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## Medicine Meets Wall Street

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# MEDICINE MEETS WALL STREET

*Caroline Poplin\**

## I. BACKGROUND

American medicine is Western medicine—Americans publish in other OECD countries' journals; Europeans, Canadians, etc. publish in ours. American healthcare finance and delivery systems, however, are uniquely our own, and have been in crisis since 1980. There is a continuous angry dispute among politicians and the public about where we are and how to proceed.

### A. *Background: Medicine*

Although scientists started to develop the core of modern physiology and bacteriology in the late 18th century, modern medical practice really got underway in this country about 1875 with the development of anesthesia and sterile techniques for surgery. (Dr. Bliss, who attended President Garfield after he was shot in 1881, was probably the last prominent American surgeon who killed his patient by not using sterile instruments or washing his hands: the President died not of his wound, but of overwhelming infection introduced by his doctor.)<sup>1</sup> Medicine—that is, non-surgical treatment of illness—came along later, although information about human health and disease continued to expand briskly. By the 1920s, X-rays, as well as insulin and thyroid hormones from animals had been developed. The first real breakthrough drug, penicillin, was not commercialized until 1946.<sup>2</sup>

The most important medical developments until then were in public health: infectious diseases were significantly reduced by vaccination (smallpox in the

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<sup>1</sup> James H. Herndon, *Ignorance Is Bliss*, 15 HARV. ORTHOPAEDIC J. 74 (2013).

<sup>2</sup> *The Discovery and Development of Penicillin*, AM. CHEMICAL SOC'Y (Nov. 19, 1999), <https://www.acs.org/content/dam/acsorg/education/whatischemistry/landmarks/flemingpenicillin/the-discovery-and-development-of-penicillin-commemorative-booklet.pdf>.

1820s, cholera 1897, diphtheria and pertussis 1920s) and public sanitation systems, starting in the West in the mid-19th century.

Diagnosis and treatment improved steadily in the forty years or so after World War II, but in the 1980s, with the acceleration of computing power and a flood of money from the Federal government (Medicare, Medicaid, the VA, etc.), the expansion of medicine really took off, with effective new drugs annually, greatly enhanced diagnostic tools and surgical techniques. Maybe the best example is HIV/AIDS, which went from an imminent death sentence in the 1990s to a manageable chronic disease ten years later.

Public health also made an important contribution: as the result of a vigorous public campaign, including ads (and ad bans), education, and smoking bans in public places—and despite ongoing vigorous opposition from the tobacco industry—smokers in the U.S. have dropped from 42.4% of adults in 1965 to 16.8% in 2014.<sup>3</sup> The decline has undoubtedly led to a reduction in the incidence of cancer and cardiovascular disease.

However, the transformation of medicine has also created new problems. In the old days, one's family doctor could handle most medical problems, in or out of the hospital (except perhaps for surgery). Medical knowledge now expands so quickly and has become so extensive that no single physician can master it all: any serious medical problem requires input from various medical specialties, as well as other types of healthcare providers. Our traditional delivery system was not set up for this, and care has become fragmented, at worst with individual doctors working at cross-purposes.<sup>4</sup> Another problem: the cost of this sophisticated care has skyrocketed, nowhere more than America. In 2015, the U.S. spent \$3.2 trillion on healthcare (a 6% increase over 2014), or 18% of GDP, far more in percentage or per capita terms than any other OECD country.<sup>5</sup> This is an increasing problem for payers, both private and public, and also an irresistible target of for-profit enterprise. Finally, modern medicine has transformed most important diseases from acute to chronic, a problem for annual insurance based on acute events.

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<sup>3</sup> *Trends in Current Cigarette Smoking Among High School Students and Adults, United States, 1965–2014*, CENTERS FOR DISEASE CONTROL AND PREVENTION, [https://www.cdc.gov/tobacco/data\\_statistics/tables/trends/cig\\_smoking/](https://www.cdc.gov/tobacco/data_statistics/tables/trends/cig_smoking/) (last updated Mar. 30, 2016).

<sup>4</sup> Caroline Poplin, *Old and Sick in America: There's No One in Charge*, ALTARUM INST. (July 31, 2012), <http://altarum.org/health-policy-blog/old-and-sick-in-america-there%E2%80%99s-no-one-in-charge>.

<sup>5</sup> *Health Expenditure, Total (% of GDP)*, THE WORLD BANK, [http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS?end=2014&locations=US&start=1995&view=chart&year\\_high\\_desc=false](http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS?end=2014&locations=US&start=1995&view=chart&year_high_desc=false) (last visited Dec. 22, 2016).

We have also learned that the health of any population depends on the so-called “social determinants of health”, of which medical care is only one, and a small one at that; there are at least 11 others, including such things as income and social status, social support networks, education, environment, and so forth.<sup>6</sup>

One thing about medicine has not changed: there is still tremendous uncertainty about diagnosis and treatment. For any serious illness, today there are generally many more options to consider: different patients present differently, and respond to treatments differently. Clinical guidelines can only be that, not rules: there will always be false positives and false negatives, and patients who we say “did not read the textbook”—outliers. We cannot and should not standardize medicine the way we do manufacturing.

### *B. Background: Health Insurance*

It is with regard to insurance that the U.S. differs radically from other OECD countries. Everywhere else, adequate healthcare constitutes a right. Insurance benefits are standardized and comprehensive; insurance is financed primarily by taxes (except in Switzerland and the Netherlands).<sup>7</sup>

Indeed, then Labor Secretary Francis Perkins suggested just such a plan to President Franklin Roosevelt as part of the New Deal, alongside Social Security.<sup>8</sup> FDR thought it was a bridge too far, and so it remained with President Truman.<sup>9</sup> President Johnson passed Medicare in 1965, a good start, but by 1970, American policy makers had different ideas.<sup>10</sup>

American-style private health insurance began in 1929, when doctors set up the first Blue Cross plan, which guaranteed hospital fees (paid to the doctors) for teachers for a small monthly premium.<sup>11</sup> Blue Cross Blue Shield plans

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<sup>6</sup> Harry J. Heiman & Samantha Artiga, *Beyond Health Care: The Role of Social Determinants in Promoting Health and Health Equity*, KAISER FAM. FOUND. (Nov. 4, 2015), <http://kff.org/disparities-policy/issue-brief/beyond-health-care-the-role-of-social-determinants-in-promoting-health-and-health-equity/>.

<sup>7</sup> Adam Wagstaff, *Social Health Insurance v. Tax-Financed Health Systems-Evidence from the OECD* 5–6 (The World Bank, Working Paper No. 4821, 2009).

<sup>8</sup> See Tiffany Koebel, *Frances Perkins and the New Deal*, U.S. DEP'T LAB. BLOG (Sept. 5, 2013), <https://blog.dol.gov/2013/09/05/frances-perkins-and-the-new-deal/>.

<sup>9</sup> See *id.*

<sup>10</sup> *Medicare Is Signed into Law*, SOCIAL SECURITY ADMINISTRATION <https://www.ssa.gov/history/lbjism.html>.

<sup>11</sup> See *An Industry Pioneer*, BLUE CROSS BLUE SHIELD (2016), <https://www.bcbs.com/about-us/industry-pioneer>.

remained non-profit until 1994.<sup>12</sup> Today, many are for-profit (although analysts argue that the excessive surpluses built up by BCBS non-profits through rate hikes make them indistinguishable from their for-profit brethren).<sup>13</sup> The remaining large insurers are all for-profit, and are profitable indeed.

Today, most Americans receive their health insurance through their employers, and value it highly—indeed, proposed reduction in benefits, or higher cost sharing, are a major cause of labor unrest. However, the system works fairly well. Employers with a large workforce of mostly healthy people (someone is working, after all) have enough leverage to secure decent deals with even large insurers, who in turn get many thousand covered lives with just one negotiation, and maybe administrative assistance to boot. The employer has knowledgeable HR people who can bargain for a good package. The employer pays most of the premium, for which it gets a Federal tax deduction, the employees receive their benefits tax free.<sup>14</sup> (Very large employers sometimes self-insure, and pay insurers only for administration.)

The sweet spot for health insurers, especially the smaller ones, were the small group and individual markets. These customers had no leverage against insurers, who competed for the healthy and wealthy only. Insurance policies for those at higher risk, or worse, with chronic disease, were very expensive or unavailable at any price. Most policies were complex, with all sorts of exclusions and limits.

The Affordable Care Act (ACA) targeted precisely this market. Between exchange policies and Medicaid extension, the law reduced the rate of uninsured Americans from 15.7% before the law was signed, to 8.6% this year, 2016.<sup>15</sup> Sick Americans were overjoyed; many people got needed healthcare for the first time. But others who did not require care or did not qualify for large subsidies were angry at the expense—high premiums, high deductibles—and the coercion; important large insurers complained of losses despite the

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<sup>12</sup> Sarah Varney, *Did Blue Cross' Mission Stray When Plans Became For-Profit?*, NPR (Mar. 18, 2010), <http://www.npr.org/templates/story/story.php?storyId=124807720>.

<sup>13</sup> Wendell Potter, *Blue Cross, Blue Shield Getting Richer, Like Corporate Insurers*, CTR. FOR MEDIA AND DEMOCRACY'S PRWATCH (May 2, 2011, 12:19PM), <http://www.prwatch.org/news/2011/05/10696/blue-cross-blue-shield-getting-richer-corporate-insurers>.

<sup>14</sup> *How Does the Tax Exclusion for Employer-Sponsored Health Insurance Work?*, TAX POLICY CTR. URBAN INST. & BROOKINGS INST., <http://www.taxpolicycenter.org/briefing-book/how-does-tax-exclusion-employer-sponsored-health-insurance-work> (last updated 2016).

<sup>15</sup> *Obamacare: Uninsured Rates*, OBAMACARE FACTS, <http://obamacarefacts.com/uninsured-rates/> (last updated 2016).

high premiums. All Republicans, including Trump, campaigned relentlessly against the ACA, and they won. The Republican replacement is likely to resemble the status quo ante, which accords with their views on health insurance.

### *C. Background: Wall Street*

After World War II, corporate leadership in the U.S. believed their companies had duties to multiple stakeholders, including their communities, their workers, presumably their customers, and society at large.<sup>16</sup> However, in 1970, Nobel economist Milton Friedman instructed businessmen that their sole mission was to increase “shareholder value.”<sup>17</sup> The corporate sector responded with enthusiasm. Executives who believed in the old ways were quickly replaced by devotees of the new. Insurers, hospitals, and other players in healthcare were no exception.

Meanwhile, we now have the most business-friendly Supreme Court since the 1920s; under Trump, it will only become more so.

## II. WALL STREET MEETS MAIN STREET: A UNIQUELY AMERICAN THEORY OF HEALTHCARE

Republicans believe that health insurance is just like car insurance—consumers should buy what they want and can afford.<sup>18</sup> Republicans also believe that healthcare is just another commodity sold by just another business: the principles are the same.<sup>19</sup> Finally, Republicans believe government should have no role, except *perhaps* for helping some deserving poor, through Medicaid. In the eyes of Republicans, the government can do nothing right, corporations can do nothing wrong.

Except for a more nuanced view of medicine—Democrats believe all Americans should be able to access basic (not necessarily comprehensive)

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<sup>16</sup> Marina N. Whitman, *New World, New Rules the Changing Role of the American Corporation*, HARV. BUS. SCH. PRESS., 1999, at 4.

<sup>17</sup> Scott Tong, *How Shareholders Jumped to First in Line for Profits*, MARKETPLACE.ORG (June 14, 2016, 6:58PM), <http://www.marketplace.org/2016/06/08/world/profit-shareholder-value>.

<sup>18</sup> See Nicholas Bagley & Austin Frakt, *The Problem with One-Size-Fits-All Health Insurance*, N.Y. TIMES: THE NEW HEALTH CARE (Dec. 5, 2016), [http://www.nytimes.com/2016/12/05/upshot/the-problem-with-one-size-fits-all-health-insurance.html?emc=edit\\_tmt\\_20161205&nliid=56072898&tntemail0=y&\\_r=0](http://www.nytimes.com/2016/12/05/upshot/the-problem-with-one-size-fits-all-health-insurance.html?emc=edit_tmt_20161205&nliid=56072898&tntemail0=y&_r=0).

<sup>19</sup> Leemore Dafny, Harv. Bus. Sch. Class of 1960 Professor of Bus. Admin., NEJM Catalyst Event New Risk, New Business Models (Oct 6, 2016).

healthcare—and a more skeptical view of private industry, Democrats basically concur.

Almost all Republican and Democratic health policy experts (but not I) agree that the way to reduce cost and improve the quality of healthcare is competition in the “free market”. They expect insurers to compete for customers on the basis of price and quality, providers to compete on price and quality for contracts with insurers. Moreover, the policy elite believe medicine will be better and cheaper when provided by large vertically integrated corporations—so called “Accountable Care Organizations” (ACOs) accountable to payers, not patients—that manage doctors, hospitals and other providers according to the very latest MBA techniques, using Big Data collected by expensive electronic health records.<sup>20</sup> ACOs are to be paid by capitation (a fee per patient rather than per service) and to take financial risk—if they provide care for less than the total capitation payment, they make money.<sup>21</sup> If care costs more, they take a loss. Finally, these corporations insist that their mission is to “produce health,” particularly “population health,” rather than treat disease. Somewhat oddly, the Federal government is to produce quality benchmarks under the Medicare Access and CHIP Reauthorization Act (MACRA), passed in 2015 with a rare bipartisan majority.<sup>22</sup>

### III. ISSUES, LEGAL AND OTHERWISE, FOR THE NEXT ADMINISTRATION: CONGRESS AND THE COURTS

#### A. *Can Market Competition Reduce the Cost of Healthcare in the U.S.?*

Of course healthcare is not a single market but a complex series of interrelated markets: for health insurance, hospital care, ambulatory care, medical supplies, imaging equipment, laboratory tests, prescription and over-the-counter pharmaceuticals, durable medical equipment and so on. Often large intermediaries, like pharmacy benefit managers, or indeed insurers, are involved. But for all, the idea is that competition will hold down prices, ideally to cost, as with, say, groceries, or apparel.

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<sup>20</sup> See Jenny Gold, *Accountable Care Organizations, Explained*, KAISER HEALTH NEWS (Sept 14, 2015), <http://khn.org/news/aco-accountable-care-organization-faq/>.

<sup>21</sup> Richard Hodach, *How Physician Practices Must Change to Effectively Manage Patient Populations*, AM. MED. GROUP ASS'N, [https://www.amga.org/wcm/PI/Collabs/ACO/Articles/CaseStudy\\_final.pdf](https://www.amga.org/wcm/PI/Collabs/ACO/Articles/CaseStudy_final.pdf).

<sup>22</sup> Medicare Access and CHIP Reauthorization Act of 2015, Pub. L. No. 114-10, 129 Stat. 87 (2015).

By 1980, it was clear that the Medicare “usual customary and reasonable” standard for physician fees, and cost-plus financing for hospitals, were driving costs sky-high.<sup>23</sup> In response, the Federal government stepped in with straightforward systems for price control, called DRGs (diagnosis-related groups) for hospitals, and RBRVS (resource-based relative value system) for physician fees, both of which have worked relatively well, although physicians complain bitterly.<sup>24</sup>

This would never happen today. In fact, in the Medicare Modernization Act of 2003, which added a prescription drug benefit to Medicare, Congress explicitly prohibited Medicare from negotiating with drug manufacturers on price.<sup>25</sup> The legislators expected market competition to keep prices reasonable.

In general, market competition produces the “right” price (price equals marginal cost or average cost) only in a special type of market, a perfect or near-perfect market, where, *inter alia*, there are so many suppliers and consumers that no one can affect price; where there is perfect information about the products, which are standardized, and prices, so buyers can compare; where entrance to the market is easy, and so forth.<sup>26</sup>

Most healthcare markets are nothing like this.

In general, market players would rather not compete, they do better if they collude or consolidate. All markets are about power: monopolistic sellers can increase profits by driving prices up above cost (and quantity down), monopolistic buyers profit by driving prices down. (The perfect market is a special case where no participant has market power.)<sup>27</sup> When monopolies or oligopolies confront one another, prices can end up anywhere, and it is to each side’s advantage to keep them hidden from competitors. In the last twenty years or so, the U.S. health insurance industry has become increasingly consolidated: mergers are pending which would reduce the five largest insurers

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<sup>23</sup> RICK MAYES & ROBERT A. BERENSON, *MEDICARE PROSPECTIVE PAYMENT AND THE SHAPING OF U.S. HEALTH CARE* 81 (2008).

<sup>24</sup> *Id.* at 87, 89.

<sup>25</sup> Medicare Prescription Drug, Improvement, and Modernization Act 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

<sup>26</sup> See William Lazonick, *What’s “Perfect” About Perfect Competition? A Prosperous Economy Needs Innovators*, HUFFINGTON POST, [http://www.huffingtonpost.com/william-lazonick/whats-perfect-about-perfe\\_b\\_945519.html](http://www.huffingtonpost.com/william-lazonick/whats-perfect-about-perfe_b_945519.html) (last updated Nov. 1, 2011).

<sup>27</sup> *See id.*

to three.<sup>28</sup> Consolidation increases their leverage with hospitals and doctors and of course, with consumers, the one group with no leverage. Hospitals in turn are consolidating into chains and/or systems for more leverage against insurers, suppliers, and again, consumers.<sup>29</sup> Pharmaceutical manufacturers have consolidated from 60 to 10 since 1995.<sup>30</sup> Insurers and pharmacy benefit managers also serve as intermediaries, in a position to keep discounts for themselves, rather than passing them on to consumers. Much of this aggressive behavior is illegal under antitrust and other laws, but enforcement has been lax and late at best, and may disappear completely under Trump.

Moreover, competition in some medical markets yields paradoxical results. For example, there is vigorous competition between manufacturers of branded pharmaceuticals—but it is over quality, not price. Each new cancer drug that is rolled out is more expensive than the last (because it is “better”); then the prices of all the other drugs in the field move *up*.<sup>31</sup> An important driver of high prices is Wall Street—these days, executive compensation depends on ever higher stock prices. Ever higher stock prices depend on creation of “blockbuster” drugs—drugs that are marketed widely at high prices, even if the FDA indication is narrow.<sup>32</sup> This includes old, generic drugs for which competition has disappeared, such as daraprim and Epipens.

Competing hospitals wage so-called “arms wars”, touting the newest, most powerful equipment, whatever the expense, to lure customers. One of the most egregious recent examples is the proton beam accelerator, at \$200 million a copy.<sup>33</sup> Although there is good evidence for proton beam treatment for only a few rare cancers, there is already an accelerator in Baltimore, a second in Washington D.C., with third for D.C. on the way.<sup>34</sup> In the U.S., there are now

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<sup>28</sup> Charley Grant, *These Health Insurance Mergers Aren't Alike*, WALL ST. J. (Oct. 12, 2016, 11:05 AM), <http://www.wsj.com/articles/these-health-insurance-mergers-arent-alike-1476284710>.

<sup>29</sup> See Robert Berenson, *Acknowledging the Elephant: Moving Market Power and Prices to the Center of Health Policy*, HEALTH AFFAIRS BLOG (June 3, 2014), <http://healthaffairs.org/blog/2014/06/03/acknowledging-the-elephant-moving-market-power-and-prices-to-the-center-of-health-policy/>.

<sup>30</sup> Ravi Vij, *Pharma Industry Merger and Acquisition Analysis 1995 to 2015*, REVENUESANDPROFITS.COM (Feb. 17, 2016), <http://revenuesandprofits.com/pharma-industry-merger-and-acquisition-analysis-1995-2015/>.

<sup>31</sup> Caroline Poplin, *Big Pharma: Pushing the Edge of the Envelope*, MEDPAGE TODAY (May 23, 2016), <http://www.medpagetoday.com/publichealthpolicy/generalprofessionalissues/58088#>.

<sup>32</sup> *Id.*

<sup>33</sup> Denise Roland, *Proton-Beam Therapy for Cancer Gets Renewed Attention*, WALL ST. J. (May 16, 2016, 3:49 PM), <http://www.wsj.com/articles/proton-beam-therapy-for-cancer-gets-renewed-attention-1463428188>.

<sup>34</sup> *Proton Therapy Centers Location Map and Listings*, NAT'L ASS'N PROTON THERAPY, <http://www.proton-therapy.org/map.htm> (last updated 2016).

24, with 11 more under construction or in development.<sup>35</sup> We all pay for them in increased hospital fees.

So free market competition may not bend the healthcare cost curve.

*B. Does Commercial Health Insurance, with Many Policy “Choices,” Still Make Sense for the U.S.?*

Commercial health insurance traditionally worked by using actuaries to divide people into risk groups, then calculating premiums for each group sufficient to cover the risk and generate a profit. The lower the risk, the lower the cost of casualties, the greater the profit. Until the 1960s, that worked: most people (except the elderly, for whom insurance was expensive or unavailable) were at the same low risk for injury or illness—as we thought; medical treatment was not costly. The role of insurance was not to have the low risk people cover the high risk; it was to have the fortunate majority cover a few unfortunates.

Modern medicine now allows us to identify risk factors for expensive chronic illness at a much earlier stage. It also allows many people to live with illnesses that fifty years ago would have killed them quickly. Commercial insurers can only do so much to reduce the cost of care; the way to make money and survive is to avoid risk in the first place, or charge sicker customers appropriately.<sup>36</sup> Also, people who know they are low risk don’t want to pay premiums high enough to cover the chronically ill. By eliminating pre-existing condition restrictions, the ACA made separating customers into risk groups much more difficult.<sup>37</sup>

The way for insurers and healthy people to “fix” this problem is to offer a choice of insurance policies with different benefit designs: free gym memberships, an inexpensive come-on for young healthy people; limited access to specialists, high co-insurance for expensive medications (for cancer, HIV, autoimmune diseases) to discourage the costly sick. Different policies with different benefits and prices also adds complication, confusion, and therefore cost.

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<sup>35</sup> *Id.*

<sup>36</sup> See Rich Avilla et al., *Health Care Under Donald Trump*, N.Y. TIMES (Dec. 10, 2016), [http://www.nytimes.com/2016/12/10/opinion/sunday/health-care-under-donald-trump.html?ref=todayspaper&\\_r=1](http://www.nytimes.com/2016/12/10/opinion/sunday/health-care-under-donald-trump.html?ref=todayspaper&_r=1).

<sup>37</sup> Patient Protection and Affordable Care Act, Pub. L. 111-148, 124 Stat. 119 (Mar. 23, 2010).

The way to reduce cost and cover everyone is social insurance, public insurance, with a comprehensive benefit package, like Medicare. However, given Trump's preference for private enterprise, for at least the next four years we will likely be back to the status quo ante, with profits for insurers, low premiums for the healthy, high costs for the sick.

### *C. Does-for-Profit Versus Non-Profit Matter in Medicine?*

At different times, there have been arguments that there really is no important difference. But now, with continuing pressure to increase "shareholder value", it seems that there may be. For example, the focus of today's for-profit business is return on investment; the focus of a non-profit should be where the need is greatest, or how it can serve its community best. A for-profit business, these days at least, takes money out of a company, to distribute to executives and shareholders; a non-profit is expected to reinvest money to maintain or expand the mission. There may be some functions that do not work as well when they are for-profit as non-profit: consider for-profit universities, for example, and some medical services: a recent example is community ambulance service; also, there have been scandals about commercial nursing homes and nursing home chains since at least the 1970s which continue today, driven by Wall Street's relentless drive for ever-increasing profits.<sup>38</sup> The needs of sick and vulnerable people are seen as an opportunity to exploit, rather than a gap to fill. Under the coming Trump administration, the role of continued conversion of entities from non-profit to for-profit bears watching.

### CONCLUSION: STILL MORE ISSUES

The U.S. has come up with a unique market-based, corporate model in its effort to reduce its uniquely high healthcare costs and improve its middle-range health outcomes. There are still more questions. For example, medicine in human civilization stretches back millennia: it has always meant care of the sick. As some doctor once said, "to heal sometimes, to relieve often, to comfort always." Medical schools still concentrate on the pathology, diagnosis and treatment of disease, a field that has expanded exponentially in the last 25 years. Recently, however, many have urged Americans to replace its "sickness

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<sup>38</sup> *Nation's Largest Nursing Home Therapy Provider, Kindred/Rehabcare, to Pay \$125 Million to Resolve False Claims Act Allegations*, U.S. DEP'T JUST. (Jan. 12, 2016), <https://www.justice.gov/opa/pr/nation-s-largest-nursing-home-therapy-provider-kindredrehabcare-pay-125-million-resolve-false>.

system” with a “health system”. The health policy community wants ACOs to take financial risk for costs and outcomes.<sup>39</sup> The consumers (patients) with the lowest costs and the best outcomes will almost always be those who are healthy to start with. Will this lead to rationing of care for the very ill, for example, those who might be within the last six months of life, where expensive care is allegedly wasted?<sup>40</sup>

Will the ACOs reduce fragmentation by reducing or eliminating patient choice of providers? Will they move money from the bedside, where it’s needed, to the boardroom?

Should support for diet and exercise, the prevention of obesity and substance abuse, and indeed improvement of the social determinants of healthcare, be primarily the function of the medical system, or matters for public health and the responsibility of the community at large?<sup>41</sup>

Then there is the reduced role of the Federal government: in December 2016, Congress passed and President Obama signed the “21st Century Cures Act” which offers new, easier pathways for drug and device manufacturers to obtain speedy approval from the FDA (using, for example, “real world evidence” instead of requiring more controlled clinical trials) and apparently reduces current FDA constraints on off-label marketing (authorized by the Kefauver Harris Amendments in 1962), already weakened by several pro-business Federal courts.<sup>42</sup>

In the meantime, OECD countries cover all their residents with standardized, comprehensive health insurance for much less than we spend.<sup>43</sup> Their systems are decentralized, as ours used to be, prices are regulated or negotiated, their people have robust public social supports, and their health outcomes are significantly better. However, our leaders believe in American Exceptionalism and free markets. Will this reduce costs and improve U.S.

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<sup>39</sup> See Rob Houston & Tricia McGinnis, *Accountable Care Organizations: Looking Back and Moving Forward*, CTR. HEALTH CARE STRATEGIES 1, 6, 8, 12–13 (Jan. 2016), <http://www.chcs.org/media/ACOs-Looking-Back-and-Moving-Forward.pdf>.

<sup>40</sup> *Costly End-of-Life Care Can Prolong Rather Than Prevent Suffering*, BLUECROSS BLUESHIELD NORTH CAROLINA, <https://www.letstalkcost.com/problems/end-of-life-care/> (last updated 2016).

<sup>41</sup> Caroline Poplin, *Obesity in America: There’s no Free Lunch: Caroline Poplin*, PLAIN DEALER (June 3, 2012), [http://www.cleveland.com/opinion/index.ssf/2012/06/obesity\\_in\\_america\\_theres\\_no\\_f.html](http://www.cleveland.com/opinion/index.ssf/2012/06/obesity_in_america_theres_no_f.html).

<sup>42</sup> 21st Century Cures Act, Pub. L. 114-225, (2015) (awaiting approval by the Senate and presentation to the president).

<sup>43</sup> *Health Expenditure and Financing*, OECD.STAT, <http://stats.oecd.org/Index.aspx?DataSetCode=SHA> (last updated 2015).

healthcare? The evidence is certainly not in. All we know for sure is that some businessmen will become very rich.