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FIRST IN A SERIES OF "HEALTH CARE 2.0" REPORTS

PART 1

KEY ECONOMIC PRINCIPLES

PART 2

FEDERAL ANTI-KICKBACK

PART 3

OUTMODED REGULATIONS

PART 4

FDA REGULATIONS

Executive Summary

s Internet-driven innovation revolutionizes the U.S. economy, many have wondered: Why isn't there an Uber of health care? Why can't we deploy, in health care, the same forces that are improving quality and lowering costs in virtually every other sector of the economy? Health care professionals are neither dumb nor averse to new technology; the U.S. health care sector employs hundreds of thousands of people with doctorate-level scientific and medical training.

The reason that health care increasingly lags the rest of the information economy is not because health care is fundamentally different. It is because decades of unwise government policy have made it almost impossible for consumers and innovators to succeed.

The Manhattan Institute's Health Care 2.0 series delves into the details of how government policy stifles innovation in the delivery of health care. This paper, Part 1, surveys the key economic principles that drive innovative, dynamic sectors of the economy—and explains why American health care does not live up to those principles. Part 2 will examine how federal anti-kickback statutes prohibit entrepreneurs from developing innovative ways for physicians and hospitals to coordinate care. Part 3 will explain how outmoded regulations and privacy laws block patients from owning their own medical records, creating needless medical errors. And Part 4 will discuss how FDA regulation of consumer-health technology, such as that produced by Apple and Fitbit, is suppressing a potential revolution in primary care.

I. Introduction: Yes, Economic Principles Apply to Health Care

any observers—especially those aligned with the political Left—argue that health care can never function like a conventional market. Certain structural aspects of health care, they say, prevent the efficient functioning of market forces and must be corrected by government action.

This argument has been espoused, most notably, by Stanford economist and Nobel laureate Kenneth Arrow. In 1963, the Ford Foundation approached Arrow, then known as a leading economic theoretician, about applying his ideas to the practical problems of health, education, and welfare. Arrow accepted the assignment and began studying the ins and outs of U.S. health care delivery.

In December 1963, Arrow published his seminal essay, "Uncertainty and the Welfare Economics of Medical Care," in *The American Economic Review*. Health care, Arrow argued, diverges from traditional markets in important ways; he concluded that "it is the general social consensus, clearly, that the laissez-faire solution for medicine is intolerable." The essay, still widely read, is credited by many as having invented the field of modern health economics.

Medical care has changed dramatically in the past half-century, and Arrow's observations have become increasingly antique. But his thesis remains at the heart of the ideological objection to market-driven health care. According to Arrow, health care is subject to five distortions that prevent the efficient functioning of market forces:

- 1. *Information is asymmetric.* Medical knowledge is complicated: the physician knows much more than the patient about the treatment of disease; the buyer of medical services is thus at a disadvantage, relative to the seller. It is also difficult for patients to make independent decisions as to the best course of action. Payment by health insurers leads to further confusion because insurers know less than patients and physicians about the particularities of each case.
- 2. *Demand is unpredictable.* Demand for medical services is unpredictable and, therefore, differs fundamentally from other common expenses, such as food. In addition, access to health care is more critical than access to many consumer products.
- 3. *Trust is unusually important.* A patient cannot test-drive a surgical procedure before undergoing it: if the procedure fails, or has adverse consequences, he is stuck with the outcome. The patient must trust that the surgeon is competent. If he is not, the consequences for the patient can include serious injury or death, for which there is no economic remedy.
- 4. *Barriers to entry are high.* Physicians must be licensed to practice medicine. To gain licensure, they must complete many years of training. As a result, the sale and consumption of medical services are constrained by the limited number of new doctors produced each year.
- 5. *Paying for health care is not consumer-friendly.* Patients now pay for health care after it is received. Patients also frequently pay indirectly for their care, via insurers. Further, patients are rarely able to shop around for a medical service based on price because there is little transparency in this area.

The aforementioned health care—market distortions have considerably worsened since Arrow described them in 1963; but in other industries less dominated by misguided government intervention, similar distortions have gradually eroded, thanks to technology, especially the rise of the Internet.



II. Professor Arrow vs. the Internet

Consider a key problem identified by Arrow: asymmetric information. It is not unusual, per se, for a buyer to have less information than a seller. The seller of a used car, for example, is likely to know more about that car's mechanical history than a buyer. The phrase "caveat emptor"—"let the buyer beware"—dates back centuries and has been enshrined in U.S. law since at least 1817.

Thanks to the Internet, the market for used cars is far less asymmetric than it once was. Before the World Wide Web, Carfax, the leading U.S. vehicle-history service, was primarily used for auto dealers, not consumers. Today, Carfax is available free online, making it possible for a consumer to review the mechanical histories of hundreds of cars before purchasing one. Indeed, in many types of transactions, the buyer now has an advantage over an inexperienced seller because the buyer has access to a wealth of data with which to compare price and quality.

Arrow also expressed concern about the unpredictability of one's need for health care. But unpredictability, as an economic principle, is far less exotic today than it was in 1963. Advances in the pricing of options contracts have allowed individuals to assign prices to risk in almost every field of endeavor. The last half-century has witnessed a proliferation of insurance products, addressing all sorts of unpredictability, including traveler's insurance, extended warranties, overdraft protection, and malpractice insurance. All these products can be priced—and compared—online.

Trust is another Arrovian economic problem that technology has made great strides to resolve. Airbnb, the home-sharing website, encourages lessees and lessors to rate each other online. In this way, Airbnb reduces the risk of bad customers invading one's home, as well as the risk of unscrupulous landlords failing to live up to consumers' expectations. Uber also encourages drivers and passengers to rate each other, simultaneously improving customer service and driver safety.

The Internet's most profound impact on the non-health care economy involves reducing barriers to entry. Mom-and-pop craftsmen can start multinational businesses by selling their crafts worldwide on Etsy. More financial information is now available to nonprofessional investors. Authors can self-publish electronic books online.

The greatest discrepancy between health care and the rest of the economy centers on the way we pay for health care goods and services. In most other sectors, consumers pay directly for goods and services, giving businesses a strong incentive to deliver those goods and services at an attractive price. But this is not what happens in U.S. health care.

More than 90 percent of Americans have health insurance, under which the vast majority of health care expenditures are paid for by a third party. But the problem extends deeper: nearly 90 percent of the 90 percent with coverage did not choose that coverage on their own. Instead, a third party—an employer or the government—purchased third-party health insurance on their behalf. On this issue, Arrow was not sufficiently concerned. We now have "ninth-party" health care—third-party payment of third-party payment of health care services. Few policymakers have sought to reverse this trend.

In sum, technology can solve many of the health care problems that Arrow identified before the information economy arose; outside health care, technology has already largely solved them. If we wish to bring Internet-like innovation to health care, we must understand the key aspects of how America's digital economy differs from its health care system—and what government policy has done to exacerbate those differences.

III. Barriers to Entry

As Arrow observed, one of the biggest differences between the digital economy and U.S. health care involves barriers to entry. The tech world is full of stories of individuals who dropped out of college to design software and hardware that changed the world. But such innovation is far less common in health care—for reasons largely determined by public policy.

The U.S. Food and Drug Administration, for instance, makes it prohibitively difficult to develop new drugs and medical devices. According to the Tufts Center for the Study of Drug Development, it now costs an average of \$2.6 billion to bring one FDA-approved drug to market. Such astronomical costs not only make pharmaceutical innovation more difficult; they also reward large incumbents that have the capital to in-license drugs from innovative start-ups. Medicines that do not gain the backing of big pharma are rarely developed, especially for common diseases requiring large clinical trials.

Innovative medicines are awarded patents—an explicit barrier to entry—that establish monopolies and oligopolies in certain therapeutic areas. While these patents are an appropriate reward for medical innovation, combining them with our ninth-party system of health care payment gives many companies an incentive to charge prices that are far higher than the clinical or economic value that their medicines deliver.

State-based certificate-of-need (CON) laws, present in 36 states, require entrepreneurs to provide extensive justification before building a new hospital or nursing home, thereby shielding incumbents from innovative competitors. New York passed the first CON law in 1964. The federal Health Planning Resources Development Act of 1974, supported by the American Hospital Association, accelerated such anticompetitive practices by offering federal funds to states that implemented CON laws. While HPRDA was repealed in 1987, CON laws have largely remained on the books.

As Arrow noted, strict licensure requirements limit how many doctors and nurses can practice in the U.S., as well as how they can do so. Licensure requirements are appropriate up to a point; but in many states, they are drawn too broadly, in an effort to protect physicians from competition. For example, scope-of-practice laws often require doctors to perform tasks that other professionals, such as nurses and physician associates, are well trained to perform.

The cumulative weight of these laws and licensure requirements makes entrepreneurship in U.S. health care extremely costly. Given that it takes hundreds of millions of dollars in investment to build an innovative health care company—compared with hundreds of dollars for an innovative software company—it is not surprising that the latter vastly outnumber the former. Indeed, at present, hospital entrepreneurs emerge about as frequently as do new airlines and car companies, and for the same reason: scarcity of capital.

IV. Competition on Price and Quality

As noted, our ninth-party system for financing health care means that few suppliers of health care services and products have an incentive to compete on price and quality. At the same time, patients ultimately pay for every health care product or service that they consume, through taxes, health insurance premiums, out-of-pocket spending, and slower economic growth. David Goldhill, author of Catastrophic Care: Why Everything We Think We Know About Health Care Is Wrong, estimates that the average American will spend "roughly \$4 million in total" for his family's health care over the course of his life.4

The digital technology sector, by contrast, is largely driven by consumer decisions about how to spend money. Someone who buys a television on Amazon, rather than at a local store, typically does so because Amazon's price is better. Yet patients rarely take price into account when choosing a doctor or hospital because the vast majority of those costs are paid for by a third, or ninth, party in the form of health insurance.

Some observers insist that high health care prices are necessary to fund innovation. Yet this is not generally true. As Clayton Christensen famously noted,⁵ disruptive innovation is driven by consumers' desire to seek out goods and services of lower price and comparable or higher quality. Japanese automakers entered the U.S. market by

producing low-priced cars, such as the Honda Accord, that were more reliable than their American competitors. For decades, Japanese cars were derided by U.S. automakers as "cheap imports." Today, Toyota, Honda, and Nissan prosper in the low end as well as the luxury end of the market, while General Motors and Chrysler were bailed out of bankruptcy by the U.S. government.

Consider LASIK eye-correction surgery. LASIK is not covered by insurance because purchasing eyeglasses is much less expensive than LASIK. Because consumers must pay directly for LASIK services, the LASIK market has behaved just as the conventional technology sector has: over time, prices have gone down, and quality has gone up. No LASIK provider or supplier has complained that the decline in prices has led to less innovation.

Google and Facebook are two of the most innovative companies in the world. Their core products—search engines and social networks, respectively—are free to the consumer. Apple's products are often more expensive than their competitors'; but even iPhones of comparable quality decline in price over time—as they must, since newer models contain newer features and consumers have alternatives—thanks to price competition.

Apple launched the iPhone in 2007. At that time, an iPhone with 8 gigabytes of memory and a 320 x 480-pixel screen

cost \$599. In 2015, Apple launched the iPhone 6s Plus. A 128-gigabyte version of the phone, with a 1080 x 1920-pixel screen, cost \$499. Over eight years, the iPhone thus experienced a 27 percent decrease in inflation-adjusted price, while harboring 16 times more memory and a 14-fold increase in screen resolution. The capabilities of the iPhone's microprocessor and its software have increased substantially, too.

Now consider Biogen, a company best known for its treatments for multiple sclerosis, such as Avonex. Avonex was approved by the FDA in 1996, at which time Biogen priced the treatment at less than \$10,000 per patient per year. Today, the list price of Avonex exceeds \$60,000 per year, despite the fact that over the intervening two decades, new drugs—including some sold by Biogen—have emerged as significantly more effective than Avonex.⁶

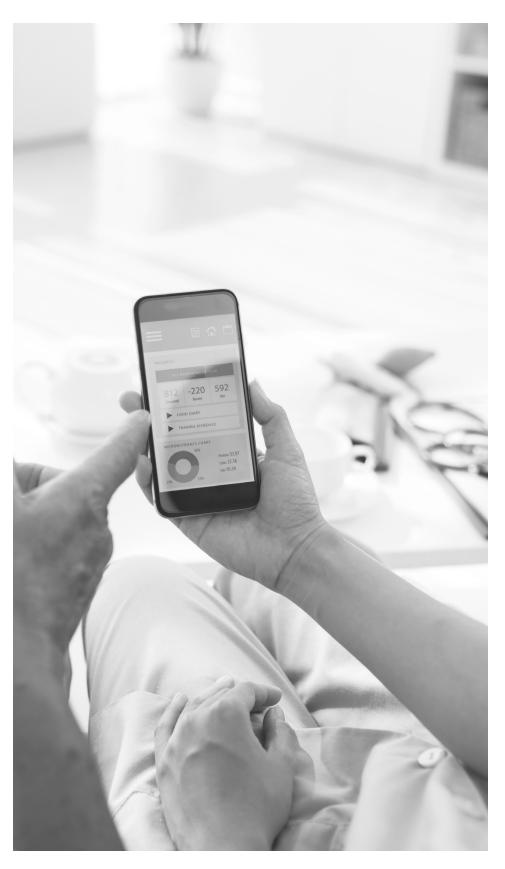
In a conventional sector of the economy, the pricing practices of the health care industry—almost completely divorced from the real costs and value for patients—would not be viable. Those practices work in health care because those who pay directly for medicines or hospital care (insurance companies and governments) are not the same as those who ultimately pay for medicines or hospital care (patients). As Milton Friedman observed, nobody spends someone else's money as wisely as he spends his own.

V. Symmetry and Mobility of Information

Innovation in software and data analytics is allowing entrepreneurs to develop methods of delivering highly customized goods and services to individual consumers. In theory, such methods are highly applicable to health care, where each patient has an individual profile that could benefit from customized treatment. However, a thicket of privacy laws, anti-kickback statutes, and other inefficiencies prevent patients from owning their health data, such as medical charts, to take advantage of new technologies.

IBM is developing software to combine patient interviews with a comprehensive review of the medical literature, in order to provide physicians with evidence-based suggestions regarding treatment algorithms. Such analyses ought to be available to patients, too—entrepreneurs could further analyze the cost-effectiveness of various treatments that a patient might consider. Yet such analyses are now difficult, if not impossible, to offer patients because patients do not own their own medical or claims data.

While some physicians may see third-party advice to patients as a threat to their authority, such software could likely do much to improve patient care by helping physicians and patients adhere to evidence-based guidelines, thereby reducing medical errors and improving clinical outcomes. One can envision a time when patients are more informed than their physicians about their own medical profiles: asymmetry of information, but in the patient's favor.



VI. Accessibility and Affordability

One key difference between consumer technology and health care is price. The vast majority of Americans can afford a television and a mobile phone. Few can afford a week in the typical American hospital—if they were paying directly for it.

Because consumer technology is frequently inexpensive, entrepreneurs have the ability to develop and test the appeal of their products with actual customers. In cases where new technologies are initially costly—such as with the earliest high-definition TVs—costs inevitably come down, as wider consumer acceptance and innovation drive manufacturing efficiencies.

But in health care, stakeholders must come together to agree to subsidize a product or service before it becomes widely used. As noted, a product or service can rarely be deployed until regulators approve it. Market forces will—and do—work best in the areas of America's health care system where insurers play less of a role, and consumers' willingness to pay is paramount.

Today, this is true with elective procedures such as LASIK surgery, as well as with over-the-counter drugs. Many medicines and other therapies are so safe that they do not require a doctor's prescription to use, such as aspirin or antihistamines. A broader cohort of prescription medicines could be converted into over-the-counter, consumer-driven use, including oral contraceptives and certain cholesterol-lowering drugs.

We could expand access to primary care by widening access to retainer-based physician practices, where a patient pays a small monthly fee to have longer, more convenient, doctor's appointments. Health care consumerism could become more widespread for a broad array of services as insurers' deductibles grow higher, giving patients more incentive to be sensitive to price and value.

VII. Conclusion

For decades, Americans have seen their individual sovereignty eroded by a health care system—and a patchwork of laws—that places the system's priorities over the patient's. Consumer-driven health care technology can put patients back in charge of events that, quite literally, can mean the difference between life and death. What stands in the way?

Each current barrier to a more innovative, competitive, affordable health care system was created for a reason. The FDA exists to protect patients from unsafe drugs and unscrupulous sponsors of new medicines. Privacy laws protect patients from having their sensitive medical records fall into the wrong hands. America's complex, inefficient method for subsidizing health coverage exists because Americans have understandably sought to protect the poor and vulnerable from unaffordable health care expenses.

But the cumulative weight of these policies has been to make U.S. health care less innovative, less patient-centered, and less affordable. Calibrated reforms, such as the ones contemplated in this Health Care 2.0 series, could do much to make health care better for everyone.

Endnotes

- ¹ See https://www.aeaweb.org/aer/top20/53.5.941-973.pdf.
- ² See http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf.
- 3 See http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx.
- ⁴ See http://www.theatlantic.com/magazine/archive/2009/09/how-american-health-care-killed-my-father/307617.
- ⁵ See http://www.amazon.com/The-Innovators-Dilemma-Revolutionary-Business/dp/0062060244.
- In the case of drug pricing, there are two mitigating factors. First, pharmacy-benefit managers make an effort to extract rebates from drugmakers, leading to lower net prices in competitive therapeutic areas. Second, because of generic medicines, prescription-drug markets for America's most common illnesses are, in fact, much more competitive than the markets for hospital care and other health care services.

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Abstract

The Manhattan Institute's Health Care 2.0 series delves into the details of how government policy stifles innovation in the delivery of health care. This paper, Part 1, surveys the key economic principles that drive innovative, dynamic sectors of the economy—and explains why American health care does not live up to those principles.

Key Findings

- 1. Health care—market distortions have considerably worsened since Kenneth Arrow famously described them in 1963; but in other industries less dominated by misguided government intervention, similar distortions have gradually eroded, thanks to technology, especially the rise of the Internet.
- 2. The tech world is full of stories of individuals who dropped out of college to design software and hardware that changed the world; but such innovation is far less common in health care—for reasons largely determined by public policy.
- 3. Each current barrier to a more innovative, competitive, affordable health care system was created for a reason; but the cumulative weight of these policies has been to make U.S. health care less innovative, less patient-centered, and less affordable.

