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ADVANCED MEDICAL
TECHNOLOGY AND ITS COST

A PROGRESS REPORT AND
FORECAST ON U.S. HEALTHCARE

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INTRODUCTION

Advanced medical technology promises a brighter, healthier future, with longer and fitter lives. Unfortunately, much of this new medicine comes at a high cost and threatens to widen the gap between the "haves," the "have-nots." As Martin Luther King noted over a half century ago, "[o]f all forms of inequality, injustice in health care is the most shocking and inhumane."¹ Yet, historically, with limited exceptions,² the United States treated health care as a privilege, available only to those who could afford it. Until this year, the United States was the only industrialized nation that did not have some form of health care guaranteed to all of its citizens. While universal health coverage still does not exist in the United States, greater breadth of coverage for more Americans is now in sight thanks to the U.S. Patient Protection and Affordable Care Act ("ACA," also sometimes informally referred to as "Obamacare" or the "Affordable Care Act").^{12]} In a landmark decision, the United States Supreme Court upheld most of the provisions of the Affordable Care Act, including a requirement for most Americans to have health insurance by March 31, 2014,³ the close of the initial open-enrollment period.⁴

Politics aside, the long term success of the ACA will likely be judged by its effect on the number of uninsured Americans, the adequacy of the coverage, and its affordability.⁵ It is too soon to tell how the Affordable Care Act will change the course of American health care in the long run, but there have already been significant changes.

This paper provides both a progress report as well as a forecast on how some of the pitfalls and promises of developing American health law and innovation may affect the health care gap.

CURRENT ACCESS TO U.S. HEALTHCARE

Before the Affordable Care Act came into effect, over 48 million Americans⁶ were without health insurance, requiring health care costs to sometimes compete with other necessities of life, including food and housing. The ACA seeks to increase coverage through various means.

The Affordable Care Act includes both proverbial "carrots," or positive incentives, to expand coverage as well as "sticks" or penalties for non-compliance. Some of the incentive "carrots" seem to be faring better than the putative "sticks" which are not faring as well. The question will be whether Obamacare can survive in the long term if the putative measures fail to survive?

¹ Martin Luther King, Jr., at the Second Nat'l Convention of the Med. Comm. for Human Rights (Chicago, Mar. 25, 1966).

² Before Obamacare, the only government paid health care coverage was for the military, disabled, elderly and only some of the poor.

³ *Nat'l Fed. of Indep. Bus. v. Sebelius*, 567 U.S. ___, 11-393 (2012).

⁴ The next open-enrollment period launches in November, 2015, through February, 2016, with annual enrollment periods thereafter. Individuals will only be able to enroll outside of the enrollment periods if they lose insurance because of job changes, marriage, aging out of parents' plans, etc. **It is estimated that 4 million people may gain health insurance this way during the open enrollment periods.** David Blumenthal & Sarah R. Collins, *Health Care Coverage Under the Affordable Care Act—A Progress Report*, 371:3 NEW ENG. J. MED., 275-83 (2014).

⁵ Blumenthal & Collins, *supra* note 4, at 276;

⁶ Carmen DeNavas-Walt, et al., *Income, Poverty, and Health Insurance Coverage in the United States: 2012*, UNITED STATES CENSUS BUREAU (Aug. 29, 2014), <http://www.census.gov/prod/2013pubs/p60-245.pdf>.

Some of the positive measures which are faring well include the fact that insurance companies are now required to cover dependents of insured parents through the age of 26; insurance plans are now prohibited from excluding preexisting conditions; marketplaces for small business owners (the Small Business Health Options Program or "SHOP") were created; and both state and federal insurance exchanges were developed to sell subsidized insurance for citizens whose income falls below a designated level.⁷ These newly minted marketplaces and exchanges seek to obtain affordable health coverage by pooling the number of enrollees and decreasing the individual cost of health insurance. These marketplaces augment the traditional American private insurance markets.

The Affordable Care Act also originally *mandated* expanded coverage through the government's Medicaid program, which provides health care for citizens with limited financial resources.⁸ The landmark United States Supreme Court decision in *National Federation of Independent Business v. Sebelius*, 567 U.S. ___, 11-393 (2012) made state participation in this expanded program optional.⁹ To date, 28 states and the District of Columbia have moved forward on the optional expansion. States that have chosen not to expand Medicaid will receive far less benefit from the ACA and since many of these states also have high insurance rates, the Affordable Care Act may "have the paradoxical effect of increasing disparities across regions even as it reduces disparities between previously insured and uninsured Americans as a whole."¹⁰

Among the more punitive measures created under the Affordable Care Act include financial penalties for Americans who do not have qualified health insurance as of the close of the March 31, 2014 enrollment period. These penalties accrue when the uninsured file their tax returns in 2015.¹¹ Penalties will increase each year the uninsured fail to enroll in some qualified plan.¹² This penalty is one of the more controversial measures designed to encourage previously uninsured Americans to obtain coverage.

Another putative plan to increase health care coverage would have required large employers to provide coverage or pay a stiff penalty.¹³ This was originally viewed as a key pillar of the Affordable Care Act. Four years later, after repeated delays, this has become somewhat of an orphan because it is

⁷ To date, fourteen states have chosen to run these exchanges themselves with the remainder of the states relying on a federal exchange.

⁸ The expanded eligibility of Medicaid to people with incomes up to 138% of the poverty level. This is the largest expansion of the program since it began in 1965. The federal government covers all of the costs through 2016 and then gradually reduces its contribution to 90% by 2020. Cite needed here.

⁹ Under the initial intent of the ACA — before the Supreme Court made Medicaid expansion voluntary — states were offered generous financial incentives to expand the public program. However, the original penalty for states' failure to expand the programs was draconian: if states didn't expand Medicaid, funding was taken away for the entire program.

¹⁰ David C. Radley, et al., *Results from a Scorecard on State Health System Performance*, 2014, THE COMMONWEALTH FUND (May 2014), www.commonwealthfund.org/~media/files/publications/fund-report/2014/opr/1743_radley_aiming_higher_2014_state_scorecard_corrected_62314.pdf.

¹¹ There is an exemption to the tax penalty for low-income individuals that would pay more than 8% of their projected annual income for health insurance.

¹² The initial penalty for lack of insurance is a minimum of U.S. \$95 or \$95 U.S. dollars (you can write it either way; it's a style choice) or 1% of income over the tax-filing limit (whichever is greater).

¹³ Paul Sisson, *Business Weigh Fines Over Paying Insurance*, UT SAN DIEGO, Feb. 5, 2013, www.utsandiego.com/news/2013/feb/05/insurance_fines/.

a touchstone for the opposition who bitterly oppose this requirement and because the "carrots" or other incentives for joining an exchange have worked so well to date.¹⁴ The fate of this requirement is in limbo.

How successful have these various attempts been at reducing the number of Americans without health insurance? When all of the various Affordable Care Act coverage expansion programs are cobbled together, it is estimated that over 20 million Americans have already gained coverage under the ACA. While some of these new enrollees may have had different health coverage before, reliable polling data from Gallup, Rand, and the Urban Institute conservatively conclude that at least 5 to 9 million uninsured Americans are now insured, and the proportion of U.S. adults lacking insurance has fallen to 13.4% as of May, 2014.¹⁵ The U.S. Congressional Budget Office projects that 25 million more Americans will have health insurance by 2017.¹⁶ Assuming these projections are accurate, and the political landscape does not change, the Affordable Care Act will have been successful in drastically reducing the number of Americans without access to health care insurance.

While the Republican-controlled U.S. Congress has attempted to repeal the Affordable Care Act on 54 different occasions since it was enacted, it will become increasingly more difficult to repeal the law as the number of citizens benefiting from it continues to grow.

It is still by no means a foregone conclusion that Obamacare is here to stay. Litigation is pending which could torpedo the financial foundation of the Affordable Care Act. Over 85% of the people who purchased health insurance during the first year's open enrollment period qualified for premium subsidies to be distributed by the U.S. Internal Revenue Service ("IRS") in the form of tax credits.¹⁷ These tax credits are incentives for individuals enrolling in "one or more qualified health plans through an Exchange."¹⁸ Although this regulation uses the general phrase "through an Exchange," there are various states exchanges as well as a federal exchange. While 16 states have their own exchanges, 34 states refuse to create such an exchange, and citizens of these 34 states are eligible for insurance through a federal exchange.¹⁹

At issue in pending litigation is whether both federal and state created exchanges qualify for the tax credit/premium subsidy. The Affordable Care Act allows for federal and state exchanges, but only *expressly* allows people insured through state exchanges to be subsidized. The Obama administration claims this was a mere drafting error and that the clear intent of the ACA is to ensure all Americans through subsidies which must be provided to all citizens who qualify, regardless of whether their state has established a state exchange.

In May 2012, the IRS issued a regulatory ruling that declared it had the power to provide subsidies to individuals who purchased insurance through the federal exchange as well as through state exchanges. In response, two key lawsuits were filed challenging the power of the federal government

¹⁴ NN Levry, *Key Part of Obamacare is Orphaned*, LOS ANGELES TIMES, July 29, 2014, at B1, B5.

¹⁵

¹⁶ *Updated Estimates of the Effects of the Insurance Coverage Provisions of the Affordable Care Act*, CONGRESSIONAL BUDGET OFFICE (Apr. 2014), <http://www.cbo.gov/publication/45231>.

¹⁷ The subsidies are given to individuals who buy a plan from an exchange and have a household income between 133% and 400% of the poverty line. Section 1401(36B) of ACA provides that each subsidy will be provided as an advance able, refundable tax credit.

¹⁸ 26 C.F.R. § 1.36B-2(a)(1) (2012).

to spend money on subsidies for policies purchased at the federal exchange.

The plaintiffs in *King v. Halbig*²⁰ lived in Virginia, a state that does not have a state exchange. Because of their modest income level, without tax credits, these plaintiffs would be exempt from purchasing mandatory health insurance and not subject to a penalty for choosing to be uninsured. However, because of the reduced costs provided by the tax credit, they were mandated to purchase minimum essential health coverage or face a penalty. The lawsuit challenged the IRS ruling and claimed the premium credit is only applicable to insurance purchased on a state exchange. Because the federal government is not a state, the lawsuit claimed that insurance purchased through a federal exchange is not eligible for a tax credit, and the plaintiffs therefore should not be penalized for failing to purchase insurance.

The U.S. Court of Appeals for the Fourth Circuit affirmed the district court decision in *Halbig*, upholding the IRS rule authorizing tax credits to individuals who purchase health insurance “regardless of whether the exchange is state-run or federally-facilitated.” The court concluded the IRS regulation advances one of the primary purposes of the ACA in providing more affordable healthcare to Americans.

On the very same day that the *King v. Halbig* decision was announced, the exact opposite result was reached in a 2-1 decision by the D.C. Circuit Court of Appeals in *Halbig v. Burwell*.^{21,22} This court held that the Affordable Care Act does *not* permit the IRS to distribute premium subsidies to people enrolled in the federal exchange, and acknowledged that those individuals must bear the full cost of their insurance because they live in states that chose not to participate in a state exchange. The majority opinion in *Halbig* found that 1) Section 36B of the Act restricts subsidy to insurance purchased on the Exchange “established by the State”; and 2) because there is no explicit provision in the Affordable Care Act allowing enrollees on the federal exchanges to receive premium tax credits, the court refused to expand coverage to members of such federal exchanges through the IRS ruling.²³ In a dissenting opinion, the Senior Circuit Judge Harry T. Edwards noted that “[t]his case is about Appellants’ not-so-veiled attempt to gut the [ACA]. At the time of the ACA’s enactment, it was well understood that without the subsidies, the individual mandate was not viable as a mechanism for creating a stable insurance market.”

Predictably, neither of these decisions are the final word on this important issue. A petition for

²⁰ No. 14-1158, 2014 U.S. App. LEXIS 13902, at *1 (4th Cir. July 22, 2014).

²¹ No. 14-5018, 2014 U.S. App. LEXIS 13880, at *1 (D.C. Cir. July 22, 2014).

²² Many of the ACA cases have *Burwell* in the case name because Sylvia Burwell is the U.S. Secretary of Health and Human Services, the entity charged with enforcing and defending the Affordable Care Act.

²³ Of interest to some legal scholars is *how* these courts reached opposite conclusions. **The *King* court** supported its decision upholding tax credits for federal exchanges by looking at the intent behind the law which is to broaden coverage to more people by making insurance more affordable. Upholding the IRS regulation allowing a tax credit for insurance purchased through the exchange is consistent with the policy of the legislation. In reaching this result, the court applied the two-step analytical framework established by *Chevron U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 843 (1984), which allows the court to defer to an agency such as the IRS’s interpretation of the law if the statute is subject to multiple interpretations and the agency’s interpretation is based on a permissible construction of the statute. **On the other hand, the *Halbig* court used a strict constructionist view of the ACA and because the statute does not expressly provide for tax credits to people purchasing insurance through a federal exchange, the court refused to expand the tax credits beyond the four corners of the statute to allow it.**

certiorari with the U.S. Supreme Court was filed by the plaintiffs in the *King* case, and an *en banc* hearing was requested in the *Halbig v. Burwell* case.

The stakes are high and the outcome of this battle will have huge repercussions for Obamacare.²⁴ Experts estimate that the ruling against the federal subsidies, if upheld, will block approximately \$36 billion in premium rebates to roughly 5 million people enrolled through a federal exchange.

Limits on What is Covered Under the ACA

Under the Affordable Care Act, insurance plans are required to offer at least a basic set of benefits, including coverage for some areas that had been severely limited in the past, such as: preventive care and wellness services (including chronic disease management); mental health (including substance abuse disorder and behavioral health treatment); and a "contraception mandate," which includes contraceptives, voluntary sterilization, and abortions.

This controversial contraception mandate is based on the recommendation of the Institute of Medicine which concluded that access to contraception is medically necessary "to ensure women's health and well-being."²⁵

Before the ink was dry on the contraception mandate, lawsuits were filed by conservative employers seeking to overturn it and to exclude a contraception mandate from its employee sponsored insurance plans. Such an attack had the potential to be far reaching because both before and after the institution of Obamacare, most Americans who have health insurance have it provided through their employment.^{26,27} Exempt from Obamacare's contraception mandate are religious employers (churches and their integrated auxiliaries, associations of churches, and any religious order), non-profit organizations that object to any required contraception,^[9] and employers with fewer than 50 employees.

All other insurance plans, including large employer sponsored insurance plans, were to provide full coverage under the contraception mandate. Companies that refuse are fined \$100 per individual per day, ^[11] or they can replace their health coverage with *higher wages and a calibrated tax*.

For-profit corporations owned by religious conservatives sued, arguing that a contraception

²⁴ *Second Circuit Disagrees, Upholds Subsidies*, THE HILL (Aug. 30, 2014), <http://thehill.com/policy/healthcare/212971-second-court-disagrees-uphold-subsidies>.

²⁵ *Recommendations for Preventive Services for Women that Should be Considered by HHS*, INSTITUTE OF MEDICINE (July 19, 2011), <http://www.iom.edu/Reports/2011/Clinical-Preventative-Services-for-Women-Closing-the-Gaps/Recommendations.aspx>

²⁶ Before the ACA, 55.9 % of adult Americans under 64 receive employer-provided health insurance. [*Insert Title of Poll in Italics*], Gallup (July 2012), <http://www.gallup.com/home.aspx>.

²⁷ Obamacare exchanges and marketplaces seek to cover those whose employers don't provide coverage, as well as the unemployed, students, etc. and businesses with less than 50 employees for whom coverage may be unaffordable.

mandate forces them to violate their personal religious beliefs. In a landmark decision, *Burwell v. Hobby Lobby*,²⁸ 573 U.S. ___, (2014), the United States Supreme Court's conservative majority directly struck down Obamacare's contraception mandate.²⁹ By a 5-4 vote, the majority opinion in *Hobby Lobby* held that closely held for-profit corporations are exempt from laws its owners religiously object to if there is a "less restrictive means" of furthering the law's interest.³⁰

The *Hobby Lobby* Court found that the mandate was not the least restrictive way to ensure access to contraceptive care, noting that a less restrictive alternative was being provided for other religious non-profits whereby they filled out certain forms for their insurers signaling that they objected to the contraception mandate, triggering the insurers to notify the government and the government to pick up the tab and pay for contraception coverage for employees of such companies.

On July 3, 2014, just three days after the *Hobby Lobby* decision was announced, in *Wheaton College v. Burwell*, 573 U. S. ___, (2014), the U.S. Supreme Court effectively ended this "least restrictive alternative," *leaving no alternative for any female employees of closely held corporations who do not wish to provide birth control.*¹⁵¹

Wheaton College is a case involving a Christian College, for which the Supreme Court granted a temporary exemption to the college so that it does not have to file forms with the insurer based on its religious objections to contraception. This system of forms was the very approach the Court had suggested as a less restrictive alternative in *Hobby Lobby*! The Supreme Court ruled that the Christian college in Illinois could temporarily abstain from following the Affordable Care Act's contraception mandate.

The *Wheaton College* decision drew a scathing dissent from the court's three female justices. "Those who are bound by our decisions usually believe they can take us at our word," Justice Sonia Sotomayor wrote in the dissent, joined by Justices Elena Kagan and Ruth Bader Ginsburg. "Not so today." In the dissent, Justice Sotomayor argued that the *Wheaton College* decision went beyond the *Hobby Lobby* ruling, suggesting the majority had gone far beyond its original decision.

Following the double blow of the *Hobby Lobby* and *Wheaton College* decisions, the Obama administration is attempting to craft further compromises, as a new way for religious employers, including some closely held for-profit companies, to opt out of the contraception mandate.

²⁸ Hobby Lobby is an arts and crafts company founded by self-made billionaire David Green and owned by the Evangelical Christian Green family. With about 21,000 employees, it provided contraceptives to its employees until it dropped its coverage in 2012, the same year it filed its lawsuit. It is the largest funder of the National Christian Charitable Foundation that uses its billion-dollar endowment to fund a network of conservative right-wing political groups .

²⁹ The decision is an interpretation of the Religious Freedom Restoration Act, ("RFRA"), and does not address whether such corporations are protected by the free-exercise of religion clause of the First Amendment of the U.S. Constitution.

³⁰ The *Hobby Lobby* case is the first time that the Supreme Court recognized a for-profit corporation's claim of religious belief, but on its face it is limited to closely held corporations. Apart from its effect on the ACA, the ruling could have widespread impact, allowing corporations to claim religious exemptions from other federal laws

The proposed regulations, if solidified, would have the faith-affiliated charities, colleges, hospitals and closely held corporations notify the government, *rather than their insurers*, that they object to contraception on religious grounds. Then the government would instruct a nonprofit's insurer or third-party administrators to take on the responsibility of paying for the birth control, at no cost to the employer.

These potential new regulations would offer wider accommodations than what were previously being offered, but they have not yet been finalized as of the time of this publication. However, it is likely some very socially conservative closely-held companies and religious entities will still object to *any regulations* that would link them, however loosely, with any coverage provisions for contraception. The long term fate of the contraception mandate is unknown.

Does Obamacare Improve Americans' Health?

A recent study published in June, 2014, evidences that despite the fact that the United States has the world's costliest healthcare; it ranks *last* among industrialized countries on healthcare quality and access.³¹ The study was conducted by the independent think tank, the Commonwealth Fund. The lead author of the study, Karen Davis, noted that this survey relies on data collected before the Affordable Care Act was in place. "With enactment of the Affordable Care Act, however, we have entered a new era of American healthcare."³²

Throughout the continuing debate over the Affordable Care Act, critics question whether expanding coverage will result in better health. It will take several years before data is available to show the long term effects of Obamacare.³³ However, some projections can be made based on a study from Massachusetts, a state whose health care reforms went into effect in 2006 and which served as the model for the ACA.

The death rate significantly dropped in Massachusetts³⁴ compared to regions across America with similar demographics, after this state began guaranteeing its residents health coverage 8 years ago, according to a comprehensive study conducted by researchers at the Harvard School of Public Health, Brigham and Women's Hospital and the Urban Institute.³⁵ Reform in Massachusetts was associated

³¹ In 2011, the U.S. spent \$8,508 per capita on health care, compared to \$3,406 in the United Kingdom which ranks first in health care. *Mirror, Mirror on the Wall, 2014 Update: How the U.S. Health Care System Compares Internationally*, THE COMMONWEALTH FUND (Aug. 29, 2014), <http://www.commonwealthfund.org/publications/fund-reports/2014/jun/mirror-mirror>.

³² Chad Terhune, *U.S. Healthcare Ranks Last in Study*, Terune C, L.A. TIMES, June 17, 2014 at B2.

³³ Sophisticated evidence based medical data will become available through the U.S. Health Information Technology for Economic and Clinical Health Act ("HITECH Act") which the U.S. enacted in 2009. Pursuant to HITECH, the U.S. government is spending tens of billions of dollars to promote and to expand health information technology. The Act has three stages which require medical data to be captured, shared and processed with the goal of having analytic techniques assess patient outcomes and preventable harm between 2012-2016. *On the Use of Electronic Health Records to Assess Patient Outcomes and Preventable Harm*, FOR THE DEFENSE (August 2014), www.forthedefense.org/ftd/2014-08F.pdf.

³⁵ B.D. Sommer, et al., *Changes in Mortality After Massachusetts Health Care Reform: A Quasi-experimental*

with a solid decrease of 8.2 deaths per 100,000 adults. Changes were larger in counties with lower household incomes and higher pre-reform uninsured rates. The number needed to treat was approximately 830 adults gaining health insurance to prevent 1 death per year. While no single study is definitive, this Massachusetts study suggests that reforms are responsible for improving health and that such wide insurance coverage saves lives.

According to recent data released by the World Health Organization ("WHO"), the United States currently ranks 37th overall in life expectancy and last in infant mortality of all industrialized countries.³⁶ If health insurance coverage for more Americans saves lives, one will expect both life expectancy and infant mortality in the United States to improve in the years to come.

Attempts to Reign in the Cost of Healthcare

The cost of private insurance in the U.S. increased an average of 50% between 2003 and 2010.³⁷ It is unknown what effect Obamacare will have on the cost of health care in years to come, in part because of the unknown fate of the substantial insurance premium subsidies which are currently heavily subsidized by the U.S. government. Additionally, the expanded Medicaid programs will also see the U.S. federal government footing the bill through 2016 and 90% of the bill for this expansion through 2020.

The Affordable Care Act does attempt to curb some costs by legislation. For example, the ACA dictates that private insurers are no longer able to set insurance premium prices on the basis of an individual's health and they are limited in what can be charged an individual based on their age. There is also widespread use of restricted or "narrow" provider networks which require enrollees in certain plans to use lower-price health care providers and charge patients more when they choose a more costly provider who is "out of network." It remains to be seen if the quality or perceived value of the care is compromised under this narrow network model.

The cost of health care varies widely from region to region in the U.S., making it difficult to gauge the effect Obamacare is having on national health rates in its first year. However, some early signs are encouraging. For example, defying an industry trend of double-digit rate hikes, California insurers are expecting only a modest 4.2% increase in coverage for 2015-2016.³⁸

It is sheer speculation at this juncture to know whether the high cost of U.S. healthcare per capita can be permanently reversed. Health insurance is still Big Business in the United States and there is no single payer system which would likely gut some of the profit that inflates current U.S. health care costs. Additionally, the ability to control the overall American health care costs is dependent on innovative approaches to health care that allow greater quality at lower cost.

Consolidation and Creation of Integrated Health Care Systems

Study, 160(9) ANN. INTERN. MED., 585-93 (2014).

³⁶ World Health Organization, World Health Statistics (2014), www.who.int/gho/publications/world_health_statistics/en/

³⁷ Cathy Schoen et al., *State Trends in Premiums and Deductibles, 2003–2010: The Need for Action to Address Rising Costs*, COMMONWEALTH FUND (November 2011).

³⁸ *California Exchange's Health Insurance Rates to Increase Modestly in 2015*, L.A. TIMES, July 31, 2014.

One apparent change in the delivery of health care services in the U.S. since Obamacare was introduced is consolidation in the industry, with the elimination of many individual and small medical groups and hospitals. This newly integrated health care system model is adopting many of the characteristics of Kaiser Permanente, the largest managed care organization in the United States.

Founded in 1945, Kaiser is a giant, integrated health care system that combines both for-profit and non-profit entities including an insurance company, hospitals, clinics, pharmacies and for-profit physician groups. Each Kaiser entity has its own management and governance structure, although all of the structures are interdependent. Kaiser Permanente employs 200,000 people, including approximately 19,000 physicians and services over 9 million patients in nine states and the District of Columbia.³⁹

While some argue that such integrated models may create local monopolies that may charge higher prices, others believe this consolidation will make health care more affordable because it is creating more fully integrated delivery systems, which may be more efficient, as well as creating a team-based approach to health care.

Unlike traditional American medicine, Kaiser places a strong emphasis on preventive care, reducing costs later on. Because its doctors are not paid per service (the traditional American model of physician compensation), Kaiser removes an incentive for doctors to perform unnecessary procedures. Kaiser attempts to minimize the time patients spend in high-cost hospitals by shifting much care to outpatient clinics. In order to contain costs, Kaiser requires advance agreement by its patients to submit patient malpractice claims to arbitration rather than court litigation.

Kaiser is not without its critics.⁴⁰ Kaiser has been accused of patient dumping—the delivery of homeless hospitalized patients to other organizations in order to avoid expensive medical care.⁴¹ While doctors are partners within the for-profit physician groups, many employees are members of various unions, depending on their role and service area. Kaiser's California operations were the target of four labor strikes in 2011 and 2012, two of which involved more than 20,000 nurses, mental health providers, and other professionals.⁴² The National Union of Healthcare Workers (NUHW) accused Kaiser of deliberately stalling negotiations while profiting \$2.1 billion in 2011 and paying its CEO \$9 million annually. The workers complained of poor staffing, delayed care, loss of pensions and other benefits.⁴³

A Developing Two-Tier U.S. Medical System: Concierge Medicine

While the Kaiser model may create greater availability of health care for the masses, the

³⁹ G. Colvin, *A Health Care Model That's Working*, FORTUNE MAGAZINE, August 11, 2014, at p 24.

⁴⁰ Chris Rauber, *More Details on Kaiser Permanente Job Cuts, 650 to Come in SoCal*, SAN FRANCISCO BUSINESS TIMES, August 12, 2009).

⁴¹ Miguel Marquez, *Archives: Patient Dumping 2002-2007*, HHS OFFICE OF INSPECTOR GENERAL (March 24, 2006); TREND: DUMPING HOMELESS ON L.A.'S SKID ROW (ABC News).

⁴² Jeremy Hay, *Two Kaiser Unions Strike in Santa Rosa, Northern California*, THE PRESS DEMOCRAT (January 31, 2012), www.pressdemocrat.com.

⁴³ *Kaiser Workers on Strike*, ROSEVILLE PRESS-TRIBUNE (January 31, 2012), www.thepresstribune.com.

development of concierge medicine demonstrates that for those who can afford it, U.S. health care is also becoming more individualized and personal.

With concierge medicine, a patient pays an annual fee, usually in addition to other charges. In exchange for the annual retainer, doctors provide enhanced care, including a commitment to limit the number of patients to ensure adequate time and availability for each patient. Concierge physician's care for fewer patients than those in a traditional practice, ranging from 50 patients per doctor to 1,000, compared to 3,000 to 4,000 patients that the average American physician sees annually.⁴⁴ Most concierge providers claim to be accessible via telephone or email at any time of day or night. The annual fees vary widely, up to U.S. \$5,000 per year *or more* for an individual with incremental savings when additional family members are added.

Concierge medicine is accused of promoting a two-tiered health system that favors the wealthy. While this health care model is more lucrative for physicians and makes care more convenient for their patients, it makes care less accessible for others who cannot afford to pay the annual retainer fee. As millions more previously uninsured Americans gain access to health insurance, there is an increasing shortage of primary care doctors. Concierge medicine exacerbates the shortage.

THE FUTURE: HOW TO INCREASE AFFORDABLE ACCESS TO HEALTH CARE

Telehealth

As the world struggles with the burden of rising costs of advanced medical technology and limited access to health care, telehealth is one vital link in cost-effective health care maintenance. Telehealth, sometimes called telemedicine,⁴⁵ is the delivery of health care services via technology to assist in the diagnosis and treatment of a patient while the patient is at one place and the health care provider is at another location.

Recent developments in technology, including high-speed internet, iCloud technology, and robotics, dramatically increase the potential to provide cutting edge medical treatment, including surgery, to more people at reduced costs. In addition, telemedicine's ability for remote monitoring, automated follow-up care and readily accessible communications, empowers patients, allowing more elderly and disabled individuals to remain at home rather than entering care facilities, at a considerable cost savings.

Even the poorest patients in remote communities at distant locations can have access to sophisticated telehealth care. Communities without trained medical personnel may satisfy their needs for professional knowledge in certain specialized fields without investing in full time providers. For physicians, telemedicine allows for a much broader healthcare markets without physically crossing borders.

Unfortunately, existing American licensing laws are an obstacle that medical technology alone cannot conquer. The United States is burdened with inconsistent and widely varying state laws which limit telehealth from easily crossing state borders, hindering telehealth from realizing its full

⁴⁴ U.S. GOV'T ACCOUNTABILITY OFFICE, REPORT TO CONGRESSIONAL COMMITTEES, PHYSICIAN SERVICES: CONCIERGE CARE AND CHARACTERISTICS AND CONSIDERATIONS FOR MEDICARE (2005).

⁴⁵ Telehealth is a broader concept including the use of technology to provide care remotely through use of electronic medical records and email, while telemedicine was originally only used to refer to the delivery of actual medical services to patients. Telehealth and telemedicine are increasingly being used interchangeably.

potential.⁴⁶

Antiquated laws written to protect the economic market share of doctors, limits the ability of scientific advancements to reach across borders to help people access and receive the potential benefits afforded by telehealth. The federal American government as well as the broader international community need to develop uniform telemedicine regulations and international trade agreements so that there can be universal access to this evolving medical science.

Advanced Technology

Separate and apart from telehealth, revolutionary medical developments also serve to lower the cost of health care and provide far greater access to more efficient treatment. The medical devices industry has experienced a significant upswing in recent years, and is considered one of the most dynamic sectors within the Life Sciences. It is certainly a large market—estimated at U.S. \$302 billion by 2017⁴⁷—with a high level of competition, rapid introduction of innovations and significant pressure to lower prices. Compared to the larger pharmaceuticals market, the medical devices market has more opportunities for new entrants.

One example of recent groundbreaking and economically efficient medical technologies is by Theranos, a California based corporation that was started in 2003 by then Stanford college student, Elizabeth Holmes. The company's first patent is a wearable patch that in addition to administering a drug, monitors variables in the patient's blood to determine if the patient's blood has the desired effect and adjusts the dosage accordingly. That invention was only the beginning....

*At a price that is one-half to one-tenth of what other American labs or hospitals charge,*⁴⁸ Theranos runs what is called a "high-complexity laboratory" offering more than 200 of the most commonly ordered diagnostic tests. Scores of different tests are run on a pinprick of blood, compared to numerous vials of blood which would be required to run such tests using conventional techniques. While a traditional emergency or "stat" blood test is highly inefficient and can only be performed on about 40 limited tests, all of Theranos' 200 test results are available within hours, and the company is on the verge of increasing their capacity to about 1000 tests.

Not only do the company's testing techniques use little blood, but the analytic systems employ nanotechnology, requiring 10 to 100 times less space than conventional labs. At the moment, the scale of Theranos' operations is humble: working out of its Palo Alto, California headquarters and 21 Walgreen drugstores. However, the company is poised to open a lab at all 8,200 Walgreens drugstores across the United States, making a lab available within five miles of almost every American. Long term plans include placing Theranos labs in Walgreen's European partner chain, Alliance Boots.

Theranos is also working closely with American hospital groups to identify hospital acquired infections. Using DNA profiling, Theranos found ways to make such testing cost efficient, allowing it to identify the type of infectious processes and its resistance profile within four hours, at far less than the cost of conventional testing.

Theranos is also working with major pharmaceutical companies conducting clinical drug trials.

⁴⁶ T. Fazer & J. Mulligan, *Doctors With Borders: How U.S and Europe Law Are Hurting/Helping the Promise of Telehealth*, J. Med. (forthcoming 2014).

⁴⁷ K. Cueto, *Innovation in Medical Devices: Looking at the IP Landscape* (April 2013), <http://www.ifi-claims.com/index.php?page=news&type=view&id=kmx%2Finnovation-in-medical>.

⁴⁸ R. Parloff, *This CEO Is Out For Blood*, FORTUNE, June 12 2005.

Their technology makes it feasible to build an early-detection system, testing people in clinical trials multiple times a week, catching adverse drug effects quickly.

Lest people think this startup company's plans are just a pipedream, a review of the people on Theranos' board of directors is sobering. The Theranos board includes former U.S. Secretary of State, Treasury and Labor George Schultz, former Secretary of Defense Bill Perry, former Secretary of State and National Security Adviser Henry Kissinger, and former U.S. Senators Sam Nunn and Bill Frist. Theranos' lawyer is David Bois, perhaps the most eminent living American lawyer, who handled the civil antitrust prosecution of Microsoft, as well as counsel of record in the epic *Bush v. Gore* Supreme Court case and he spearheaded the recent legalization of same-sex marriage in America.

Theranos is just one of many companies poised to change the way medicine is practiced, providing greater access to medical care at a fraction of the traditional cost.

Societal Attitudes Can Increase Access to Health Care

Organ Donor Laws

Successfully providing greater health access to more people isn't just a question of new technology at lower costs; it is also a question of re-adjusting societal norms. For example, on a global level, there is a large gap between the numbers of registered organ donors compared to those awaiting organ transplants.

There are two main ways of obtaining a donor's voluntary consent: "opt in" consents (requiring explicit, affirmative agreement) and "opt out" (mandating that anyone who has not refused is automatically a donor). Opt-out systems dramatically increase effective rates of donation.⁴⁹ For example, Germany, which uses an opt-in system, has an organ donation consent rate of 12% among its population, while Austria, a country with a very similar culture and economic development, but which uses an opt-out system, has a consent rate of 99.98%.⁵⁰

This crisis within the United States is growing rapidly. As of the date of this publication, 123,328 Americans were awaiting an organ donation, with less than twenty percent of this number having transplantations each year, leaving thousands of Americans to die each year, lacking an available donor organ. The Uniform Anatomical Gift Act of 1987 was adopted in several states, and allowed medical examiners to determine if organs and tissues of cadavers could be donated. By the 1980s, several states adopted different laws that allowed only certain tissues or organs to be retrieved and donated, some allowed all, and some did not allow any without consent of the family. In 2006 when the UAGA was revised, the idea of presumed consent was abandoned. In the United States today, organ donation is done only with express consent of the family or donor themselves ("opting-in").⁵¹

⁴⁹ Eric J. Johnson & Daniel G. Goldstein, *Do Defaults Save Lives?*, SCIENCE, Nov. 2003, at 1338-1339.

⁵⁰ Richard H. Thaler, *Opting In v. Opting Out*, N.Y. TIMES, Sept. 2014.

⁵¹ David Orentlicher, *Presumed Consent to Organ Donation: Its Rise and Fall in the United States*, 61 RUTGERS L. REV. 295 (2009), available at http://www.uiowa.edu/~ibl/documents/Orentlicher_Macro.pdf.

The United States Department of Health funded a study by the University of Wisconsin Hospital to increase the number of donors by pursuing members of the university and their family and friends through social media. The results of the study showed a 20% increase in organ donation by creating support and awareness through social media.⁵² By promoting college students' awareness of organ donation and increasing social support for organ donation, more likely people will be to register as organ donors.

End-of-Life Planning

In a single year, the United States spends about U.S. \$170 billion on patients' last six months of life.⁵³ La Crosse, Wisconsin spends less on health care for patients at the end of life than any other place in the United States according to the Dartmouth Health Atlas.⁵⁴

Why? Some 96 percent of people who die in La Crosse have an advance directive or similar documentation. An **advanced health care directive** is a legal document in which a person specifies what actions should be taken for their health if they are no longer able to make decisions for themselves because of illness or incapacity. Nationally, only about 30 percent of American adults have such a document.

Reducing costs wasn't the reason this community has an aggressive advance directive program. It started with a single medical ethicist, Bud Hammes, who was trying to help patients. He discovered that when he took the time to explain options to people, they almost universally did not want to be kept artificially alive if their prognosis was bleak. The reduction in spending from people opting out of expensive and unwanted care was an accident. But now, other communities are trying to copy the program.⁵⁵ Unfortunately, this issue created near epic political polarization in the United States in 2009 when former United States Republican vice presidential candidate Sarah Palin, referred to a similar end of life provision in the Affordable Health Care Act (ACA) that would have offered patients end-of-life consultations with their physicians as "death panels." That comment, and the ensuing rhetoric surrounding it, forced the elimination of this provision from the ACA.

CONCLUSION

⁵². James W. Peltier et al., *Use of Social Media and College Student Organizations to Increase Support for Organ Donation and Advocacy: A Case Report*, PROGRESS IN TRANSPLANTATION 436-41 (2012).

⁵³ S. Pasternak, *End-of-Life Care Constitutes Third Rail of U.S. Health Care Policy Debate*, THE MEDICARE NEWSGROUP (June 3, 2013), <http://www.medicarenewsgroup.com/context/understanding-medicare-blog/Understanding-medicare-blog/2013/06/03/end-of-life-care-constitutes-third-rail-of-u.s.-health-care-policy-debate>

⁵⁴ THE DARTMOUTH ATLAS, <http://www.dartmouthatlas.org/data/region/profile.aspx?loc=189&tab=21>

⁵⁵ *The Town Where Everyone Talks About Death*, National Public Radio (Mar. 5, 2014), available at <http://www.npr.org/blogs/money/2014/03/05/286126451/living-wills-are-the-talk-of-the-town-in-la-crosse-wis>.

The United States made groundbreaking leaps forward in its' citizens access to healthcare when it enacted the Affordable Care Act. While it is still too early to tell, the Obamacare's long term impact, by all counts it already appears to be providing millions more Americans with access to care.

Going forward, the ability to expand the benefits of medical technology to large numbers of people will require a combination of a more integrated and efficient medical system, together with a change in American laws permitting the spread of telehealth to cross borders in order to deliver treatment and monitoring of patients through the use of the internet and robotics. Innovative medical technology must be promoted and efforts must also be made to change societal values towards thorny issues such as organ transplants and end-of-life planning.

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