of America (HIAA) ran television ads, including \$15 million spent on notorious "Harry and Louise" commercials in which a middle-class couple worried about new bureaucracy implied by the health alliances.⁴⁹ Other opposition came from lobbyist-funded citizen groups and the AMA. According to an analysis published in 1994, the reform proposal was "the most heavily lobbied legislative initiative in recent U.S. history."⁵⁰ As public sentiment shifted against the bill, Republican congressional leaders saw opportunities for gains in the upcoming 1994 election and began to attack it as excessively bureaucratic. In the end, it did not come up for a vote in either the House or the Senate.

3. The Patient Protection and Affordable Care Act of 2010

Healthcare again took center stage during the 2008 presidential campaign, and candidate Barack Obama frequently invoked the inequalities and inefficiencies of the U.S system. Once

⁴⁵ E. Tanouye, "Drug Industry Darkens View of Clinton Health Plan," *The Wall Street Journal* (October 29, 1993).

⁴⁶ Merck and Co., Inc. "Open Letter from Merck and Co., Inc." Two page advertisement in *The New York Times* (February 19, 1993), Section A.

⁴⁷ W.C. Steere, "The Changing Pharmaceutical Marketplace and the Health Care Reform Debate," address to the Pharmaceutical Manufacturers Association Annual Meeting (March 30, 1993).

⁴⁸ P. Abelson, "Improvements in Health Care," *Science* 260 (1993): 11.

⁴⁹ T. Skocpol, *Boomerang: Health Care Reform and the Turn Against Government* (New York: W.W. Norton, 1997), esp. 134-172.

⁵⁰ Center for Public Integrity, *Well-Healed: Inside Lobbying for Health Care Reform* (Washington, D.C.: Center for Public Integrity, 1994), 1.

elected, president Obama was confronted with opposing forces in the healthcare system. In 2009, total spending for Medicaid and Medicare comprised over 6 percent of GDP; it was expected to rise to 15 percent of GDP by 2040.⁵¹ Together the two programs covered 45 million Americans and made up 20 percent of the federal budget. Yet, unions and employers were tacitly allied in opposition to cost reduction and system rationalization. Workers losing jobs in manufacturing were retraining in record numbers for positions as medical assistants or in medical billing and administration. In 2009, healthcare provided over 12 percent of employment in the United States. Balancing these tensions, the White House Council of Economic Advisors argued that universal coverage would make it easier for Americans to switch jobs, less risky for entrepreneurs to start new firms, and less disadvantageous to manufacture products in the United States compared to other countries.⁵²

3.1. Initial Proposals and Policy Debates

By March 2009, president Obama and congressional committee leaders had reached consensus on overall parameters for reform legislation. Democrats argued that every American must have insurance, employers should be required to help their employees pay for it, and the government should either create a new public insurance option or expand Medicare for citizens unable to obtain affordable private insurance. Members of both parties railed against insurance firms that dropped coverage when patients were diagnosed with cancer or other life-threatening diseases. Less consensus was apparent, even within the Democratic party, on how to pay for expanded coverage. Republicans, in the minority after a severe electoral setback in November 2008, issued few formal statements on reform as the process began.

In late spring and early summer 2009, congressional Democrats initiated and advanced separate bills through House and Senate committees. As first proposed, the House bill included provisions that mandated universal coverage, offered a public insurance option with discrete benefit categories for those who did not have private insurance sponsored by an employer, and created a new agency to regulate the insurance industry. Under the proposed bill, the Department of Health and Human Services (HHS) would gain regulatory authority over some aspects of care delivery in order to reduce cost growth and set outcome metrics. Senate bills had

⁵¹ Council of Economic Advisers, *The Economic Case for Health Care Reform* (Washington, D.C.: 2009), 6.

⁵² Council of Economic Advisers, *The Economic Case*, 31-38.

similar provisions for improving quality and reducing waste, but planned to establish private insurance exchanges on the state level and instituted additional regulation through existing government agencies.

Pharmaceutical, insurance, and other healthcare industries sought to influence the ACA from the initial concept well into late-stage negotiations. Ultimately, key interest groups would support the ACA. Insurers accepted stricter regulations, including on premiums, the elimination of annual and lifetime caps, and a ban on exclusions for preexisting conditions. Universal coverage was attractive to insurers once it became clear that it was likely to increase revenue and profitability thanks to the inclusion in insurance pools of young and healthy individuals who often opted not to purchase coverage.⁵³ However, private insurers were concerned that a public plan would have the power to negotiate lower prices for care and could then offer lower-priced plans to the public. The lead health insurance trade association, America's Health Insurance Plans (a successor organization to AHIP, which vociferously fought the Clinton plan) then began to lobby against the public option.

Like insurers, the pharmaceutical industry supported the individual mandate while opposing public insurance plans. Specific negotiations took place concerning Medicare drug payment rebates and the process and speed with which generic biological drugs would come to market.⁵⁴ PhRMA, the pharmaceutical industry trade association, publicly supported reforms that "transform our sick-care system to a 21st century healthcare system that focuses on disease prevention and management to help keep patients out of the hospital and most importantly, help keep Americans from getting sick in the first place."⁵⁵ In an open letter to president Obama supporting reform and summarizing the industry's position in June 2009, PhRMA argued: "better use of medicines can save lives, decrease utilization of other health care services, enhance productivity and save money."⁵⁶ Concerned about cost-cutting measures in the proposed bills, the pharmaceutical industry ramped up lobbying spending in 2009 to \$271.7 million, a 13.5 percent increase on the already high spending of the 2008 election year; by some

⁵³ J. Quadagno, "Interest-Group Influence on the Patient Protection and Affordable Care Act of 2010: Winners and Losers in the Health Care Reform Debate," *Journal of Health Politics, Policy and Law* 36 (2011), 449-453.

⁵⁴ K. Tumulty and M. Scherer, "How Drug Industry Lobbyists Won on Health Care," *Time* (October 22, 2009); N. Levey, "Drug Makers Try to Sidetrack Demands for Discounts," *Los Angeles Times* (July 9, 2011).

⁵⁵ Pharmaceutical Researchers and Manufacturers of America, "White House Healthcare Summit Offers Opportunity for Input into Reform," PhRMA press release (March 12, 2009), www.phrma.org, accessed September 2011.

⁵⁶ "Letter to President Obama," from AdvaMed, AHIP, AHA, AMA, PhRMA, and SEIU (June 1, 2009), www.ama-assn.org, accessed September 2011.

accounts the industry mobilized nearly 3,000 lobbyists on Capitol Hill.⁵⁷ In exchange for expanding Medicare drug coverage without authorizing the government to negotiate prices and eliminating the public option, the industry committed to \$80 billion in reduced drug spending (versus projections) over the following decade through Medicaid rebates and an FDA approval pathway for generic biological drugs.

During the 2009 Congressional summer recess, vocal opposition to the draft bills grew and connected with broader concerns of excessive government intervention in the economy. In August, former Alaskan Governor and 2008 Vice Presidential candidate Sarah Palin attacked the proposals on a Facebook posting: "The Democrats promise that a government health care system will reduce the cost of health care, but ... government health care will not reduce the cost; it will simply refuse to pay the cost. The America I know and love is not one in which my parents or my baby with Down Syndrome will have to stand in front of Obama's 'death panel' so his bureaucrats can decide, based on a subjective judgment of their 'level of productivity in society,' whether they are worthy of health care."⁵⁸ Congressional representatives meeting with constituents in town hall settings soon discovered that the public was deeply divided on the issue. Opponents to any greater government role in healthcare focused their criticisms and began to mobilize, including through the emerging "Tea Party" that was gathering momentum across the country.⁵⁹

3.2. Congressional Maneuvers

Upon reconvening in fall 2009, floor debates in the House added strict restrictions on funding for abortions and the requirement that any public insurance option negotiate rates in the same way as private plans, rather than setting fixed rates at or just above Medicare levels. The emerging House bill also mandated the creation of health insurance exchanges to provide a way for individuals and small businesses to purchase coverage.⁶⁰ After multiple rounds of negotiations, the House approved the bill by a vote of 220 to 215 in early November. The

⁵⁷ Open Secrets, "Pharmaceuticals / Health Products," www.opensecrets.org, accessed September 2011; O. Pierce, "Medicare Drug Planners Now Lobbyists, With Billions at Stake," *ProPublica* (October 20, 2009). Pharmaceutical industry lobbying subsequently declined by over 10 percent in 2010.

⁵⁸ S. Palin, "Statement on the Current Healthcare Debate," *Facebook* (August 2009)

http://www.facebook.com/note.php?note_id=113851103434, accessed February 2010.

⁵⁹ K. Zernike, *Boiling Mad: Inside Tea Party America* (New York: Times Books, 2010).

⁶⁰ "Focus on health reform: Side-By-Side Comparisons of Major Health Care Reform Proposals" *The Kaiser Family Foundation* (December 23, 2009), 7.

Congressional Budget Office (CBO) estimated health expenditure savings of \$109 billion over ten years and insurance coverage for an additional 36 million people.⁶¹ However, the plan did not include any new revenue sources, despite president Obama's suggestion to levy an excise tax on premium insurance plans.⁶²

Meanwhile, in early October, the Senate Finance Committee voted 14-9 in favor of a bill that mandated insurance coverage. A month later, Senate majority leader Harry Reid introduced it as the "Patient Protection and Affordable Care Act." Needing 60 votes to avoid a Republican filibuster, Reid had to align razor-thin support. Almost immediately, Joseph Lieberman of Connecticut stated that he would block any bill with a public insurance option. After several efforts at compromise failed, the public option was dropped. Working on Christmas Eve for the first time since 1895, the Senate ultimately passed a revised bill that aimed for universal coverage through subsidies to low and middle-income Americans for the purchase of private insurance, as well as a significant expansion of Medicaid.⁶³

Momentum in favor of reform stalled in January 2010. Scott Brown, a Republican who campaigned against the healthcare reform bills, won a special election in Massachusetts to fill the Senate seat formerly held by Ted Kennedy, a lifelong proponent of universal coverage. With Brown seated as the 41st Republican senator, Democrats lost their 60-vote "supermajority," which was needed to close off debate and prevent a filibuster by Republican opponents.

Insurance and pharmaceutical industry support for the ACA grew more muted in late 2009 and early 2010 as Republicans voiced ever-greater concerns with the proposed reform. However, no industry-backed campaign against the ACA emerged comparable in size and reach to the successful effort to block the Clinton reform proposals. PhRMA instead issued press releases and other public statements throughout the process that supported reform. Overall, industry groups appear to have weighted heavily the likely gains from larger insured markets as well as the loss to public reputation from a sudden switch in position.

Confronted with the possibility that no reform bill would pass, in late February 2010 president Obama proposed a compromise that integrated key elements from the House and Senate bills. Responding to growing public concern with government debt, Obama suggested

⁶¹ "Health Care Reform," *The New York Times* (December 24, 2009).

⁶² D. Herszenhorn, "Obama Backs Senate on Health Bills' Disparities," *The New York Times* (November 26, 2009).

⁶³ R. Pear, "Senate Passes Health Care Overhaul on Party-Line Vote," *The New York Times* (December 25, 2009).

paying for increased coverage through new sources of revenue. The reconciliation proposal had four major dimensions. First, individuals would be subsidized to obtain coverage through insurance exchanges, while businesses that failed to insure workers and individuals who did not obtain insurance would be fined. Second, a Health Insurance Rate Authority would determine “reasonable” annual rate increases and regulations would prevent insurers from dropping patients for pre-existing conditions. Third, coverage would expand with closure of the “donut hole” in Medicare prescription coverage, additional federal funds would be provided for Medicaid, and insurers would have to cover dependents until they were 26 years old. Fourth, taxes would be levied on high cost insurance plans, costs would be reduced through preventive screenings and immunizations, and new revenue would come from taxes on pharmaceutical and medical device firms.⁶⁴

3.3. A Final Legislative Push

Even as some political commentators and leading Republicans declared the legislation dead, Obama and Democratic legislative leaders began a renewed push for its passage. House speaker Pelosi spearheaded a 150-page reconciliation bill that aligned the House bill to that of the Senate and added budget provisions sought by president Obama, including additional Medicare taxes on families earning over \$250,000 per year, a 40 percent tax on high-value employer-provided insurance (with implementation ultimately delayed until 2018), and fees on insurers, pharmaceutical firms, and medical device companies. In an analysis that proved instrumental to the Act’s final passage, the non-partisan Congressional Budget Office calculated that expanded coverage would cost \$940 billion over 10 years in subsidies for the uninsured and increased Medicare and Medicaid spending. But the new taxes, gains from reduced spending on emergency room care, cuts in reimbursements to physicians, and other efficiencies together would generate over \$1 trillion in savings. Overall, the act would have a positive balance of \$14 billion annually.⁶⁵

Initiating a dramatic week that featured legislators working well past midnight and boisterous, sometimes violent protests in front of the U.S. Capitol, the House passed the

⁶⁴ B. Obama, “The President’s Proposal,” www.whitehouse.gov/sites/default/files/summary-presidents-proposal.pdf, accessed February 2010.

⁶⁵ Congressional Budget Office, “Estimate of Direct Spending and Revenue Effects for the Amendment in the Nature of a Substitute,” (March 18, 2010), www.cbo.gov, accessed March 2010.

Senate's bill by a vote of 219 to 212 on Sunday, March 21.⁶⁶ On March 25, the Senate approved the reconciliation bill by a vote of 56 to 43, after which the House passed it by a vote of 220 to 207.⁶⁷ No Republican in the House or Senate voted in favor of either final bill.

4. The Aftermath of Reform

4.1. Public Opinion and Legal and Legislative Stalemates

Republicans and "blue-dog" (conservative) Democrats condemned the ACA in advertisements, on websites, and during public appearances over the summer and early fall of 2010. After the November Congressional election, the balance of power shifted considerably in the House, where Republicans gained 63 seats and took over the majority. In the Senate, Democrats retained a slim majority after the party lost 6 seats. Exit polls revealed that healthcare ranked second after the economy in voters' minds. Given the choice, 48 percent of voters held that Congress should repeal the new law, 31 percent thought it should be expanded, while 16 percent wanted no additional changes.⁶⁸

Within days of the new Congress convening in 2011, House Republicans voted to repeal the law. With no vote pending in the Senate, the move was largely symbolic. Starting in February, Republicans began adding amendments to federal funding bills to prohibit government agencies from spending money to implement reforms. Tensions rose as legislators introduced additional demands to cut a variety of government programs during negotiations on successive spending bills.

Opinion polls in mid-2011 continued to find a country evenly split on healthcare reform. In a Gallup poll, 46 percent of Americans rated the law "a good thing," while 44 percent considered it "a bad thing."⁶⁹ A Rasmussen poll, by contrast, found that 51 percent of likely voters either "strongly" or "somewhat" favored repeal.⁷⁰ Overall, Americans were slightly more pessimistic than optimistic that reforms would improve care.

⁶⁶ G. Hitt and J. Adamy, "House Passes Historic Health Bill," *The Wall Street Journal* (March 22, 2010), A1.

⁶⁷ D. Herszenhorn and R. Pear, "Final Votes in Congress Cap Battle on Health Bill," *The New York Times* (March 25, 2010), A1.

⁶⁸ "Election 2010: Exit Polls," *The Washington Post*, (November 2, 2010), www.washingtonpost.com, accessed April 2011.

⁶⁹ Gallup, "Healthcare Law Remains Divisive One Year Later" (March 23, 2011), www.gallup.com, accessed April 2011.

⁷⁰ Rasmussen Reports, "Health Care Law" (April 11, 2011), www.rasmussenreports.com, accessed April 2011.

Less than an hour after ACA went into force, attorneys general from 13 states filed suit in a Florida district court (the case was later expanded to encompass 26 states). Other suits followed around the country. Several cases were quickly dismissed, but rulings in Virginia in December 2010 and in Florida in January 2011 held that Congress had no authority to mandate economic activity, specifically, the purchase of health insurance.

Filing appeals in circuit courts, the Obama administration invoked the U.S. Constitution's commerce clause and argued: "the uninsured are not passive bystanders whom the ACA forces to enter the health care market ... the substantial majority of the uninsured participate actively in that market, for example, by procuring medical services – for which they often are unable to pay."⁷¹ The administration also warned that other components of the law, including provisions to block insurers from denying coverage because of pre-existing conditions and to eliminate annual or lifetime coverage caps, would be unworkable without the coverage mandate. Ultimately, the Supreme Court was expected to hear arguments on the law and to make or break the coverage mandate.

Divergent visions for American capitalism were in play. Under ACA and the existing Medicare system, the government intervened in the healthcare market through overall reimbursement levels and by regulating annual rate increases by insurance firms. Under Republican alternatives, individuals would purchase independent coverage, which was expected to generate competitive pricing pressure among insurers, and in turn, lead to less costly and more efficient delivery of care.⁷²

4.2. *Physicians and Accountable Care Organizations*

In conjunction with the ACA, Accountable Care Organizations (ACO) were proposed as a way to control costs without sacrificing access to care or good outcome metrics. The concept of ACOs originated in experiments at the Duke Medical Center and the Giesinger Health System (in conjunction with Dartmouth-Hitchcock care) in the mid-2000s.⁷³ Structured as provider-led organizations, ACOs combined primary care and specialist physicians, hospitals, and other

⁷¹ Arguments central to subsequent appeals by the Department of Justice can be found in: State of Florida v. U.S. Department of Health and Human Services, "Defendants' Memorandum in Opposition to Plaintiffs' Motion for Summary Judgment," Case No. 3:10-cv-00091-RV/EMT (November 23, 2010), p. 1, www.justice.gov/healthcare/docs, accessed April 2011.

⁷² House Budget Committee, "The Path to Prosperity" (April 5, 2011), www.budget.gop.gov, accessed April 2011.

⁷³ R. Bohmer and L. Feldman, "The Duke Heart Failure Program," Harvard Business School case 604-033 (2010).

aspects of patient care into a virtual organization. At Duke, an integrated treatment program cut the costs of treating congestive heart failure by 40 percent, but the hospital dropped the program after it lost money under Medicare's fee schedule. Under the ACA, Medicare was responsible for advancing the ACO model in a way that would broaden its appeal and create financial incentives to participate.⁷⁴

After gathering extensive public comment, the Department of Health and Human Services (HHS) issued proposed rules in mid-2011 to standardize approaches and expand the ACO model nationally. In an effort to underwrite ambitious goals for ACOs of "better care for individuals, better health for populations, and lower growth in expenditures," and to implement use of electronic medical records, continuous monitoring approaches, and "patient centeredness criteria," HHS offered "shared savings."⁷⁵ Specifically, ACOs would be scored on a set of 65 clinical performance measures intended, for example, to reduce infections or to ensure that patients take prescribed medicines. ACOs will earn bonus payments if patient care costs less than under existing Medicare reimbursement rates.

Critics, however, have noted that ACOs are barely distinguishable from preferred provider organizations (PPOs), many of which failed in the late 1990s and early 2000s when employers and patients chose plans managed by insurers over those managed by providers.⁷⁶ Of particular concern, under the HHS proposal, ACO care teams will not know prospectively which patients are in the group, undermining a necessary link between treatment plans and reaching incentives for lower costs. Generally targeted to costs of out-patient and hospital care, which together comprise nearly 70 percent of U.S. health spending, HHS also plans to use ACOs to constrain pharmaceutical spending. As with other combinations of insurance and care, including HMOs and PPOs, however, ACOs most likely will find it difficult to force or entice physicians to limit use of expensive newer pharmaceuticals or to switch patients to generics.

Associated with the rise of ACOs, physicians in private practice were in rapid decline in the United States. In 2008, 47 percent of MDs still worked in practices of 5 or fewer physicians and another 25 percent worked in independent groups of 6 or more. By contrast, only 24 percent

⁷⁴ M. Pauly, "Patient Protection and Affordable Care Act Cost-Containment Choices: The Case for Incentive-Based Approaches," *Journal of Health Politics, Policy and Law* 36 (2011), 591-596; S. Glickman and E. Peterson, "Innovative Health Reform Models: Pay-for-Performance Initiatives," *American Journal of Managed Care* 15 (2009), S300-S305.

⁷⁵ U.S. Department of Health and Human Services, "Medicare Shared Savings Program: Accountable Care Organizations," *Federal Register* 76 (2011), 19528-19654, quote at 19533.

⁷⁶ "The Accountable Care Fiasco," *The Wall Street Journal* (June 20, 2011), A14.

worked for hospitals, universities, or HMOs, PPOs, or ACOs. However, a 2010 physician's trade association study projected that under the ACA: "Most physicians will be compelled to consolidate with other practitioners, become hospital employees, or align with large hospitals and health systems for capital, administrative and technical resources."⁷⁷

Surveys and interviews of physicians suggest that new rules governing patient care and costs associated with handling insurance reimbursement for both private and public coverage were combining to drive them out of private practice.⁷⁸ Longer-term, this shift is likely to force changes to a pharmaceutical marketing model predicated on one-to-one communication between sales representatives and doctors. In turn, changes to the relationship between pharmaceutical companies and physicians will have implications for the organization of firms and may affect the industry structure more generally.

5. The Pharmaceutical Industry and the ACA

5.1. Ascendancy of the U.S. Pharmaceutical Industry

Pharmaceutical manufacturers have long operated on the boundary between free-market inventors and sellers of drugs and providers of a key component to public health and welfare.⁷⁹ Since its origins in the late 19th century, the industry has played a leading role in globalization by developing, testing, and marketing new drugs worldwide. Leading firms originated with apothecaries that moved into wholesale production of drugs in the middle of the 19th century and chemical companies that established research labs and discovered medical applications for their products starting in the 1880s. A merging of these two types of firms into an identifiable pharmaceutical industry took place nearly simultaneously in Germany, Switzerland, France, the United Kingdom, and United States at the end of the 19th century. Companies coalesced around a vertically integrated organizational model under which they carried out nearly every aspect of drug discovery, testing, and commercialization. Pharmaceutical firms built networks of contacts with academic chemists and physicians, but operated largely independent of one another.⁸⁰ As a

⁷⁷ The Physicians Foundation, "Health Reform and the Decline of Physician Private Practice" (October, 2010), p. 4, www.physiciansfoundations.org, accessed April 2011.

⁷⁸ L. Sun, "Hospitals Courting Primary-Care Doctors," *Washington Post* (June 19, 2011).

⁷⁹ A. Daemmrich, *Pharmacopolitics: Drug Regulation in the United States and Germany* (Chapel Hill: University of North Carolina Press, 2004).

⁸⁰ J. Swann, *Academic Scientists and the Pharmaceutical Industry: Cooperative Research in Twentieth-Century America* (Baltimore: Johns Hopkins University Press, 1988); N. Rasmussen, "The Commercial Drug Trial in Interwar America: Three Types of Clinician Collaborator," *Bulletin of the History of Medicine* 75 (2005): 50-80.

sector, the pharmaceutical industry during its first century was characterized by low levels of concentration, heterogeneity in firm size and disease orientation, and relatively high barriers to entry stemming from patent strategy and government regulations that require testing new drugs for up to a decade prior to their marketing.⁸¹

From its historical origins concentrated in a few geographic locations, the pharmaceutical industry evolved into one of the first global industries. Yet, even though drug firms expanded sales internationally already in the 1920s and 1930s, and located manufacturing in a variety of countries after the 1950s, many of the benefits – employment of skilled labor, development of new research technologies, and tax revenues – accrue primarily to the country where firms are headquartered.⁸² Nations thus compete for pharmaceutical industry research laboratories and clinical testing sites in order to benefit from the economic growth they stimulate, the scientists and other skilled workers they employ, and to ensure access to the medicines they invent and manufacture. In some cases, notably in France, governments have sought to protect the pharmaceutical firms located within their borders when cross-national mergers were proposed, viewing them as national assets.⁸³

Despite increasing regulatory requirements for pre-market testing and proof of drug safety and efficacy starting in the late 1930s, the industry historically faced few price controls. Ironically, one consequence of the post-WWII growth of state-financed and state-run healthcare systems in Europe, and greater availability of private health insurance in the United States, was that neither patients nor physicians paid close attention to drug prices. Governments became slowly aware of drug prices in the 1960s as overall prescription use shifted from short-duration antibiotics to treatment for long-term chronic diseases.⁸⁴

Starting in the late 1980s, a variety of price regulation mechanisms were implemented, initially in northern Europe, but soon mimicked elsewhere. These varied among direct price

⁸¹ E. Cefis, M. Ciccarelli, and L. Orsenigo, "Heterogeneity and Firm Growth in the Pharmaceutical Industry," in M. Mazzucato and G. Dosi (eds.), *Knowledge Accumulation and Industry Evolution* (Cambridge: Cambridge University Press, 2006), 163-207; P. Nightingale and S. Mahdi, "The Evolution of Pharmaceutical Innovation," in M. Mazzucato and G. Dosi (eds.), *Knowledge Accumulation and Industry Evolution* (Cambridge: Cambridge University Press, 2006), 73-111.

⁸² B. Achilladelis, "Innovation in the Pharmaceutical Industry," in: R. Landau, B. Achilladelis, and A. Scriabine (eds.), *Pharmaceutical Innovation: Revolutionizing Human Health* (Philadelphia: Chemical Heritage Press, 1999), 1-147.

⁸³ S. Anwar, "Creating a National Champion or a Global Pharmaceutical Company: A Tale of French Connection," *Journal of Business and Industrial Marketing* 23 (2008), 586-596; C. Aubert, O. Falck, S. Heblich, "Subsidizing National Champions: An Evolutionary Perspective," CESifo Working Paper No. 2380 (August, 2008), www.CESifo-group.org/wp.

⁸⁴ J. Greene, *Prescribing by Numbers: Drugs and the Definition of Disease* (Baltimore, MD: Johns Hopkins University Press, 2007).

controls, for example, in France; indirect controls through national pharmaceutical budgets accompanied by mandates for rebates from manufacturers, for example, in Germany; and profit controls accompanied by reimbursement decisions based on quality of life metrics, for example, in the United Kingdom. As these policy experiments proceeded, countries continually modified approaches, making it nearly impossible to undertake comparative analysis between price policy and either health outcomes or industry research investments. In many cases, policies promoted perverse outcomes, such as firms in France promoting new products with the knowledge that budget overruns were spread across the industry, or German patients having to seek out a physician who had not yet exceeded their annual prescription limit for a particular drug.⁸⁵ In the 2000s, reference pricing – based on a median cost within a therapeutic class, or an average price across comparator countries – drew the attention of European policymakers.

Germany, Europe's largest pharmaceutical market, began to implement a novel reference pricing approach in 2011 that also covered new drugs. Under the new legislation, after a one-year period of industry-determined prices, negotiations will set prices based on calculations of a drug's costs and benefits compared with other pharmaceuticals in the same class, but in any case below a reference price based on median prices across other EU countries.⁸⁶ Broadly, Germany's move is part of an international convergence in price regulation through reference pricing, albeit with the United States as an outlier with no national approach to drug price negotiations. Yet, as numerous critics have observed, treating pharmaceutical prices in a silo misses the fact that drugs are but one part of patient care, which often involves a variety of treatments and payments to physicians, hospitals, and other service providers in the course of generating "health" as an outcome.⁸⁷

⁸⁵ C. LePen, "The Drug Budget Silo Mentality: The French Case," *Value in Health* 6 (2003), S10-S19; T. Schwermann, W. Greiner, and J. Schulenberg, "Using Disease Management and Market Reforms to address the Adverse Economic Effects of Drug Budgets and Price and Reimbursement Regulations in Germany," *Value in Health* 6 (2003), S20-S30.

⁸⁶ D. Cassel and R. Zeiner, "GKV-Arzneimittelmarkt im Zeichen des Arzneimittelmarkt-neuordnungsgesetzes (AMNOG), Teil 1," *Die Pharmazeutische Industrie* 72 (2010), 1858-1864; D. Cassel and R. Zeiner, "GKV-Arzneimittelmarkt im Zeichen des Arzneimittelmarkt-neuordnungsgesetzes (AMNOG), Teil 2," *Die Pharmazeutische Industrie* 72 (2010), 2044-2050.

⁸⁷ L. Garrison and A. Towse, "The Drug Budget Silo Mentality in Europe: An Overview," *Value in Health* 6 (2003), S1-S9; D. Cassel, "Arzneimittel-Innovationen in Visier der Kostendämpfungspolitik," *Gesundheit und Gesellschaft Wissenschaft* 11 (February, 2011), 15-24.

5.2. Competitive Dynamics in the Pharmaceutical Sector

Since 1980 and at a rate that accelerated in the 1990s, the United States became the leading worldwide location for pharmaceutical research, clinical testing, and marketing. The “pharmacy to the world,” once located at the intersection of Germany, Switzerland, and France, today is found in the United States.⁸⁸ Studies of the industry have attributed this comparative advantage to a variety of factors, including U.S. intellectual property policies, funding for biomedical research through the National Institutes of Health, the absence of government drug price controls, and the availability of venture capital and other factors that fostered the growth of the biotechnology industry.⁸⁹ It should be noted that the combination of higher prices and large numbers of prescriptions, described here as beneficial to the U.S. comparative advantage in the pharmaceutical industry, also contribute to the U.S. cost spiral in healthcare. Broadly, three interconnected factors are important to the baseline against which to evaluate how the ACA will affect the pharmaceutical market, notably current drug sales, research and development investments, and the attractiveness of the United States for the clinical testing of new drugs.

The United States provides the world’s largest and least restricted pharmaceutical market once the Food and Drug Administration (FDA) authorizes drugs for marketing. In 2010, total prescription drug sales exceeded \$250 billion, some 30-35 percent of the global total of \$850 billion.⁹⁰ Despite its larger population and more encompassing insurance coverage, Europe’s share of global pharmaceutical sales was ten percent less than that of the United States (see Table 2). The difference is largely explained by higher drug prices; for many of the top-selling drugs, the U.S. wholesale price was between two and three times as high as in Germany or the United Kingdom, and consumers (or their insurer) paid retail prices between two and four times as high as in other countries.⁹¹ Thus, even though the number of prescriptions filled annually in Canada (an average of 14 per person) and the United Kingdom (an average of 15

⁸⁸ A. Daemmrich, “Where is the Pharmacy to the World? Pharmaceutical Industry Location and International Regulatory Variation.” in: J.-P. Gaudillière and V. Hess (eds.) *Ways of Regulating: Therapeutic Agents between Plants, Shops, and Consulting Rooms*. (Berlin: MPIWG, 2008), 271-290.

⁸⁹ A. Gambardella, L. Orsenigo, and F. Pammolli, “Global Competitiveness in Pharmaceuticals: A European Perspective” (Luxembourg: Office for Official Publications of the European Communities, 2001); R. Gilmartin, “The Impact of Economic and Political Factors on Pharmaceutical Innovation,” 1998 CMR International Annual Lecture (London: CMR, 1998).

⁹⁰ Estimates of total U.S. prescription drug sales vary; according to IMS, sales in 2010 were \$307.4 billion, whereas according to the Centers for Medicare and Medicaid Services, they were \$258.6 billion. See: IMS Health, “Top-Line Industry Data 2010,” www.imshealth.com; CMMS, “National Health Expenditure Data,” www.cms.gov, accessed August 2011.

⁹¹ A. Daemmrich and E. Cameron, “U.S. Healthcare Reform: International Perspectives,” Harvard Business School case 710-040 (2010), 21.

per person) exceed the United States (an average of 12 per person), international pharmaceutical firms are drawn to the U.S. market.⁹² In many instances, European-based pharmaceutical companies have sought market authorization first in the United States, despite the FDA's international reputation for rigorous review.⁹³

Table 2. Global Distribution of Pharmaceutical Sales, Clinical Trials, and Population

	2010 Pharma Sales (\$BN) and % Total	Clinical Trials Underway and % Total	Population (millions) and % Total
North America	\$334.7 (39%)	64,224 (51%)	347 (5%)
Europe (incl. Russia)	\$245.3 (29%)	28,540 (23%)	836 (12%)
Africa, Australia, Asia, and Middle East	\$84.5 (10%)	24,225 (19%)	3,619 (53%)
China	\$42.0 (5%)	8,418 (7%)	1,331 (20%)
Japan	\$96.5 (11%)	1,932 (2%)	128 (2%)
Latin America	\$53.4 (6%)	6,538 (5%)	518 (8%)

Note: Percentages may not add to 100 due to rounding.

Sources: IMS Health, www.ims.gov, accessed August 2011; ClinicalTrials.gov (clinical trials data based on reporting to U.S. National Institutes of Health as of July 2011), accessed August 2011.

Even though pharmaceuticals are easily shipped internationally, world-leading sales appear to have contributed to spending on research and development in the United States by pharmaceutical firms. Seven of the top fifteen global pharmaceutical and biotechnology firms are headquartered in the United States, and all of the top twenty firms have research labs in the country. Total R&D spending in the United States exceeded \$45 billion in 2010. Of approximately 6,500 drugs in clinical development worldwide in 2007, over 40 percent were discovered in the United States.⁹⁴ As a consequence, pharmaceutical firms in the United States provided employment for more than 700,000 workers in 2010, along with approximately 2.5 million jobs in supporting industries.⁹⁵

⁹² Per capita prescriptions calculated by dividing the total number of prescriptions filled by the total population. Data sources: Kaiser Family Foundation, "Health Costs and Budgets: United States," www.statehealthfacts.org; National Health Service, "Statistics and Data Collections," www.ic.nhs.uk/statistics-and-data-collections; IMS Health, "Canadian CompuScript: Statistics Canada," www.imshealth.com. The comparable figure for Germany is 7 prescriptions filled per person annually.

⁹³ P. Danzon, Y. Wang, and L. Wang, "The Impact of Price Regulation on the Launch Delay of New Drugs: Evidence from Twenty-Five Major Markets in the 1990s," *Health Economics* 14 (2005): 269-292.

⁹⁴ Source: Wolters Kluwer Health, *Adis R&D Insight Database*, custom data run August 2011.

⁹⁵ Pharmaceutical Research and Manufacturers of America, *Pharmaceutical Industry 2009 Profile* (Washington, DC: PhRMA, 2009), 5.

Likewise, the opportunity to price drugs at high levels has helped create an investment climate in which venture funds with high risk tolerances support entrepreneurial new biotechnology firms. The biotechnology industry started in the United States in 1980 when the Supreme Court ruled that genetically modified organisms were patentable, Congress allowed recipients of federal research to take out patents, and Genentech held the biotech industry's first initial public stock offering.⁹⁶ Biotech as an industry has undergone repeated cycles of boom and bust; nevertheless, in 2010 there were 1,452 biotech companies in the United States employing 180,000 people.⁹⁷

Remarkably, the United States has in recent years maintained and even increased its leading position in clinical testing. While press attention has focused on the outsourcing of clinical trials to developing countries, the vast majority of trials underway are located in North America and Europe (see Table 2, above). Location decisions by the industry for clinical trials appear to align far more closely with pharmaceutical sales than with available patient populations. The United States thus benefits from a virtuous cycle linking R&D investment to testing to new drug availability. Despite predictions in the mid-2000s that India, China, and other developing countries would soon gain comparative advantage in running clinical trials, the number of trials underway in the United States has remained above 50 percent of the global total.⁹⁸

5.3. *The Pharmaceutical Market under the ACA*

The institutional structure of health insurance and delivery of care drives system costs and will determine the size of the U.S. pharmaceutical market in the future. At the same time, demographic shifts, growth in drug prices and sales volumes, and broader insurance coverage also will affect total drug sales. This article contends that over the course of its implementation in coming years, the ACA will significantly expand prescription drug use, including at the relative expense of other health services. This finding is supported by two sets of forecasts developed here following different methods. The first employs a "bottom-up" approach based

⁹⁶ A. Daemmrich, "BioRisk: Interleukin-2 from Laboratory to Market in the United States and Germany," in: T. Schlich and U. Tröhler (eds.) *The Risks of Medical Innovation: Risk Perception and Assessment in Historical Context*. (London: Routledge, 2006), 242-261.

⁹⁷ Biotechnology Industry Organization, "Facts and Figures," www.bio.org, accessed August 2011.

⁹⁸ For the earlier predictions, see: W. Bailey, C. Cruickshank and N. Sharma, "Clinical Trial Offshoring: Country Attractiveness Index" (AT Kearney, October 2006); data for clinical trials underway are from ClinicalTrials.gov (which tracks trials reported to the U.S. National Institutes of Health), accessed August 2011.

on per-capita prescription drug spending, calibrated by age demographic, insurance status, and annual increases in prescription drug sales and prices. The second employs a “top-down” method derived from historical growth rates of total health spending and projects shifts in the division of expenditures among major healthcare categories based on changes likely to result from implementation of the ACA. While the figures should be understood as rough estimates, some robustness is provided from the two methods forecasting pharmaceutical markets for 2015 and 2020 that vary from one another by less than 1 percent.

Pharmaceutical use ranges by age and insurance status. Consequently, overall demographic shifts, notably an aging population, and the ACA’s broadening of insurance coverage both will expand future drug sales. Figures shown in Table 3 are calculated based on three key variables that shape the pharmaceutical market. First, according to U.S. government statistics, prescription drug spending per person under age 65 in 2008 was \$273 for the uninsured (paid out-of-pocket and by various public sources and charities), compared to \$619 for those who were privately insured. By contrast, people under age 65 with public insurance (Medicaid) spent an average of \$943 on drugs annually and retirees spent between \$1,810 and \$2,458, depending on their purchase of supplemental insurance to Medicare.⁹⁹ Thus as the uninsured are brought into insured status – in 2011 for Americans under age 26, and in 2014 for those between 26 and 64 – pharmaceutical spending is likely to rise proportionally. To keep projections conservative, calculations advanced here assume a 125% growth in drug spending among the newly insured that corresponds to the difference in drug spending between the uninsured and people with private insurance.

Second, estimates of the number of uninsured Americans vary by reporting agency (in the range of 40-50 million) and in any case, lack of coverage is not spread evenly across all age groups. Figures developed here draw on the U.S. Census Bureau’s estimate of 49.1 million uninsured below age 65 in 2010.¹⁰⁰ These were calibrated to the age groupings relevant under the ACA. Over 16 million uninsured under age 26 will have access to coverage in 2011, and another 33.7 million uninsured (projected from the 2010 figure of 32.3 million uninsured) between 26 and 64 will be covered through their employers or via subsidized individual plans

⁹⁹ Agency for Healthcare Research and Quality, Medical Expenditure Panel Survey, “Prescription Medicines Expenses per Person by Source of Payment: United States, 2008,” <http://meps.ahrq.gov>, accessed September 2011.

¹⁰⁰ U.S. Census Bureau, “Income, Poverty, and Health Insurance Coverage: 2010,” www.census.gov, accessed September 2011. The number of uninsured in the United States rose significantly in 2009 and 2010 due to the recession and spike in unemployment.

in 2014. While some people in each of these groups will obtain coverage via Medicaid or other government programs that correspond to higher per capita drug spending, others will remain uninsured and have lower per capita expenditure. Overall, these are likely to offset. The forecasts developed here thus use the private insurance average of \$619 per person in annual prescription spending for the newly insured.

Third, prescription drug sales historically have grown at above-inflation rates, although generic substitution slowed price growth from nearly 11 percent in the 1990s to 8 percent in the past decade.¹⁰¹ To account for this growth, the spending per capita on drugs is projected to grow at the lower-bound figure of 8 percent yearly for each of the age groups.

Table 3. U.S. Population and Prescription Drug Expenditures

Age Cohort	2008		2015		2020	
	Population	Rx spending per capita	Population	Rx spending per capita	Population	Rx spending per capita
0-25	107,065,000	\$213	106,517,000	\$390	108,690,000	\$575
26-64	157,569,000	\$892	167,997,000	\$1,435	171,136,000	\$2,110
65 and over	39,742,000	\$2,114	46,571,000	\$3,260	54,297,000	\$4,790
Total*	304,376,000	\$247,400	321,085,000	\$437,700	334,123,000	\$688,200

*Population is actual or projected number rounded to nearest thousand; total prescription drug (Rx) spending is in millions of US\$, nominal.

Sources: Population data from U.S. Census Bureau, "Projections of the Population by Selected Age Groups: 2010 to 2050, Constant Net International Migration Series," (December 16, 2009); prescription drug spending for 2008 from Agency for Healthcare Research and Quality, Medical Expenditure Panel Survey, "Prescription Medicines Expenses per Person by Source of Payment: United States, 2008," <http://meps.ahrq.gov>.

Since the ACA ensures coverage Americans under age 26 through their parent's health policies starting in 2010, prescription drug sales to this category will grow nearly immediately. The largest net change, however, will come from the 26-64 age demographic, as the bulk of the uninsured obtain coverage either through their employer or via subsidized individual plans. For senior citizens, closure of the Medicare coverage gap is likely to generate modest growth in drug expenditure per person among patients who previously failed to get prescriptions filled after hitting the "donut hole." To be conservative, the population-calibrated average of \$2,114 in 2008 drug spending is projected forward adjusted only for 8% annual growth in drug sales.

¹⁰¹ U.S. Centers for Medicare and Medicaid Services, "National Health Expenditure Data," www.cms.gov, accessed September 2011.

Based on this “bottom-up” approach, the total U.S. drug market will be nearly \$437 million in 2015 and nearly \$690 million in 2020.

A second method for estimating the future pharmaceutical market in relation to the ACA is based on macroeconomic trends in total healthcare spending and the allocation of expenditures among major types of care. Quantitative projections of national health spending by the Centers for Medicare and Medicaid Services (CMMS) combine trends in insurance coverage; spending in major categories, including hospital care, physicians and other services, nursing and home health care, medical products, drugs, and equipment, and administration (of government and private insurance); and “judgments about future events and trends.”¹⁰² For the pharmaceutical market specifically, estimates developed here build upon the CMMS data by adding both macroeconomic projections concerning healthcare expenditure as a percentage of GDP and sector-level projections based on the growing U.S. pharmaceutical market (see Table 4).

Between 1980 and 2010, healthcare spending in the United States grew by a compound annual growth rate (CAGR) of 8 percent; as a percentage of the GDP, healthcare expanded from just over 9 percent to 17.6 percent. As the ACA is implemented, national health spending will increase as more Americans are covered, though the growth will be offset in part through reduced emergency room care and other cost savings compared to paying to treat the uninsured. Using very optimistic growth projections for the overall economy, CMMS has forecast total healthcare spending to rise to 18.3 percent in 2015 and to remain slightly below 20 percent in 2020.¹⁰³ However, the economic recovery slowed in mid-2011, and recent evidence suggests the United States may experience modest growth in coming years, even as healthcare costs rise thanks to a spike in retirement by the baby boom generation and greater use of primary care by the newly insured.¹⁰⁴ By 2015, over 30 million Americans will become newly insured, either through their employer or by purchasing coverage on a state-based exchange. By 2020, an additional 14 million Americans will join Medicare and an additional 10 million will

¹⁰² S. Keehan, et al., “National Health Spending Projections through 2020: Economic Recovery and Reform Drive Faster Spending Growth,” *Health Affairs* 30 (2011), 1594-1605.

¹⁰³ U.S. Centers for Medicare and Medicaid Services, “National Health Expenditure Data: Projections,” www.cms.gov, accessed August 2011.

¹⁰⁴ B. Bernanke, “The Near- and Longer-Term Prospects for the U.S. Economy,” speech at the Federal Reserve Bank of Kansas City Economic Symposium, Jackson Hole, Wyoming (August 26, 2011), www.federalreserve.gov, accessed August 2011.

have some coverage under Medicaid.¹⁰⁵ Under that scenario, total health spending will be \$3.5 trillion in 2015, making up 20 percent of GDP. Spending will rise further to \$5 trillion in 2020, over 22.5 percent of GDP.

Table 4. U.S. GDP and Major Categories of Healthcare Expenditure (millions of US\$, nominal)

	U.S. GDP	Total Health Spending	Prescription Drugs	Hospital Care	MD & Outpatient
1980	2,788,000	255,700	12,000	100,500	47,700
1990	5,801,000	724,000	40,300	250,400	158,900
2000	9,951,500	1,378,000	120,900	415,500	290,000
2010	14,660,400	2,584,200	258,600	794,300	517,800
CMMS 2015	18,405,800	3,417,900	361,600	1,041,300	654,100
CMMS 2020	23,096,400	4,638,400	512,600	1,410,400	867,700
Projected 2015	17,592,500	3,519,000	440,000	1,075,000	649,500
Projected 2020	22,044,000	4,960,000	695,000	1,530,000	845,000

Sources: Congressional Budget Office, "Detailed Economic Projections," Budget and Economic Outlook (August 2011), www.cbo.gov; U.S. Centers for Medicare and Medicaid Services (CMMS), "National Health Expenditure Data" www.cms.gov, accessed August 2011.

The U.S. prescription drug market grew by nearly 11 percent CAGR from 1980 to 2010, though it slowed slightly to 8 percent CAGR in the decade starting in 2000.¹⁰⁶ Within healthcare expenditure, drugs have grown by 2 to 3 percent annually on average since 1980; as a consequence, growth in spending on hospitals and primary care physicians declined slightly as a percentage of overall healthcare expenditures in the past two decades. Yet, the same combination of national demographics and changes to coverage under the ACA that will drive greater overall healthcare spending also will lead to greater spending on pharmaceuticals within the healthcare domain. The newly insured and elderly with greater prescription drug coverage under Medicare are likely to consume more prescriptions, in part thanks to lower out-of-pocket costs. From the present 10 percent of healthcare spent on pharmaceuticals, making up \$260 billion in 2010, it is reasonable to project that expenditure will rise to 12.5 percent in 2015, based on \$440 billion in sales. Based on these projections, in 2020 the pharmaceutical market will be nearly \$700 billion, making up 14 percent of healthcare spending.

¹⁰⁵ Congressional Budget Office, "Healthcare Reform Reconciliation Bill Analysis," (March 2010), www.cbo.gov, accessed August 2011.

¹⁰⁶ *Ibid.*

Segmenting the pharmaceutical market, generic drugs have risen rapidly from 30 percent of all prescriptions dispensed in the 1980s to 75 percent in 2010. Despite growing volume, generics comprised only 16.5 percent of the market measured in sales dollars, generating \$43 billion in 2010.¹⁰⁷ By 2015, an additional \$95 billion of current prescription drug revenue has the potential to switch to generics as existing patents expire, although since the revenue per drug will drop steeply, this sum will not simply be added to existing generic sales. With deep pipelines of drugs in testing, including for diseases that impact millions of senior citizens (e.g., arthritis and Alzheimer's), branded drugs will continue to dominate overall sales figures, even as generics continue to gain ground in the number of prescriptions.

Growth in pharmaceutical spending, including as a percentage of total healthcare spending, will be made possible by comparatively slower growth in primary care and outpatient spending. In-patient care at hospitals will grow initially under the ACA, but with the rise of ACOs and specialty care sites, it will level off at just over 30 percent of healthcare spending. As a result, hospitals will make up slightly over \$1 trillion of healthcare spending in 2015 and \$1.5 trillion in 2020. In turn, spending on primary care in physician's offices will decline from its 2010 peak of 20 percent of healthcare spending to 18.5 percent in 2015 and 17 percent in 2020.

Prospects for strong growth in the U.S. pharmaceutical market nevertheless will be tempered for individual firms by shifts in the industry's competitive structure. Firms across the industry have moved slowly but inexorably away from a fully vertically integrated model as some aspects of research and testing have been outsourced to contract research organizations (CROs). As accountable care organizations expand in number and reach under the ACA, pharmaceutical marketing by means of sales representatives meeting individually with physicians will be reduced further from current levels. As a consequence, firms will need to pioneer new ways of marketing to physicians and of communicating with patients, who play an ever-greater role in discussing treatment decisions with caregivers. The future pharmaceutical firm therefore will need to manage more diverse information about drugs in a less vertically structured environment.

At the same time, implementation of an independent payment advisory board and outcomes research funded by the federal government will draw greater attention to the value of

¹⁰⁷ IMS Health, "National Sales Perspectives," (January 2011), www.imshealth.com, accessed August 2011.

prescription drugs relative to health outcomes. For some diseases, outcomes research will drive greater drug sales relative to more costly alternatives. However, a core dilemma will arise for payers, since for many drugs it will take a decade or more to measure with accuracy the gains from delaying or averting other care through prescription drug use. Overall, reforms to the U.S. healthcare system are likely to result in major pharmaceutical firms relying not just on blockbuster drugs, but also on therapies for specific cancers or treatments for patients with particular genetic or disease profiles. While not “personalized” medicine as envisioned by some of its early advocates, greater market segmentation and product customization will occur in the pharmaceutical sector as the ACA is implemented.

6. Conclusions

Health insurance provides a safety net in moments of crisis (e.g., recession and high unemployment, when many people lose employer-linked insurance) and may underpin people’s willingness to undertake other potentially economically beneficial activities (e.g., starting entrepreneurial ventures). In the United States, healthcare also has become an integral part of employer – employee relations and a major point of negotiation in employment contracts.

The ACA is significant first and foremost for its expansion of insurance coverage. But it also includes provisions that regulate private insurance firms and increase the government’s insurance role by enlarging Medicare and Medicaid. The most novel part of the Act creates state-based insurance exchanges for individuals to purchase coverage. In Massachusetts, a similar exchange has been in operation for several years, but it has taken considerable state subsidies to make insurance universally affordable. Longer-term, it is unclear whether U.S. firms will shift their management of insurance options for employees to these exchanges by ceasing to provide coverage. They may be attracted to quit subsidizing and managing insurance options as part of cost-cutting initiatives, but then would lose an important way of building loyalty among their employees. Those decisions will ultimately determine the size and risk structure of the exchanges.

Insurance implies a collective pooling of risk and redistribution within the pool. International comparisons of welfare systems reveal that redistribution requires particular

political constructions of “similarity.”¹⁰⁸ People need to feel not just sympathy, but deeper community connections to those who benefit from redistribution by means of insurance. Healthcare, in principle, offers an approach to building community connections, since everyone faces disease risks, often at unpredictable moments. In the United States, a longstanding drive to individualize risk is playing out in healthcare. Opposition to ACA, at least in part, stems from a desire to have individual accounts and greater market discipline in health care. However, markets need price transparency, which requires comparison among standardized products and services.

Since each patient is a unique individual and diseases are unique events (e.g., a particular type of fracture in a specific location, a particular set of cancerous lesions, or a specific type of leukemia in a patient of a particular configuration of age, gender, weight, etc.), comparison based on price and quality has not emerged organically. Furthermore, it is not clear that more information would resolve seeming market failures of inadequate competition and above-inflation price increases. The information asymmetries between individuals and physicians, hospitals, and insurers are vast. Furthermore, unlike automobile or homeowners insurance, consumers need medical care when ill, not compensation or reimbursements after the fact.

The United States has little consensus on collective risk, for a variety of reasons related to its diverse demographics, history of distrust with the kinds of central authority necessary to administer a coordinated national healthcare system, and a free-market ideology that guides much federal policy. Rather than gain efficiencies of scale in health insurance, there is a constant drive to individualize risk and individualize pricing. In fact, the very notion that healthcare is an instrument of social justice and redistribution is contested in the United States. The same principles are very different across Europe and in most other OECD countries. Yet, ties among healthcare, insurance, and culture are not immutable. It will take decades, but the achievement of more universal coverage under ACA may establish an institutional underpinning in the United States to a more collective approach to insuring against health risk.

The creation of state-run insurance exchanges as the means by which the United States will achieve universal coverage under the ACA is an effort to draw upon the advantages of

¹⁰⁸ A. Alesina, E. Glaeser, and B. Sacerdote, “Why Doesn’t the U.S. Have a European-Style Welfare State?” National Bureau of Economic Research Working Paper No. 8524 (October 2001); A. Lijphart, *Patterns of Democracy* (New Haven: Yale University Press, 1999); C. Loh, K. Nihalani, and O. Schnusenberg, “Measuring Attitude Toward Social Health Insurance,” *European Journal of Health Economics* on-line (June 1, 2011).

competition to reduce costs and expand choices. Likewise, pharmaceutical price policy in the United States has been strongly shaped by economists' ideas concerning the relationship of market prices to incentives for research and development. In a series of studies dating back to the Kefauver investigation in the late 1950s, economists have found that drug price regulation would reduce expenditures in the pharmaceutical "silo," but at the cost of greater healthcare spending in other areas and more significantly, a reduction in industry research.¹⁰⁹ Some studies have gone so far as to quantify the likely affects of U.S. price regulation as a reduction in research spending between 36 and 47.5 percent.¹¹⁰ While it seems unlikely that a research-intensive industry would simply close down and cease to create new drugs, international imbalances in drug price policy have become more pronounced over the past three decades. The United States, by virtue of minimal controls on pharmaceutical prices compared to other developed economies, benefits from a profitable domestic pharmaceutical industry and the rapid market availability of new treatments, even as consumers pay more for drugs.

Intriguingly, arguments concerning the relationship of price to industry R&D investments (and the resulting public gains) have been persuasive only to policymakers in the United States. In Europe, Japan, and elsewhere, by contrast, pharmaceutical price control by means of reference pricing or delayed entry of new drugs has become the norm.¹¹¹ Despite enthusiasm among some economists for drug price variation across countries, the long-term sustainability of this model, in which U.S. consumers pay more than anyone else, is questionable.¹¹² By expanding coverage with modest revenue offsets through taxes, rather than copy reference pricing or other pharmaceutical price controls, the ACA will perpetuate and even exacerbate international price discrimination. As these differences become ever more visible to consumers and policymakers, additional pressure will build in the United States to adopt some form of price negotiation with manufacturers.

¹⁰⁹ For two useful reviews of this literature, see: W. Comanor, "The Political Economy of the Pharmaceutical Industry," *Journal of Economic Literature* 24 (1986), 1178-1217; D. Kessler, "The Effects of Pharmaceutical Price Controls on the Cost and Quality of Medical Care: A Review of the Empirical Literature," white paper presented to the U.S. Department of Commerce and International Trade Administration (June 2004), www.ita.doc.gov.

¹¹⁰ J. Vernon, "Drug Research and Price Controls," *Regulation* 25 (2003), 22-25; T. Abbott and J. Vernon, "The Cost of U.S. Pharmaceutical Price Reductions: A Financial Simulation Model of R&D Decisions," NBER Working Paper No. 11114 (2005), www.nber.org.

¹¹¹ M. Kyle, "Pharmaceutical Price Controls and Entry Strategies," *Review of Economics and Statistics* 89 (2007), 88-99.

¹¹² F. Lichtenberg, "Pharmaceutical Companies' Variation of Drug Prices Within and Among Countries can Improve Long-term Social Well-being," *Health Affairs* 30 (2011), 1539-1544).

Reviewing the history of healthcare reform in the United States, this article finds that American exceptionalism remains a potent force, with deep political contestation over mandates for insurance coverage and the role of government. Even if universal coverage grows less controversial over time, the United States will continue to sustain dual public and private insurance systems and a growing corporate presence in care delivery. The pharmaceutical market will increase under the ACA, including as a percentage of overall healthcare spending. At the same time, firms will be pressured to cut rebate deals or otherwise lower prices through longer-term contracts with insurers.

Finally, the ACA holds the potential for the United States to be the first country to break out of the silo framework that dominates health budgeting and to instead set budgets at the disease (or patient) level, linked to health outcomes. For this to happen, health providers will need to find it profitable to undertake greater disease prevention while more tightly integrating otherwise dispersed care of the 20 percent of patients that account for 80 percent of healthcare spending, and to especially target the 5 percent that are responsible for 50 percent of spending.¹¹³ Such an approach has eluded even more coordinated health systems in Europe, but may be possible under the accountable care model now emerging in the United States. To realize the cost savings potential of integrated care on a system level, however, will require a step further than currently envisioned under new methods for calculating costs.¹¹⁴ Breaking down budget silos of prescription drugs versus hospitalization versus outpatient care is necessary. At the same time, pharmaceutical manufacturers will need to monitor prescription drug use in order to demonstrate long-term cost savings in relation to health outcomes from the use of pharmaceuticals.

¹¹³ R. Herzlinger, "Healthcare Reform and its Implications for the U.S. Economy," *Business Horizons* 53 (2010), 105-117; M. Stanton, "The High Concentration of U.S. Health Care Expenditures," Agency for Healthcare Research and Quality, *Research in Action* 19 (2006), www.ahrq.gov, accessed September 2011.

¹¹⁴ R. Kaplan and M. Porter, "How to Solve the Cost Crisis in Health Care," *Harvard Business Review* (September 2011), 47-64.