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MEDICAL COST CONTAINMENT
A Microeconomic Approach

by Marc D. Joffe

MERCATUS CENTER
George Mason University

About the Author

Marc D. Joffe
Principal Consultant
Public Sector Credit Solutions
415-578-0558
marc@publicsectorcredit.org

Abstract

The high and rising cost of US medical care is partially attributable to legally enforced rigidities in the health care system. By relaxing restrictions, the government can unlock competitive forces that drive prices down and empower individuals to avoid unnecessary, expensive medical services. A more open health care market would give providers incentives to innovate in ways that not only improve the quality of care but also reduce the cost of offering it. In this report, I suggest that significant cost savings can be achieved by encouraging medical tourism, empowering "mid-level" providers, using administrative law procedures as an alternative to malpractice litigation, reducing the scope of drug patents, and switching prescription medicines to over-the-counter dispensing.

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Medical Cost Containment:

A Microeconomic Approach

Marc D. Joffe

According to government figures, health care spending in 2012 represented 17.9 percent of gross domestic product (GDP).[1] Although medical cost inflation slowed in the aftermath of the recession, it is likely to escalate again as aging baby boomers place more demands on the country's finite health resources. The Centers for Medicare and Medicaid Services forecast shows health care spending rising to 19.9 percent of GDP by 2022[2] while government actuaries predict that the Medicare Hospitalization Insurance trust fund will be exhausted in 2026.[3] There may be no one big idea that will bring medical costs under control without introducing some sort of rationing—which could worsen health outcomes. While it is true that high-income nations with single payer systems or socialized medicine have lower costs and longer life expectancies than we do in the United States,[4] it is less clear that we can successfully replicate one of their systems here. Also, poor relative performance in the United States is largely attributable to Americans' less healthy lifestyle choices and greater violence relative to peer countries. Once an individual reaches 75 years of age in the United States, his or her remaining life expectancy is greater than in any other high-income nation.[5]

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[1] Centers for Medicare and Medicaid Services, *National Health Expenditure Projections 2012–2022*, Centers for Medicare and Medicaid website, 2013, http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Proj2012.pdf.

[2] Ibid.

[3] Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, *2013 Annual Report*, Centers for Medicare and Medicaid website, 2013, http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2013.pdf.

[4] Institute of Medicine, *US Health in International Perspective: Shorter Lives, Poorer Health*, 2013, http://www.iom.edu/~/media/Files/Report%20Files/2013/US-Health-International-Perspective/USHealth_Intl_PerspectiveRB.pdf.

[5] Ibid.

Although there may not be a silver bullet, a combination of incremental, market-oriented reforms can make a significant dent in the nation's health costs while maintaining or enhancing health outcomes. This study explores four opportunities for reform: medical tourism incentives, greater use of nonphysician providers, medical liability reform and changes to how prescription drugs are sold.

Medical Tourism

According to Patients Beyond Borders, about 900,000 Americans traveled outside the United States for medical care in 2013.[6] They often did so in order to save money on medical services. Table 1 (page 34) shows a list of procedures with comparative costs across various countries. As the table suggests, cost savings upwards of $60,000 for a single procedure are possible abroad.

These cost savings are not necessarily associated with lower quality. As Josef Woodman, CEO of Patients Beyond Borders, notes,

> Veteran health travelers know that facilities, instrumentation, and customer service in treatment centers abroad often equal or exceed those found in the US. Governments of countries such as India and Thailand have poured billions of dollars into improving their healthcare systems, which are now aggressively catering to the international health traveler. VIP waiting lounges, deluxe hospital suites, and staffed recuperation resorts are common amenities, along with free transportation to and from airports, low-cost meal plans for companions and discounted hotels affiliated with the hospital.[7]

[6] Patients Beyond Borders, "Medical Tourism Statistics and Facts," 2013, http://www.patientsbeyondborders.com /medical-tourism-statistics-facts. Estimates of the size of the medical tourism industry vary widely. A 2009 Deloitte study projected 1.6 million American medical tourists by 2013. Deloitte, "Medical Tourism: Update and Implications," 2009, http://www.deloitte.com/assets/Dcom-UnitedStates/Local%20Assets/Documents/us_chs _MedicalTourism_102609.pdf. A different study estimated 60,000 to 85,000 *inpatient* tourists annually. Tilman Ehrbeck, Ceani Guevara, and Paul D. Mango, "Mapping the Market for Medical Travel," *The McKinsey Quarterly*, May 2008, http://www.heal-wheel-india.com/white-pappers/McKinsey-Report-Medical-Travel.pdf. A large part of this difference is definitional since dental and cosmetic surgeries, which account for a large proportion of medical travel, are usually performed on an outpatient basis.

[7] Josef Woodman, *Patients Beyond Borders*, 2nd ed. (Chapel Hill, NC: Healthy Travel Media, 2010), 10–11.

The most common services sought by medical tourists include cosmetic procedures, dental surgery, and infertility treatments. These procedures are often excluded from insurance coverage or subject to high copayments—thereby creating an incentive for patients to seek cost savings. Other procedures performed offshore, including cancer treatments, heart surgery, and orthopedics (such as hip and knee replacements), typically appeal to smaller groups of uninsured or underinsured patients.[8]

Given the large cost savings available, insurers should be able to benefit by offering policyholders incentives to use foreign facilities. Over the last few years, some insurers have piloted plans with such incentives. In January 2009, Wellpoint began offering employees of Serigraph Inc. the option of having hip and knee replacements, spinal surgeries, and certain other elective procedures performed in India. Patients choosing this option pay lower out-of-pocket costs. Travel expenses for both the patient and a companion are covered by the plan.[9] BlueCross BlueShield of South Carolina offers members the option of receiving medical services at various overseas hospitals through the firm's alliance with Companion Global Healthcare. In addition to cost savings, members may be able to receive room upgrades and hospitality services not available to them in the United States.[10]

The largest population of Americans receiving insurance coverage for non-US medical care consists of California plan participants eligible to see providers in Tijuana and elsewhere

[8] Deloitte, "Medical Tourism"; Woodman, *Patients without Borders*.
[9] Wellpoint Inc., "WellPoint Introduces International Medical Tourism Pilot Program," press release, 2009, http://ir.wellpoint.com/phoenix.zhtml?c=130104&p=irol-newsArticle&ID=1225569&highlight=.
[10] South Carolina Blues, "Companion Global Health," BlueCross BlueShield of South Carolina website, 2013, http://www.southcarolinablues.com/members/discountsaddedvalues/companionglobalhealthcare.aspx; Companion Global Healthcare, "BlueCross and BlueChoice HealthPlan Pioneer Global Healthcare Alternative," 2007, http://www.companionglobalhealthcare.com/news.aspx?article=35.

in the Mexican State of Baja California. Aetna, Blue Shield of California, and Health Net[11] all provide discounted plans that include Mexican providers. Aetna and Health Net use the provider network managed by a Mexican insurance company, Sistemas Medicos Nacionales, S.A. de C.V. (SIMNSA). Participants in these insurance plans are part of a large population of California residents seeking care south of the border. In 2010, Oscar Escobedo Carignan, secretary of tourism for Baja California, reported that his state was receiving 500,000 monthly visits from tourists seeking health care products and services—mostly from California.[12] Steven Wallace and his colleagues estimate that 952,000 adult California residents used medical, dental, or prescription drug services in Mexico during 2001. Slightly over half were Mexican immigrants, suggesting that more than 400,000 Americans living in California consumed health care services in Baja.[13]

In a report for KPBS (San Diego public radio and TV), Tom Fudge found that California residents were attracted to Mexican medical care primarily to achieve cost savings, but users also noted that practitioners spend more time with patients and that hospital rooms were sometimes larger and more appealing.[14] Sarah Varney reports that many South Texas residents also crossed the Mexican border for health care in the past but now rarely do so because of gang violence and tougher border restrictions.[15]

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[11] Aetna, *Health Benefits Close to Home: Vitalidad Plus℠ California con Aetna*, 2013, http://www.aetna.com /employer-plans/document-library/states/ca-vitalidad-plus.pdf; Blue Shield of California, *Blue Shield Speaks Your Language: Access Baja Plans*, 2013, https://www.blueshieldca.com/producer/download/public/A11980.pdf; Health Net, *Salud Plan Highlights: HMO, PPO, and EPO, Health Care Coverage for Your Diverse Workforce*, 2013, https://www.healthnet.com/static/broker/unprotected/pdfs/ca/salud/salud_broker_brohure.pdf.

[12] Oscar Escobedo Carignan, *The Future of Health Care in Mexico for Americans*, Bonanova Clinic website, 2010, http://www.bonanovaclinic.com/wp-content/uploads/2011/01/HealthCareMexico.pdf.

[13] Steven Wallace, Carolyn Mendez-Luck, and Xochitil Castañeda, "Heading South: Why Mexican Immigrants in California Seek Health Services in Mexico," *Med Care* 47 (2009): 662–69.

[14] Tom Fudge, "Many Americans Going to Mexico for Health Care," KPBS website, May 19, 2010, http://www .kpbs.org/news/2010/may/19/why-americans-choose-health-care-mexico/.

[15] Sarah Varney, "Texas' Struggling Rio Grande Valley Presses for Medicaid Expansion," *Kaiser Health News*, 2013, http://www.kaiserhealthnews.org/Stories/2013/May/21/Texas-Border-Counties-Medicaid.aspx.

While medical care in Baja California is 60–80 percent less expensive than in the United States, American retirees living in Mexico generally return home for treatment.[16] With rare exceptions, Medicare benefits can only be paid to US service providers. If Mexican and other foreign providers became eligible to bill Medicare, substantial savings would be possible. According to US government statistics, over 25,000 retirees living in Mexico were receiving Social Security benefits at the end of 2011.[17] These individuals, as well as many of their spouses, widows, and widowers, are Medicare eligible. To the extent that they seek care in the United States strictly for the purpose of receiving their benefits, it would be less expensive to allow them to use Mexican providers within Medicare. On the other hand, to the extent that these potential beneficiaries pay for their care out of pocket or use Mexico's public health insurance system administered by Instituto Mexicano del Seguro Social (IMSS), a reform could increase costs.

Marla C. Haims and Andrew W. Dick consider various ways of structuring a Medicare benefit in Mexico so that it improves health outcomes for retirees while reducing overall Medicare costs. They conclude that the government could best accomplish these objectives by structuring a new program in Mexico or enhancing Medigap[18] plans, rather than simply extending the existing Medicare program across the border. They also note that if attractive Medicare benefits could be provided in Mexico, more baby boomer retirees would choose to retire south of the border, producing additional savings.[19]

Further savings would be possible by allowing US-based Medicare beneficiaries to use lower-cost, foreign medical facilities and even offering them incentives to do so. Medicare could

[16] Fudge, "Many Americans Going to Mexico for Health Care."
[17] Social Security Administration, table 5J11, *Annual Statistical Supplement, 2012*, http://www.ssa.gov/policy/docs/statcomps/supplement/2012/5j.html#table5.j11.
[18] Medigap plans are private insurance products that pay certain costs not covered by Medicare.
[19] Marla C. Haims and Andrew W. Dick, "Extending U.S. Medicare to Mexico" (Rand Health Occasional Paper, Rand Corporation, 2010), http://www.rand.org/content/dam/rand/pubs/occasional_papers/2010/RAND_OP314.pdf.

follow the example of private insurers by covering travel expenses (for both patients and companions) as well as room upgrades for beneficiaries choosing to have procedures abroad. Given the very large savings available, it may even be appropriate for Medicare to provide cash incentives to patients choosing medical tourism. Further, a medical tourism benefit could be added to Medicaid and to federal employee benefit systems.

One factor limiting medical tourism is the long distances that patients need to travel to reach quality offshore facilities. Thailand, Singapore, and India are at least 12 hours away from any point in the United States by air. While Mexico is easily accessible from certain states, it is not adjacent to Florida—home to several million retirees.

Only 90 miles from Key West, Florida, the nation of Cuba has its own medical tourism industry catering mostly to Canadian and European patients. If US travel restrictions to Cuba were lifted, Florida's large retiree population would have access to low-cost medical care with only a one-hour flight or even a boat ride. As this author learned when he visited Cuba in 2012, some Florida residents already access Cuban medical tourism facilities. Americans with family in Cuba can visit relatives on the island and pay for health services while there. Some use Clínica Central Cira García when visiting Havana. This hospital is more modern than most of the facilities available to the average Cuban, which can be quite primitive and thus unattractive to American patients. For example, local health clinics often do not use disposable syringes.

In his movie *Sicko*, Michael Moore escorted several patients from the United States to Cuba to obtain medical care. While he did this to ridicule the US insurance system and argue for single payer health care, the fact is that he was arbitraging a cost differential between the American and Cuban medical systems. This is one cost arbitrage that should be legally available

to all Americans. While some patients may be rightly concerned that their medical tourism dollars may serve to prop up the Castro regime, the choice to use facilities in Cuba—or other countries with dubious human rights records—is most efficiently made by individual patients rather than by the federal government.

By removing travel restrictions and offering patients incentives to take advantage of less costly medical facilities outside the United States, the government can accelerate the globalization of the health care industry and realize significant savings.

Alternatives to Medical Doctors

The number of medical doctors (MDs) in the United States is effectively limited by state licensing laws and federal immigration restrictions. In 2013, the nation had only 141 accredited medical schools and 17,343 new medical graduates.[20] As a result, most doctors are highly compensated and many parts of the country have physician shortages.

Anyone who has been to a primary care physician should realize that much of his or her work does not require a medical degree. Nurses and other professionals can use a stethoscope to assess heart function, order tests, interview patients, and refer them to specialists if needed. Unfortunately, state laws often impede the efforts of these professionals to directly serve patients and thereby reduce health system costs.

State regulation of the medical profession has a complex history. While the usual justification for medical licensing laws is to protect patients from unqualified practitioners, many

[20] American Association of Medical Colleges, *Annual Report 2012*, 2012, https://www.aamc.org/download/272698/data/2012-annual-report.pdf; American Association of Medical Colleges, table 27, "Total Graduates by U.S. Medical School and Sex, 2009–2013," 2013, https://www.aamc.org/download/321532/data/2013factstable27-2.pdf.

authors who have reviewed the historical record conclude that these regulations were instead intended to increase the earning power of incumbent practitioners.[21]

As Robert Hudson notes, most states had medical licensing laws in the early 19th century but began repealing them after 1830. He attributes the deregulation wave to public dissatisfaction with physicians and the conflicting claims of different practitioner groups (called "sects"), each advocating different types of therapy. Rather than pick winners from among these sects, many state legislatures decided to withdraw their legal endorsement from all practitioner groups.[22]

Barbara Ehrenreich and Deirdre English credit the deregulatory wave to the Popular Health Movement of the 1830s and 1840s.[23] This movement was a revolt against traditional and ineffective treatments such as bleedings and administering calomel (a poisonous compound of mercury and chlorine), while emphasizing preventative measures including frequent bathing, eating whole grain cereals, and practicing temperance.

By the late 19th century, the deregulatory trend ended. Advances such as the germ theory of disease made the medical practice more scientific and more effective. The American Medical Association (AMA) gained an audience in state capitols as it lobbied to professionalize the field and drive out what it regarded as unqualified practitioners. As Ronald Hamowy documents, limiting the number of practitioners and increasing their compensation had been among the AMA's objectives since its founding in 1847.[24]

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[21] Ronald Hamowy, "The Early Development of Medical Licensing Laws in the United States, 1875–1900," *Journal of Libertarian Studies* 3, no. 1 (1979): 73–119; Reuben A. Kessel, "Price Discrimination in Medicine," *Journal of Law and Economics* 1, no. 1 (1958): 20–53.
[22] Robert P. Hudson, "Abraham Flexner in Perspective: American Medical Education, 1865–1910," *Bulletin of the History of Medicine* 56 (1972): 545–61.
[23] Barbara Ehrenreich and Deirdre English, *Witches, Midwives, and Nurses*, 2nd ed. (New York: Feminist Press at the City University of New York, 2010).
[24] Hamowy, "The Early Development of Medical Licensing Laws."

Since most states required licensed physicians to be medical school graduates, the number of medical schools was a major driver of physician supply. To the distress of existing providers, the number of schools rose rapidly in the late 19th century, increasing from 100 in 1880 to 160 in 1900. However, the number of medical graduates per 1,000 population only rose from 0.064 to 0.070 during this time of rapid population growth.[25]

In the early 20th century, the AMA and its think tank supporters successfully reversed the trend of medical school growth. In 1904, the AMA organized a Council on Medical Education, which established relatively high standards for medical schools. It then inspected all operating medical schools, rating almost half as "doubtful" or "nonacceptable."[26] Next, the AMA's Council on Medical Education convinced the Carnegie Foundation to conduct its own study of medical schools, using the council's input. Carnegie appointed Abraham Flexner, a secondary school educator with no medical background, to lead the project.[27]

Flexner's highly influential study appeared in 1910. It found many medical schools inadequate and called for their closure. Flexner considered admission requirements, school funding, and facilities; he did not look at the quality of teaching staff, curriculum, or instruction. Flexner's analysis of Alabama medical schools is indicative of the study's approach and his cavalier attitude toward physician supply: "Really satisfactory medical education is not now to be had in Alabama. The entrance standards are low; the schools are inadequately equipped; and they are without proper financial resources. . . . As the state now contains one physician to every

[25] William G. Rothstein, *American Medical Schools: A History* (Oxford: Oxford University Press, 1987).
[26] Ibid.
[27] Abraham Flexner, *Medical Education in the United States and Canada* (New York: Carnegie Foundation for the Advancement of Teaching, 1910), http://books.google.com/books?id=lxgTAAAAYAAJ&printsec=frontcover&dq=flexner+report+1910&hl=en&sa=X&ei=QwFCUp-WDMjPiwKKn4DwCA&ved=0CC8Q6AEwAA#v=onepage&q=flexner%20report%201910&f=false.

984 inhabitants, the restriction or suspension of clinical teaching for some years to come involves no danger to the community."[28]

After the Flexner Report appeared, the number of medical schools, students, and graduates fell sharply. Between 1910 and 1920, the number of medical schools declined from 131 to 96, students from 21,526 to 13,798, and graduates from 4,440 to 3,047.[29] The report cemented in place the now mainstream view that only individuals with years of training in selective, expensive medical schools are qualified to see patients. It also installed the regime of low physician supply and high cost that persists even today.

Ehrenreich and English attribute the drive for stricter medical standards to elitism and sexism.[30] They note that as late as 1910, midwives attended half of American childbirths. The emerging, male-dominated obstetrics profession was able to portray midwives as "hopelessly dirty, ignorant and incompetent."[31] Despite a 1912 study showing that midwives were more competent than obstetricians, states outlawed midwifery and restricted child delivery to hospital-based doctors. By the early 1970s, midwifery had virtually disappeared in the United States.[32]

According to midwifery advocates, obstetrician dominance of the birth attendance field has more than just monetary costs. In a 2008 position paper, a midwife advocacy group, the North American Registry of Midwives, argued,

> This shift from midwives to physicians as the primary maternity care providers set the stage for the medicalization of birth and has contributed to a number of troubling and persistent problems. These include: the escalating use of birth interventions, often without evidence of benefit and with reliable evidence of harm; a Cesarean rate that is nearing one-third of all births; soaring costs with no evidence of an increase in healthy

[28] Ibid., 186–87.
[29] Rothstein, *American Medical Schools*.
[30] Ehrenreich and English, *Witches, Midwives, and Nurses*.
[31] Ibid., 34.
[32] Richard W. Wertz and Dorothy C. Wertz, *Lying-In: A History of Childbirth in America*, expanded edition (New Haven, CT: Yale University Press, 1989).

> outcomes for women and infants; and, possibly most troubling of all, a severe erosion of women's belief in their ability to give birth.[33]

More recently, the use of midwives has enjoyed a renaissance, stemming from the feminist movement. Today, American midwives fall into two broad categories: those with a nursing background and the so-called direct-entry midwives who learn the discipline directly, without participating in a nursing program. Nurse-midwives are generally certified; direct-entry midwives may be certified professional midwives (CPMs) or may not be certified at all. Today, state regulation of midwifery varies. Currently 28 states legally authorize CPMs to practice.[34] Of the remaining 22 states, it is not clear how many prohibit direct-entry midwifery or simply do not distinguish between certified and uncertified practitioners.

An issue related to the professional attending the birth is the location of the birth because direct-entry midwives often cannot practice in or choose not to practice in hospitals. Planned at-home births are more comfortable for many women, and they eliminate hospitalization costs. According to US government statistics, less than 1 percent of births are planned to occur at home.[35] By contrast, over 20 percent of births in the Netherlands occur at home. Research in that country shows no significant difference in outcomes for planned at-home births and planned hospital births.[36] In the Netherlands, midwives receive about $1,500 for each birth they attend, including both prenatal and postnatal care.[37] This compares to a

[33] North American Registry of Midwives et al., *Certified Professional Midwives in the United States*, Midwives Alliance of North America website, 2008, p. 2, http://mana.org/pdfs/CPMIssueBrief.pdf.
[34] Big Push for Midwives, "Certified Professional Midwives (CPMs) Legal Status by State," Big Push for Midwives website, 2013, http://pushformidwives.org/#sthash.kwKw2CyS.dpuf.
[35] Marian F. MacDorman, T. J. Mathews, and Eugene Declercq, "Home Births in the United States, 1990–2009," NCHS Data Brief Number 84, National Center for Health Statistics website, http://www.cdc.gov/nchs/data/databriefs/db84.pdf.
[36] Koninklijke Nederlandse Organisatie van Verloskundigen, "Midwifery in the Netherlands," 2012, http://www.knov.nl/uploads/knov.nl/knov_downloads/526/file/KNOV_Midwifery_in_the_Netherlands_20121112.pdf.
[37] Ibid.

Medicare reimbursement rate of $2,150 when the equivalent services are provided in the United States by an obstetrician.[38]

Aside from midwives, a number of other medical professions have developed in recent decades to offset physician shortages. For example, there are over 170,000 nurse practitioners (NPs) in the United States.[39] NPs are advanced practice nurses who have received an extra certification, such as a master's degree, that enables them to provide health care services similar to those provided by a doctor. Another group of advanced practice nurses carry the title of clinical nurse specialist (CNS). CNSs have additional specialized training above that required to become a registered nurse. These specializations enable the nation's 69,000 CNSs to assist patients in the "prevention or resolution of illness, with medical diagnosis and treatment of disease, injury and disability."[40] Finally, the nation's 80,000 physician's assistants (PAs) provide specialized care in emergency rooms, operating rooms, and other medical settings.[41]

While NPs and other so-called mid-level providers are qualified to provide advanced medical care, many states restrict their rights to practice and/or require that they work under the supervision of a doctor—at extra cost. The American Association of Nurse Practitioners reports that only 15 states allow NPs to independently offer the full panoply of services for which they are qualified according to the Institute of Medicine.[42] State-level restrictions are cataloged by

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[38] This is the national rate displayed by the Medicare Physician Fee Finder for code 59400. See "Physician Fee Schedule Search," Centers for Medicare and Medicaid website, 2012, http://www.cms.gov/apps/physician-fee-schedule/search/search-criteria.aspx. Some regions have higher or lower costs. While CPT Code 59400 includes antenatal, natal, and postnatal care for vaginal deliveries, it is possible that some physicians receive additional reimbursement by separately billing for additional visits.

[39] American Association of Nurse Practitioners, *NP Facts*, American Association of Nurse Practitioners website, 2012, http://www.aanp.org/images/documents/about-nps/npfacts.pdf.

[40] National Association of Clinical Nurse Specialists, CNS FAQs, NACNS website, 2013, http://www.nacns.org/html/cns-faqs1.php.

[41] American Association of Physician Assistants, *Physician Assistant Census Report: Results from the 2010 AAPA Census*, American Association of Physician Assistants website, 2011, http://www.aapa.org/uploadedFiles/content/Research/2010%20Census%20Report%20National%20_Final.pdf.

[42] National Association of Clinical Nurse Specialists, CNS FAQs.

Barton Associates.[43] Their data show that seven states do not even allow NPs to sign handicapped parking permits—clearly a low-risk procedure.

In a meta-analysis of 37 studies conducted between 1990 and 2008, Robin P. Newhouse and her colleagues find that patients seen by NPs had similar outcomes and similar levels of reported satisfaction to those seen by physicians. Further, Newhouse's review of an additional 21 studies concludes that certified nurse midwives achieved health outcomes similar to those of obstetricians with less reliance on cesarean sections.[44]

Michael Dill and his colleagues provide survey evidence suggesting that medical consumers are willing to use alternative providers for primary care.[45] Instructed to assume that they had a worsening cough, respondents to an online survey were asked whether they would prefer to see a physician tomorrow or an alternative provider today. The majority of respondents (59.6 percent) preferred to be seen by a PA or NP today, compared to 25.3 percent who preferred to wait a day to see a physician; the remaining 15.1 percent had no preference or did not know.

Fully independent nonphysician medical professionals who are allowed to offer the full range of medical services for which they have been trained can provide cost-effective care. While many state legislatures may be unable to overcome local AMA lobbies to make such reforms, the federal government could use its financial power to encourage states to move in this direction. For example, the federal government could require that states relax restrictions on nurse practitioners, clinical nurse specialists, physician's assistants, and midwives in order to

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[43] Barton Associates, *NP Scope of Practice Laws*, 2013, http://www.bartonassociates.com/nurse-practitioners/nurse-practitioner-scope-of-practice-laws/.
[44] Robin P. Newhouse et al., "Advanced Practice Nurse Outcomes 1990–2008: A Systematic Review," *Nursing Economics* 29, no. 5 (2011): 1–22.
[45] Michael J. Dill et al., "Survey Shows Consumers Open to a Greater Role for Physician Assistants and Nurse Practitioners," *Health Affairs* 32, no. 6 (June 2013): 1135–42.

receive future Medicaid matches.[46] Medicare reimbursement rates for nurse practitioners, physician's assistants, and clinical nurse specialists are 85 percent of the rates for physicians providing identical services.[47] Increasing the proportion of services performed by these alternative providers can yield immediate savings to taxpayers.

Medical services vary in complexity. Many of these services can be provided quite adequately by professionals who have less than the four years of post-baccalaureate education (plus residency) demanded of today's licensed physicians. Practitioners with appropriate, but not excessive, training can afford to treat patients at lower cost. These mid-level providers do not need to offset the very large investment of time and money that today's doctors make in their medical education.[48] Adjustments to medical licensing laws that recognize these realities would result in a greater availability of care at lower cost. Any such adjustments should be carefully crafted to ensure that "mid-level" practitioners are authorized to provide those services for which they have been fully trained.

Malpractice Reform

High US health care costs are often attributed to the nation's malpractice system. Plaintiffs sometimes receive very large judgments that can easily bankrupt providers. To avoid this possibility, physicians purchase costly liability insurance and practice defensive medicine—prescribing unnecessary tests and treatments to guard against potential allegations of negligence.

[46] It may be appropriate to add other groups of mid-level practitioners, such as registered radiology assistants, to this list.
[47] Centers for Medicare and Medicaid Services, *How to Use the Searchable Medicare Physician Fee Schedule (MPFS)*, Centers for Medicare and Medicaid Services website, 2012, http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/How_to_MPFS_Booklet_ICN901344.pdf.
[48] Theodore Levy, "The End of Medicine: Not with a Bang, but a Whimper," *Freeman* 60, no. 3 (2010): 13–14.

Overall, the medical liability system is estimated to account for about 2.4 percent of US medical expenditures.[49] Most of the estimated cost is attributed to defensive medical practices; only about 0.4 percent of medical expenditure (about $9 billion in 2008) is associated with administrative expenses and the cost of paying claims. Punitive and noneconomic damages totaled less than $3 billion in 2008. These estimates may understate the true costs of the malpractice system by excluding effects that are harder to quantify. For example, certain medical innovations may not be coming to market because providers fear that, by introducing new health care technologies, they will be subject to lawsuits.

The malpractice system may also contribute to low physician morale and thus early retirements. Seth A. Seabury and his colleagues estimate that the average doctor faces an unresolved malpractice claim during 50.7 months of his or her career.[50] The fear and uncertainty associated with these claims undoubtedly impose a psychic burden on physicians. Sherry Gorman contends that many physicians view a malpractice suit as an attack on their honor. The self-reproach physicians feel when sued is exacerbated by "concerns over loss of livelihood, loss of control, damage to reputation, loss of assets, and lack of knowledge regarding legal proceedings."[51] Gorman describes an extreme case in which a Memphis doctor committed suicide as a result of malpractice litigation—a casualty of what she calls medical malpractice stress syndrome.[52]

However, Tom Baker cites evidence that malpractice insurance costs do not generally affect the supply of physicians. The only specialty that shows a significant impact is obstetrics. If

[49] Michelle M. Mello et al., "National Costs of the Medical Liability System," *Health Affairs* 29, no. 9 (2010): 1569–77.
[50] Seth A. Seabury et al., "On Average, Physicians Spend Nearly 11 Percent of Their 40-Year Careers with an Open, Unresolved Malpractice Claim," *Health Affairs* 32, no. 1 (2013): 111–19.
[51] Sherry Gorman, "Medical Malpractice Stress Syndrome: The Ignored Side of Litigation," *KevinMD.com* (blog), March 21, 2013, http://www.kevinmd.com/blog/2013/03/medical-malpractice-stress-syndrome-side-litigation.html.
[52] Ibid.

the use of midwives were further encouraged, as suggested earlier, obstetrician shortages would have less of an impact on expectant families. Baker also admits that malpractice insurance costs may reduce the number of rural providers in general.[53]

Other studies suggest a relationship between malpractice costs and early retirements in obstetrics and other medical specialties. Britta Anderson and her colleagues report that most OBGYNs who retired early cited malpractice costs as a reason for the early retirement decision.[54] Frances Farley and her colleagues find that orthopedic surgeons who retire before age 65 consistently cite malpractice costs as among the factors that affected their retirement plans.[55] However, it is worth noting that medical costs may not react to relatively small changes in supply, such as those resulting from a moderate uptick in the number of retirements, given the fact that pricing is often determined by Medicare reimbursement schedules rather than by market forces.

All things considered, the cost-saving opportunities offered by tort reform may not be large in the context of overall medical spending. However, as suggested in the introduction, there is no silver bullet to medical cost-containment problems, so an array of reforms—including changes to the medical liability system—are worth considering. A number of states have implemented tort reforms. These state-level reforms can be classified into four categories:

- caps on punitive damages
- caps on noneconomic damages

[53] Tom Baker, *The Medical Malpractice Myth* (Chicago: University of Chicago Press, 2005).
[54] Britta L. Anderson et al., "Outlook for the Future of the Obstetrician-Gynecologist Workforce," *American Journal of Obstetrics & Gynecology* 199, no. 1 (July 2008): 88.e1–88.e8.
[55] Frances A. Farley, Jeffrey Kramer, and Sylvia Watkins-Castillo, "Work Satisfaction and Retirement Plans of Orthopaedic Surgeons 50 Years of Age and Older," *Clinical Orthopaedics and Related Research* 466, no.1 (2008): 231–38.

- collateral source reforms, which allow or require courts to reduce a plaintiff's award by payments from other (collateral) sources such as worker's compensation or the plaintiff's insurance
- joint and several liability reform, which requires the apportionment of liability when multiple defendants are sued in a single claim[56]

Academic research on the impact of tort reform is mixed, with some studies finding significant variation among the types of reform. Avraham, Dafny, and Schanzenbach conclude that tort reforms are associated with lower employer-sponsored health insurance premiums. They find that caps on noneconomic damages and collateral source reforms are more effective than caps on punitive damages or joint and several liability reform.[57]

Ronald Stewart and his colleagues review malpractice claims at an academic medical center in San Antonio, Texas, both before and after that state's 2003 tort reform. That law included a cap of $250,000 on noneconomic damages in most medical malpractice cases. The researchers find that the rate of malpractice lawsuit filings dropped by about 80 percent after the reform was implemented. Annual liability and defense costs fell from $595,000 per year to $515 per year.[58] Daniel Kessler and his colleagues report that physician supply expanded 2.4 percent faster in states that carried out "direct" tort reforms such as limits on economic and punitive damages than in states that did not enact such reforms.[59]

On the other hand, J. William Thomas, Erika C. Ziller, and Deborah A. Thayer find that the opportunities for savings on defensive treatment costs—the largest component of malpractice

[56] Ronen Avraham, Leemore Dafny, and Max Schanzenbach, "The Impact of Tort Reform on Employer-Sponsored Health Insurance Premiums," *The Journal of Law, Economics, & Organization* 28, no. 4 (2010): 657–86.
[57] Ibid.
[58] Ronald M. Stewart et al., "Malpractice Risk and Cost Are Significantly Reduced after Tort Reform," *Journal of the American College of Surgeons* 212 (2011): 463–69.
[59] Daniel P. Kessler, William M. Sage, and David J. Becker, "Impact of Malpractice Reforms on the Supply of Physician Services," *Journal of the American Medical Association* 293, no. 21 (2005): 2618–25.

overhead—are limited. In a study of a large database of medical treatments provided by CIGNA Health Insurance, they find that a 10 percent reduction in medical malpractice insurance rates is associated with only a 0.7 percent reduction in medical care expenses.[60]

Limitations on punitive and noneconomic damages do not provide unalloyed benefits. Toshiki Izuka finds evidence that higher liability pressure deters preventable medical complications associated with four specific obstetric and gynecologic procedures. He also concludes that caps on punitive and noneconomic damages, as well as collateral source reforms, were associated with higher rates of preventable complications. On the other hand, he finds that joint and several liability reform is associated with lower complication rates.[61]

In some cases, egregious acts by physicians may arouse legitimate outrage that can best be satisfied through a large jury award. Further, damage caps can be seen as a legislative intervention into a system that has evolved through common law. F. A. Hayek and other social theorists warn about the unintended consequences of state interventions into systems that arise through spontaneous order.[62] Baker argues that medical lawsuits shed light on medical errors and shoddy practices that may otherwise have been covered up. As an example, he cites a 2002 *Chicago Tribune* exposé on hospital-borne infections that was based primarily on records from a malpractice lawsuit against Bridgeport Hospital.[63]

Another institutional alternative examined by Michelle Mello and her colleagues involves the replacement of the tort system by an administrative law process. The authors find that Sweden, Denmark, and New Zealand have achieved lower costs with these systems.

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[60] J. William Thomas, Erika C. Ziller, and Deborah A. Thayer, "Low Costs of Defensive Medicine, Small Savings from Tort Reform," *Health Affairs* 29, no. 9 (2010): 1578–84.
[61] Toshiki Izuka, "Does Higher Malpractice Pressure Deter Medical Errors?" *Journal of Law and Economics*, 56, no.1 (2013): 161–88.
[62] F. A. Hayek, *Law, Legislation, and Liberty* (London: Routlege and Kegan Paul, Ltd., 1982).
[63] Baker, *Medical Malpractice Myth*.

Claimants do not need to prove negligence on the part of the provider to receive an award, thereby minimizing the adversarial aspect of the compensation system, limiting physician stress, and thus increasing provider cooperation. Although this lower standard results in more awards, costs are reduced by replacing expensive litigation with an administrative procedure, and, more importantly, by severely restricting the size of awards. The authors report that the average award is $40,000 or less in all three countries, compared to over $300,000 in the United States.[64]

Rather than eliminate the malpractice litigation option, the US government could permit patients and physicians to elect an administrative law or arbitration procedure before treatment begins. Under this approach, physicians would ask patients to sign an agreement before beginning care under which they waive the right to sue. A fair criticism of such an option is that it might crowd out the traditional scenario under which providers are at risk of being sued. All providers could demand that patients sign the waivers, thereby effectively eliminating their choice to retain the right to sue.

Another policy option would be to implement an administrative law system for patients receiving federally funded medical services, for example, through Medicare and Medicaid. Providers may then be more likely to accept these patients despite the fact that Medicare and Medicaid usually provide lower reimbursement rates than private insurance. Given the cost savings and stress reduction that an administrative law system offers physicians, it may be possible for the federal government to achieve further discounts on payment rates while still attracting providers, thus yielding savings for taxpayers. Also, because the traditional litigation

[64] Michelle M. Mello, Allen Kachalia, and David M. Studdert, "Administrative Compensation for Medical Injuries: Lessons from Three Foreign Systems," the Commonwealth Fund website, July 2011, www.commomwealthfund.org /Publications/Issue-Briefs/2011/Jul/Medical-Injuries.aspx.

system remains in place for private patients, the reform may elicit less resistance from tort lawyers and others that benefit from the status quo.

In summary, tort litigation (or, more precisely, the fear of tort litigation) adds modestly to overall medical costs and damages physician morale. Legislative interventions may limit these effects but may also restrict the system's ability to identify incompetent providers. Increased use of administrative law procedures would enable us to unearth more cases of malpractice but at a far lower overall cost.

Prescription Drug Patent and Dispensing Rules

According to data from the Centers for Medicare and Medicaid Services, prescription drug costs amounted to $269.2 billion in 2011, accounting for about 10 percent of total health care costs and almost 1.8 percent of GDP.[65] Much of this cost is attributable to patent protections and restrictions on the way in which prescription drugs are dispensed. Drug patents give pharmaceutical companies a 20-year monopoly on a drug's sales.[66] In the absence of competition, pharmaceutical firms can charge much higher prices than they would under normal market conditions. Meanwhile, the use of pharmacists to dispense prescription drugs further adds to the visible price of these medications, while imposing substantial time costs on patients. If all prescription drugs were sold over the counter without patent protection, it is likely that their costs would fall substantially. It is less clear that eliminating or at least reducing patent protections and restrictions on dispensing would have the side effects feared by many.

[65] Centers for Medicare and Medicaid Services, *National Health Expenditure Projections.*

[66] In addition to patent protection, the US Food and Drug Administration grants exclusive marketing rights upon approval of a new medication. The exclusivity period is generally concurrent with the period of patent protection but may run somewhat shorter or longer. To simplify the prose in this section, I only refer to patent protection, but the analysis applies equally to FDA marketing exclusivity.

In 2003, the Food and Drug Administration approved a request by the pharmaceutical company AstraZeneca to reclassify Prilosec, its highly profitable heartburn treatment, from prescription to over-the-counter (OTC) distribution. The FDA usually reclassifies drugs from prescription to OTC only after the manufacturer files a New Drug Application (NDA) requesting the reclassification. Since Prilosec lost patent protection and became vulnerable to competition from low-cost generic drugs, it made business sense for AstraZeneca to make Prilosec available on an OTC basis.

At about the same time, the company introduced a new prescription heartburn medication named Nexium. The company's sales force has encouraged physicians to prescribe Nexium—instead of recommending Prilosec—at a cost per dose that is several times higher than Prilosec OTC.[67] Marketing claims aside, Prilosec and Nexium are very similar molecules that produce very similar results.[68] The crucial difference is that Prilosec has lost patent protection and Nexium still has it. The stated benefit of dispensing drugs through a prescription process is that it reduces the risk of patients using the medications improperly.[69] But, if Prilosec and Nexium are basically the same, why should one be sold over the counter and the other be available only by prescription?

According to IMS Health data published on Drugs.com, Nexium had 2013 retail sales of almost $6 billion.[70] If these sales had been replaced by purchases of Prilosec OTC, expenditure on acid reflux medications would have been reduced by at least $4 billion. Nexium would be

[67] A check of the website RxUSA.com on July 3, 2013, showed a per-pill price of $9.08 for 20mg Nexium and $0.69 for 20mg Prilosec. According to GoodRX.com on the same day, 20mg Nexium was available at Walmart for $7.19 per pill; Prilosec cost $0.44 per pill. Mark Hoofnagle quotes the cost difference as "4–8 times." Mark Hoofnagle, "Why No One Should Take Nexium and It Should Never Have Been Approved," *Denialism Blog*, ScienceBlogs website, January 9, 2012, http://scienceblogs.com/denialism/2012/01/09/why-no-one-should-take-nexium/.
[68] Hoofnagle, "Why No One Should Take Nexium"; Colleen Schmitt et al., "A Multicenter, Randomized, Double-Blind, 8-Week Comparative Trial of Standard Doses of Esomeprazole (40 mg) and Omeprazole (20 mg) for the Treatment of Erosive Esophagitis," *Digestive Diseases and Sciences*, 51, no. 5 (2006): 844–50.
[69] Texas State Board of Pharmacy, "Why Do I Need a Prescription from a Doctor for Some Medications and Not for Others?" Texas State Board of Pharmacy website, 2013, http://www.tsbp.state.tx.us/consumer/broch1.htm.
[70] Drugs.com, "Top 100 Drugs for 2013 by Sales," Drugs.com website, 2014, http://www.drugs.com/stats/top100/2013/sales.

somewhat less expensive if it did not have to be dispensed by a pharmacist. Since the dangers of Nexium self-medication are similar to the risk with consumers' direct purchases of Prilosec, it is hard to see the social benefit of restricting the manner in which Nexium is dispensed.

A larger question is whether Nexium should have even received patent protection in the first place. By legally prohibiting competition from generic alternatives, drug patents lock in high prices for newer medications. While it is argued that patent restrictions provide a social benefit by encouraging research into new lifesaving drugs, it is clear that many drug patents do not provide such a benefit. Undoubtedly the patent system could be reformed in such a way that "me-too" drugs like Nexium receive less or no protection without undermining incentives for truly original research.

More generally, evidence regarding the incentive benefits of pharmaceutical patents is mixed. Michele Boldrin and David Levine observe that Italy had a thriving pharmaceutical industry before patent protections were implemented in 1978. They find that the pace of drug discovery in Italy did not increase after intellectual property was implemented. One possibility is that Italian firms had been conducting research in hopes of taking advantage of patent protections in export markets.[71] Boldrin and Levine also note that India had a thriving pharmaceutical industry with limited patent rights prior to its 2005 admission to the World Trade Organization, which requires members to raise intellectual property standards.[72] However, their reference, Jean Lanjuow, found that research and development spending by Indian drug companies was not large and was at least partially driven by opportunities to gain patent protection in foreign markets.[73]

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[71] Michele Boldrin and David K. Levine, *Against Intellectual Monopoly*, chapter 9, 2007, http://levine.sscnet.ucla .edu/papers/imbookfinal09.pdf.
[72] Ibid.
[73] Jean O. Lanjouw, "The Introduction of Pharmaceutical Product Patents in India: 'Heartless Exploitation of the Poor and Suffering'?" (National Bureau of Economic Research Working Paper 6366, National Bureau of Economic Research, 1998), http://www.nber.org/papers/w6366.pdf.

In the computer software industry, the prevalence of open source technologies suggests that innovation can occur in the absence of intellectual property protections. Some very large software projects, such as the Linux operating system and Firefox web browser, flourish despite the fact that anyone is free to copy them. Some preliminary efforts have been made to extend this open source paradigm to the pharmaceutical industry. Matthew Todd introduced a new, faster process for producing Praziquantel, using open source methods.[74] Although Praziquantel, a treatment for the parasitic infection Schistosomiasis, has long been manufactured and distributed by Eli Lilly, new methods of producing already existing drugs are patentable. Todd published his findings without a patent,[75] and has now started an open-source drug-discovery project targeting malaria.[76]

Another pharmaceutical researcher taking an open source approach is Jay Bradner at Harvard University. In 2010, Bradner's team isolated a molecule that appeared to trick cancer cells into becoming normal cells. He published the compound's structure and mailed samples to other labs rather than attempting to patent it.[77] Bradner discussed his advocacy of open source drug discovery in a 2011 TEDx Boston talk.[78]

These cases suggest that pharmaceutical research would continue at some level without any patent protection. Drug discoveries offer strong nonpecuniary benefits (pride in accomplishment, favorable publicity) that would provide incentives for ongoing research in the

[74] Alius Noreika, "Open Source Drug Discovery," Technology.org website, 2013, http://www.technology.org/2013/04/24/open-source-drug-discovery/.
[75] Schisto Research Community, "Enantioselective Synthesis of Praziquantel," 2012, http://www.thesynapticleap.org/book/export/html/51.
[76] OpenWetWare.org, OpenSourceMalaria webpage, OpenWetWare website, 2013, http://openwetware.org/wiki/Open_Source_Drug_Discovery_-_Malaria.
[77] Dan Morrell, "Brave New Thinkers 2012: Jay Bradner," *Atlantic*, November 2012, http://www.theatlantic.com/magazine/archive/2012/11/jay-bradner/309122/.
[78] Jay Bradner, "Open-Source Cancer Research," TED.com website, filmed May 2011, http://www.ted.com/talks/jay_bradner_open_source_cancer_research.html.

absence of opportunities to receive monopoly rents from the introduction of new medicines. How much beneficial research would occur in the absence of an international pharmaceutical patent regime is difficult to estimate, since it is impossible to conduct a controlled experiment.

Likewise, it is difficult to determine whether narrowing patent protections would significantly reduce beneficial research. However, there are reasons to think that such a narrowing would have limited adverse side effects. First, we already know that some research would continue without financial incentives. Second, much of the current research expenditure is partially or fully directed at capturing rents rather than producing meaningful clinical benefits.[79] A substantial investment was required to isolate Nexium and then shepherd it through the approval process. And Nexium is but one example of a me-too drug that provides marginal benefits. Other instances include male erectile dysfunction medications Levitra and Cialis—developed as alternatives to Viagra. Crestor, a drug with 2013 retail sales of $5.2 billion,[80] is one of several statins that lower cholesterol. A recent study found that Crestor had only marginal benefits over a competing statin, Lipitor,[81] which is now off patent and sells for a small fraction of Crestor's price.[82]

In fact, it is possible that rents derived from patent protection actually shift research toward me-too medications. Drugs that cause the same biological effects as previously approved medications are more likely to pass clinical trials. As a result, their risk-adjusted returns should be higher. A profit-maximizing firm thus has a strong incentive to focus on molecules that are more likely to generate a payoff.

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[79] Donald W. Light and Joel R. Lexchin, "Pharmaceutical Research and Development: What Do We Get for All That Money?," *BMJ: British Medical Journal* 345 (August 2012): e4348.
[80] Drugs.com, "Top 100 Drugs."
[81] Stephen J. Nicholls et al., "Effect of Two Intensive Statin Regimens on Progression of Coronary Disease," *New England Journal of Medicine* 365, no. 22 (2011): 2078–87.
[82] Based on a comparison of prices at http://www.goodrx.com/lipitor and http://www.goodrx.com/crestor.

Finally, pharmaceutical companies do not finance the most consequential research. Merrill Goozner concludes that most important discoveries in recent decades have emerged from universities and nonprofit medical facilities, often funded by the National Institutes of Health.[83]

These observations suggest that some marginal changes to the patent system *could* substantially reduce health care costs without seriously impacting consequential research.[84] One such change would involve restricting patent protection to those drugs that have major benefits over previously approved treatments. A second change would be shortening the period of patent protections for any new drug. Marcia Angell points out that average effective patent life (the remaining period of patent protection after FDA approval) increased from 8 to 14 years between 1980 and 2000 as a result of legislative changes and aggressive litigation on the part of drug companies.[85]

Reducing the scope of patent protection for new drugs should create neither constitutional issues nor moral objections from intellectual property advocates. The Constitution states that "Congress shall have the power . . . [t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." The term "limited Times" leaves the government wide discretion in determining the length of patent protection. Ayn Rand, a vocal defender of intellectual property, observed that "Since intellectual property rights cannot be exercised in perpetuity, the question of their time limit is an enormously complex issue."[86]

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[83] Merrill Goozner, *The $800 Million Pill: The Truth behind the Cost of New Drugs* (Berkeley, CA: University of California Press, 2004).
[84] The only way to conclusively determine the research impact of different patent regimes is through a controlled experiment. Since this is impossible, any assertion about the effects of patents must be qualified.
[85] Marcia Angell, *The Truth about the Drug Companies: How They Deceive Us and What to Do about It* (New York: Random House, 2004).
[86] Ayn Rand, *Capitalism: The Unknown Ideal* (New York: Random House, 1967).

A smaller, but still substantial, contributor to high drug costs is their method of dispensation. Prescription drug prices reflect the cost of paying a pharmacist to read the prescription, locate the appropriate medication, count pills or measure dosages, and advise the patient. While the exact price impact is difficult to estimate, it is likely to be substantial given what is known about pharmacist compensation. According to the Bureau of Labor Statistics, median pharmacist pay was $56.09 per hour in 2012.[87] An informal poll posted on a pharmacy blog reports that the average pharmacist fills about 15 prescriptions per hour,[88] suggesting a dispensing cost of about $3.74 per prescription. This does not include the cost of lower-paid pharmaceutical technicians (who assist pharmacists but cannot dispense on their own). With over 3.7 billion prescriptions filled in the United States annually,[89] the incremental cost of prescription dispensation exceeds $10 billion per year. This estimate excludes the opportunity cost of patients waiting for their prescriptions to be filled—a cost that does not appear in the statistics. It also does not include the cost of extra medical appointments patients make specifically for the purpose of getting a prescription.

Significant cost savings could thus be achieved by switching a substantial proportion of prescription drugs to over-the-counter distribution. Further, there is reason to believe that the social cost of switching prescription drugs to OTC are minimal. Prescription requirements have varied across time in the United States and vary internationally—permitting comparisons between various dispensing regimes.

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[87] Bureau of Labor Statistics, US Department of Labor, *Occupational Outlook Handbook: Pharmacists*, 2014, http://www.bls.gov/ooh/Healthcare/Pharmacists.htm.
[88] Eric Durbin, "Prescriptions per Hour," *Eric, Pharmacist* (blog), June 7, 2011, http://eric-rph.blogspot.com/2011/06/prescriptions-per-hour.html.
[89] Kaiser Family Foundation, "Total Number of Retail Prescription Drugs Filled at Pharmacies," Kaiser Family Foundation website, 2012, http://kff.org/other/state-indicator/total-retail-rx-drugs/.

Peter Temin reports that prescription drug requirements did not exist during much of the 20th century. Before 1938, only certain narcotics were restricted. In that year, Congress passed the Federal Food, Drug, and Cosmetic Act of 1938.[90] The law imposed detailed labeling requirements on medications not prescribed by a physician. FDA regulations implementing the law required that certain drugs—those that would otherwise have warning labels—be sold only by prescription. Since labeling content was left to the discretion of manufacturers, the FDA could not enforce the new regulation in a uniform manner. In 1951, Congress codified the FDA's authority to determine which drugs could be dispensed only by prescription.

Sam Peltzman reports that many foreign countries either did not have or did not enforce prescription requirements in the 1980s. In a statistical comparison between countries with permissive and restrictive prescription regimes, he found that strong prescription controls do not reduce mortality from drug poisoning or infectious diseases. He also did not find benefits in the United States when comparing poisoning rates before and after the imposition of prescription requirements in the United States.[91]

Aside from the benefit-cost issues associated with prescription requirements, there are also philosophical issues. Jessica Flanigan argues that self-medication is a right. She finds prescription mandates to be inconsistent with the doctrine of informed consent, under which patients have the right to refuse physician-recommended treatments and the right to purchase firearms, the use of which could cause injury or death. Flanigan concludes that the only restrictions on self-medication should involve antibiotics—the overuse of which could give rise to resistant superbugs.[92] Flanigan also observes that the elimination of prescription drug requirements does not mean that patients

[90] Peter Temin, "The Origin of Compulsory Drug Prescriptions," *Journal of Law and Economics* 22 (1979): 91–105.
[91] Sam Peltzman, "The Health Effects of Mandatory Prescriptions," *Journal of Law and Economics* 30 (1987): 207–38.
[92] Jessica Flanigan, "Three Arguments against Prescription Requirements," *Journal of Medical Ethics* 38 (2012): 579–86.

cannot still rely on the judgment of pharmacists and physicians.[93] The use of prescriptions pre-dated the Federal Food, Drug, and Cosmetic Act of 1938,[94] so it appears that patients delegated authority over their pharmaceutical choices even before they were legally obliged to do so.

Switching a large proportion of drugs from prescription to nonprescription status would pose at least one transitional challenge. Since insurance plans are typically limited to prescription drug coverage, out-of-pocket costs would rise for many patients.[95] To offset this effect, it would be necessary to expand pharmaceutical coverage to some types of OTC medications. Such a change is already warranted because the present system creates incentives to purchase unnecessarily expensive medications. Returning to the example I used at the beginning of this section, many insured patients may face lower out-of-pocket costs for prescription Nexium than for Prilosec OTC—even though the former is much more expensive.

Before concluding this discussion, it is worth addressing two more commonly advanced explanations for the high cost of prescription drugs in the United States: (1) the federal government's failure to control or at least negotiate drug prices, and (2) the high cost of shepherding new drugs through the FDA approval process.

Other advanced nations limit prescription drug costs by controlling prices or using their monopsony buying power to negotiate lower prices.[96] It is possible that other countries succeed in pursuing these policies because pharmaceutical companies can shift costs onto the relatively large US market. If the United States were to impose similar restrictions, drug shortages may

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[93] Ibid.
[94] Samuel Otway Lewis Potter, *A Compend of Materia Medica Therapeutics and Prescription Writing* (Philadelphia: P. Blakiston's Son and Company, 1906).
[95] Eve Tahmincioglu, "Over the Counter, Yes, but Out of the Insurance Plan," *New York Times*, July 4, 2004, http://www.nytimes.com/2004/07/04/business/sunday-money-spending-over-the-counter-yes-but-out-of-the-insurance-plan.html?pagewanted=all&src=pm.
[96] AARP, *European Experiences with Prescription Drug Pricing*, AARP website, 2006, http://assets.aarp.org/www.aarp.org_/cs/gap/ldrstudy_prescdrugs.pdf.

become common. Drug shortages associated with price controls already occur both in the United States[97] and abroad.[98] But, for the reasons discussed earlier, the cost of many medications include large monopoly rents. Thus, for the most common prescription drugs, price controls may not result in shortages. That said, competition arising from the reduced scope of patent protection is a more reliable way to achieve cost savings while minimizing the risk of shortages. As long as low-cost competitors are free to enter the marketplace, the US government and other large buyers should be able to receive bids close to cost when they purchase supplies through a competitive bidding process.

Pharmaceutical companies and their supporters sometimes attribute high drug costs to the FDA's complex approval process.[99] However, some argue that thorough testing is required to protect consumers from dangerous and ineffective medications.[100] One alternative to relaxing or eliminating the FDA testing regime would be to allow consumers to freely import unapproved drugs. Since the imported medications would not have the FDA seal of approval, they would clearly be provided on a "buyer beware" basis. Consumers would have the choice to take on the risk of drug importation or avoid it by only purchasing medications approved by the FDA and manufactured in the United States.

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[97] John Goodman, "Rx Drug Shortages: Regulation Can Be Deadly," *Health Affairs Blog*, June 8, 2011, http://healthaffairs.org/blog/2011/06/08/rx-drug-shortages-regulation-can-be-deadly/.

[98] Linda Gorman, "Price Controls Create Drug Shortages in Britain," *John Goodman's Health Blog*, National Center for Policy Analysis website, May 26, 2010, http://healthblog.ncpa.org/price-controls-create-drug-shortages-in-britain/; Tom Blackwell, "Drug Shortage 'Crisis' May Have Contributed to Deaths of Four Canadians Last Year, Anesthetists Say," *National Post*, October 14, 2013, http://news.nationalpost.com/2013/10/14/drug-shortage-crisis-may-have-contributed-to-deaths-of-four-canadians-last-year-anesthetists-say/.

[99] See, for example, Avik S. A. Roy, *Stifling New Cures: The True Cost of Lengthy Clinical Drug Trials*, Project FDA Report No. 5., Manhattan Institute for Policy Research website, 2012, http://www.manhattan-institute.org/html/fda_05.htm.

[100] See, for example, Bernard Munos, "In Defense of the FDA," Forbes website, December, 19, 2012, http://www.forbes.com/sites/bernardmunos/2012/12/19/in-defense-of-fda/; Union of Concerned Scientists, "FDA's Drug Safety System Fails to Protect Public," Union of Concerned Scientists website, 2006, http://www.ucsusa.org/scientific_integrity/abuses_of_science/vioxx.html.

In conclusion, drug patents and prescription requirements substantially increase pharmaceutical costs without necessarily providing health benefits. As we have seen, pharmaceutical research would continue without the incentives afforded by patent protection. Removing these protections would open up drug manufacture to competition and thus substantially lower prices. Consumers are often capable of filling prescriptions on their own and do not always require the assistance of a pharmacist. Allowing consumers to self-medicate would produce a further reduction in costs, just as self-service options produce economies in other industries.

Conclusion

The debate over the Affordable Care Act (ACA) has focused more on the allocation of medical costs than on their overall size. Mandates to purchase insurance, elimination of lifetime caps, and premium subsidies shift costs among taxpayers, insurance carriers, and providers. These core ACA features only incidentally impact the share of GDP devoted to health care. Other aspects of the 2010 law are intended to contain costs but may not have a substantial impact. For example, the Independent Payment Advisory Board (IPAB) may be dissuaded from making consequential changes as its members worry about accusations that the IPAB constitutes a death panel. Preventative medicine, encouraged by the ACA, is good for health outcomes, but generally it does not achieve advertised cost outcomes.[101] Finally, the Accountable Care Organization (ACO) concept, which promises to shift the paradigm from payment for quantity to payment for quality, may not scale beyond a few successful prototypes.[102]

[101] Sharon Begley, "Think Preventive Medicine Will Save Money? Think Again," *Reuters*, January 29, 2013, http://www.reuters.com/article/2013/01/29/us-preventive-economics-idUSBRE90S05M20130129.
[102] Jeff Goldsmith, "Pioneer ACOs' Disappointing First Year," *Health Affairs Blog*, August 15, 2013, http://healthaffairs.org/blog/2013/08/15/pioneer-acos-disappointing-first-year/.

Once the economy fully emerges from recession and baby boomers flood the medical system, it should become apparent that the passage of the ACA and the slowing of medical cost inflation were not causally linked. New reforms are needed to really bend—let alone break—the cost curve.[103]

As we have seen, the high and rising cost of US medical care is partially attributable to legally enforced rigidities in our health care system. By relaxing restrictions, the government can unlock competitive forces that drive down prices and empower individuals to avoid unnecessary, expensive medical services. A more open health care market would give providers incentives to innovate in ways that not only improve the quality of care, but also reduce the cost of offering it.

In this report, I have suggested that significant cost savings can be achieved by encouraging medical tourism, empowering mid-level providers, using administrative law procedures as an alternative to malpractice litigation, reducing the scope of drug patents, and switching prescription medicines to over-the-counter dispensing. A full list of reforms presented in this study is provided in table 2 (page 35).

As consumers, we expect higher quality and lower costs over time from many of the products and services we purchase on the market. Such results may also be possible in many aspects of the health care industry—if federal and state governments will allow it.

[103] Robert Graboyes, "The American Health Care System: Principles for Successful Reform" (Economic Perspectives, Mercatus Center at George Mason University, Arlington, VA, October 14, 2013), http://mercatus.org/publication/american-health-care-system-principles-successful-reform.

Table 1. International Comparison of Costs for Major Procedures, as of March 2013

Procedure	US	Brazil	Costa Rica	India	Malaysia	Mexico	Singapore	South Korea	Thailand	Taiwan	Turkey
Average savings		30–45%	45–65%	65–90%	60–80%	40–70%	30–45%	30–45%	50–70%	40–55%	50–65%
Coronary artery bypass graft—CABG	$88,000	$35,000	$31,500	$9,500	$20,800	$27,500	$22,500	$29,000	$23,000	$21,000	$20,500
Valve replacement with bypass	$85,000	$33,000	$29,000	$8,500	$18,500	$23,500	$29,500	$33,000	$22,000	$18,000	$20,000
Hip replacement	$33,000	$15,000	$14,500	$8,000	$12,500	$14,300	$20,700	$15,500	$13,000	$10,500	$11,800
Knee replacement	$34,000	$12,000	$9,500	$7,500	$12,500	$12,500	$18,500	$15,000	$11,500	$12,000	$12,000
Spinal fusion	$41,000	$22,000	$17,000	$9,500	$17,900	$16,200	$17,000	$18,000	$16,000	$18,000	$16,500
IVF cycle, excluding medication	$15,000	$4,800	NA	$3,300	$7,200	$4,600	$9,500	$7,500	$6,500	$4,800	$9,500
Gastric bypass	$18,000	$12,000	$11,200	$6,800	$8,200	$11,500	$14,000	$12,500	$12,000	$13,000	$13,000
Full facelift	$12,500	$5,200	$4,500	$3,500	$5,500	$5,400	$7,000	$5,900	$4,700	$5,600	$4,800
Rhinoplasty	$6,200	$2,600	$3,400	$2,800	$3,600	$3,500	$4,800	$4,700	$3,700	$3,500	$3,300

Source: Patients Beyond Borders, "Medical Tourism Statistics & Facts," last modified June 16, 2013, http://www.patientsbeyondborders.com/medical-tourism-statistics-facts.

Notes: US costs vary based on location, materials and equipment used, and individual requirements. Average rates reflect some discounts available to uninsured patients. International estimates include all treatment-related costs but exclude travel and accommodations. Figures are averages and reflect more common incidence of cost. All figures are in US dollars.

Table 2. Summary of Policy Recommendations

Medical tourism	Allow and incentivize Medicare patients to obtain lower-cost treatment in Mexico and other medical tourism destinations.
Prescription drugs	Do not extend patent protection to pharmaceuticals that do not demonstrate substantial benefits relative to existing treatments.
	Shorten the length of patent protection.
	Switch more drugs from prescription to over-the-counter dispensing.
Alternative providers	Allow nurse practitioners, physician's assistants, and clinical nurse specialists to provide the full ranges of services for which they have been trained, independent of a physician.
	Allow direct-entry midwives to practice in all states and encourage women with normal pregnancies to give birth at home.
Medical malpractice	Implement an administrative law procedure for Medicare and Medicaid patients that makes obtaining recoveries easier while limiting damages and avoiding litigation.