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ADVANCE DIRECTIVE

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Advance Directive

THE *STUDENT* HEALTH POLICY AND LAW REVIEW OF LOYOLA UNIVERSITY CHICAGO SCHOOL OF LAW

BRINGING YOU THE LATEST DEVELOPMENTS IN HEALTH LAW

Beazley Institute for Health Law and Policy

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ANNALS OF HEALTH LAW
Advance Directive

Editors' Note

The *Annals of Health Law* is proud to present the Fifteenth Issue of our online, student-written publication, *Advance Directive*. *Advance Directive* aims to support and encourage student scholarship in the area of health law and policy. In this vein, this issue explores the legal, regulatory, and economic challenges to innovation in health care. Healthcare innovation may conventionally be thought of as limited to issues related to technology, or development of new drugs and therapies or medical devices; however, healthcare innovation is decidedly broader, encompassing a vast array of different industries, providers, and legal frameworks. Here, the authors examine a variety of topics on the issue of healthcare innovation, ranging from the integration of social services into the traditional medical model to policies relating to increased transparency within the pharmaceutical industry.

This issue begins with a discussion of the managed care model. Our first author examines how integration of legal aid into the managed care model could expand access to preventive care, thereby decreasing overall healthcare costs for individuals. Thereafter, another author critiques the financial success of managed care models, focusing on how demographics might negatively impact such success.

Our discussion continues with the impact the Affordable Care Act ("ACA") has had on innovation. First, one author considers the Hospital Readmissions Reduction Program, established in Section 3025 of the ACA, and argues that the Centers for Medicare & Medicaid Services successfully utilized this program to lower readmission rates, thus contributing to lower costs for healthcare organizations overall. The next article offers an author's perspective on how the ACA has impacted innovation, with a specific focus on the influence of the Physician Payment Sunshine Act ("Sunshine Act"). The author examines how the Sunshine Act has possibly discouraged physician cooperation or participation in the development and advancement of the industry.

Additionally, we navigate current debates within the pharmaceutical industry. One author discusses the role of genetics in the industry, arguing in favor of the use of genetic information to improve the effectiveness of medication. Another author discusses the patentability of genetic information. Finally, we end our focus on the pharmaceutical industry with an author who argues that drug transparency could potentially stifle innovation, rather than having the intended effect of decreasing cost.

Lastly, we evaluate how innovation affects the traditional doctor-patient relationship. One author notes that medical mobile applications affect this traditional relationship by increasing consumer knowledge and participation in the health care process but argues that the Food & Drug Administration must increase regulation on these types of applications for them to remain safe and effective. We then discuss the ACA's mandate that healthcare organizations meet a certain minimum level of patient satisfaction to receive Medicare funding. In this realm, our final author discusses the possibility that an increased focus on patient satisfaction, especially with an increasingly engaged consumer population might negatively impact the quality of care provided.

We would like to thank Amy Michelau, our Technical Production Editor, because without her knowledge and commitment this Issue would not have been possible. We would like to give special thanks to our *Annals* Editor-in-Chief, Ryan Marcus, for his leadership and support. The *Annals* Executive Board Members, Sarah Kitlinski, Sumaya Noush, Amy Michelau, and Morgan Carr, and the *Annals* Senior Editors, Holly McCurdy, James Flannery, Joseph Willuweit, and Christopher MacKenzie provided invaluable editorial assistance with this Issue. The *Annals* members deserve special recognition for their thoughtful and topical articles and for editing the work of their peers. Lastly, we must thank the Beazley Institute for Health Law and Policy and our faculty advisors, Professor Lawrence Singer, Professor John Blum, and Kristin Finn for their guidance and support.

We hope you enjoy our Fifteenth Issue of *Advance Directive*.

Sincerely,

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Integrating Legal Aid in the Medicaid Managed Care Model

*Lindsey Croasdale**

I. INTRODUCTION

With federal and state budgets in crisis, government health care spending on the rise, the passage of the Patient Protection and Affordable Care Act ("PPACA"),[1] and the moral commitment to provide affordable, high-quality health care to indigent populations, there has been a push in recent years for innovation in the public health care delivery system to contain the cost of providing quality care in the face of expanding access pressures.[2] In particular, thirty-one states have expanded their Medicaid programs[3] and many states have implemented a managed care delivery system, often administered by Managed Care Organizations ("MCOs"), into their Medicaid programs in an effort to make the delivery of care more efficient and to provide health care at a lower cost.[4] Managed care is a type of health care delivery system in which state agencies contract with insurers who in turn contract with health care providers and medical facilities to provide care for patients at reduced costs.[5] As of March 2015, there were 275 Medicaid MCOs nationwide.[6]

Managed Care Organizations open a window for innovation in the delivery

* J.D. Candidate, May 2017, Loyola University Chicago School of Law. I thank Emily Benfer and John Blum for their gracious guidance and support.

1. *See generally* Patient Protection and Affordable Care Act, Pub. L. No. 111–148, 124 Stat. 119 (2010) (to be codified in scattered sections of 42 U.S.C.).

2. *Managed Care*, MEDICAID.GOV, http://www.medicaid.gov/medicaid-chip-program-information/by-topics/delivery-systems/managed-care/managed-care-site.html (last visited Oct. 1, 2015) [hereinafter *Managed Care*] (official federal website providing information on the Medicaid program).

3. *Status of State Action on the Medicaid Expansion Decision*, KAISER FAMILY FOUND., http://kff.org/health-reform/state-indicator/state-activity-around-expanding-medicaid-under-the-affordable-care-act/ (last updated Nov. 2, 2015) (displaying a chart of which U.S. states are expanding the Medicaid program at this time).

4. *Managed Care*, *supra* note 2.

5. *Id.*

6. *Total Medicaid MCOs*, KAISER FAMILY FOUND., http://kff.org/other/state-indicator/total-medicaid-mcos/ (last updated Mar. 2015) (counting and comparing the number of managed care organizations by state).

of health care.[7] Although every state requires MCOs to provide particular services, each one has the flexibility to offer a package of special services to their members to provide more integrated and holistic care, including innovative preventive care and social services.[8] For example, some MCOs offer job training, after-school programs, a free cellphone for calls to the doctor or care coordinator, free Weight Watchers membership, discounted gym memberships, gift cards for over-the-counter items, English as a Second Language classes, and tobacco cessation counseling.[9] Prevention, chronic disease management, and healthier lifestyles are key to reducing health care spending.[10] Presumably, the healthier a person is, the less health care he or she will use, and therefore he or she will cost less for the taxpayers.[11] As such, MCOs promote preventive care services to keep their members healthier and their cost of health care down.[12]

Although MCOs have started to implement programs to improve individual behavior and access to health services, they do not conventionally address all social determinants of health.[13] The World Health Organization defines the social determinants of health as the conditions in which people are "born, grow, work, live, and age, and the wider set of forces and systems shaping the conditions of daily life."[14] Health conditions of Medicaid-eligible populations are typically influenced by the social determinants of health.[15] Because of the numerous social problems and external factors affecting an individual's health, Medicaid MCOs must address socioeconomic, cultural, and logistical barriers to care faced by their particularly vulnerable

7. *Managed Care*, *supra* note 2.

8. *Id.*

9. *See generally Client Enrollment Services*, ILL. DEP'T OF HEALTHCARE & FAMILY SERVS., http://enrollhfs.illinois.gov/choose/plans-by-county/cook (last visited Nov. 29, 2015) [hereinafter *Client Enrollment*] (displaying the managed care plan options by county in Illinois so that Medicaid recipients can compare plans).

10. *Preventive Health Care*, CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/healthcommunication/toolstemplates/entertainmented/tips/preventive health.html (last updated June 12, 2013) [hereinafter *Preventive Health*] (explaining what preventive care is and why it is important).

11. *See id.*

12. Deborah A. Freund & Eugene M. Lewit, *Managed Care for Children and Pregnant Women: Promises and Pitfalls*, 3 HEALTH CARE REFORM 92, 99 (1993) (examining the claimed advantages and disadvantages of managed care for children and pregnant women enrolled in managed care).

13. *See generally Client Enrollment*, *supra* note 9 (describing the various benefits of the plans offered in Illinois, but no plan addresses all of the social determinants of health with its services).

14. *Social Determinants of Health*, WORLD HEALTH ORG., http://www.who.int/social_ determinants/en/ (last visited Oct. 7, 2015).

15. *The Cycle of Poverty and Poor Health*, HEALTH POVERTY ACTION, http://www. healthpovertyaction.org/info-and-resources/the-cycle-of-poverty-and-poor-health (last visited Nov. 29, 2015) [hereinafter *Cycle of Poverty*].

populations to improve the health of their members.[16]

The Medical-Legal Partnership ("MLP") model can be a useful tool to address social determinants of health.[17] A Medical-Legal Partnership is a partnership between the health care community and the civil legal aid community, in which the two work together to address and prevent health-harming social conditions for patients and communities.[18] While health care has traditionally treated individual health and has not traditionally addressed broader social issues, the MLP model works to remedy the causes of poor health through civil legal aid.[19] For example, for patients whose utilities have been shut off, which can lead to asthma attacks or inability to refrigerate medicine, the patient's doctor can consult with a MLP attorney to remedy the harmful situation and improve the health condition as a result.[20]

This article argues that MCOs could keep health care costs down by expanding the preventive care services they cover to include legal services for their members. A MCO can partner with a MLP to address the legal issues that are negatively impacting the health of their members, and thus resolve health issues in a way that traditional medicine has not.

This article will first address the importance of reducing health care costs while also improving quality of care, followed by a discussion on how PPACA encourages innovation in the Medicaid program to reduce government health care spending while improving quality. Following a discussion of how the MLP model works to improve health outcomes, this article will address how MCOs and MLPs can work together to integrate care and provide lower-cost, quality care to low-income populations. Finally, this article will discuss the barriers to integrating MLPs into a MCO network.

II. HEALTH CARE EXPENDITURES RANK HIGHER THAN QUALITY IN THE UNITED STATES

The United States has an interest in improving quality of care while

16. Sharon Silow-Carroll & Diana Rodin, *Forging Community Partnerships to Improve Health Care: The Experience of Four Medicaid Managed Care Organizations*, COMMONWEALTH FUND (Apr. 2013), http://www.commonwealthfund.org/~/media/files/publications/issuebrief/2013/apr/1687_silowcarroll_forging_community_partnerships_medicaid_managed_care_ib.pdf (discussing four Medicaid MCO models in a post-PPACA environment that are working to achieve the goals of managed care, higher quality and lower cost of health care, while addressing the barriers that vulnerable populations face).

17. *FAQ: About the Medical-Legal Partnership Approach*, NAT'L CTR. FOR MED.-LEGAL PARTNERSHIPS, http://medical-legalpartnership.org/faq/ (last visited Oct. 8, 2015) [hereinafter *FAQ*].

18. *Id.*

19. *Id*.

20. *How Medical-Legal Partnership Works: A Case Study*, NAT'L CTR. FOR MED.-LEGAL PARTNERSHIPS, http://medical-legalpartnership.org/mlp-response/how-medical-legal-partnership-works/ (last visited Oct. 8, 2015).

reducing health care spending. In a survey by the Commonwealth Fund comparing health care systems in eleven developed nations, the U.S. ranked highest in health care costs and cost-related problems accessing care, and lowest in efficiency, equity, and health outcomes.[21] In other words, the U.S. generally spends a higher premium for lower quality care than other developed nations.[22] In 2013, about seventeen percent of the country's gross domestic product went toward health expenditures—the highest percentage of GDP toward health expenditures in the world.[23] In 2014, about twenty-four percent of the federal budget went toward financing four federal health insurance programs – Medicare, Medicaid, the Children's Health Insurance Program ("CHIP"), and PPACA marketplace subsidies.[24] About one-third of the financing for federal health insurance programs, or $325 billion, funds Medicaid and CHIP.[25] In a typical month, Medicaid and CHIP provide health care or long-term care to about seventy million low-income children, parents, elderly people, and people with disabilities.[26] Both Medicaid and CHIP require matching payments from the states.[27] In 2014, state funding for Medicaid and CHIP amounted to about sixteen percent of state budgets – roughly $183 billion.[28] Health care spending per capita has grown at a historically low rate since 2008.[29] Although spending has slowed since the passage of PPACA, health care spending is expected to rise again.[30] Since public health insurance and PPACA marketplace subsidies constitute such a substantial portion of federal and state budgets and because health care spending is expected to continue rising, the states and the federal government

21. Lenny Bernstein, *Once Again, U.S. Has Most Expensive, Least Effective Health Care System in Survey*, WASH. POST (June 16, 2014), https://www.washingtonpost.com/news/to-your-health/wp/2014/06/16/once-again-u-s-has-most-expensive-least-effective-health-care-system-in-survey/ (comparing the cost and quality of care among eleven developed countries).

22. *Id.*

23. *Health Expenditure, Total (% of GDP)*, WORLD BANK, http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS (last visited Oct. 1, 2015).

24. *Policy Basics: Where Do Our Federal Tax Dollars Go?,* CTR. ON BUDGET & POL'Y PRIORITIES 1 (Mar. 11, 2015), http://www.cbpp.org/sites/default/files/atoms/files/4-14-08tax.pdf (demonstrating the different federal programs and the amount of tax dollars that are appropriated to each program).

25. *Id.*

26. *Id.*

27. *Id.*

28. *Policy Basics: Where Do Our State Tax Dollars Go?* CTR. ON BUDGET & POL'Y PRIORITIES 2 (Apr. 14, 2015), http://www.cbpp.org/sites/default/files/atoms/files/policybasics-statetaxdollars.pdf (demonstrating the different state programs and the amount of tax dollars that are appropriated to each program).

29. *How Much Is Health Spending Expected to Grow?* HEALTHSYSTEMTRACKER.ORG, http://www.healthsystemtracker.org/chart-collection/the-latest-health-spending-projections/ (last visited Oct. 1, 2015) [hereinafter *How Much Is*] (discussing the changes in health care spending since the 1970s and projecting where spending is going based on recent trends).

30. *Id.*

have a considerable interest in minimizing the cost of health care in order to keep government spending under control.

III. MEDICAID MANAGED CARE AND WAIVERS

The states have been struggling with the cost of Medicaid since its inception, but have been progressively implementing innovative ways to reduce public funding of health care since the passage of the Patient Protection and Affordable Care Act.[31] To allow for innovation, Congress amended the Social Security Act (the "Act") to allow for states to apply for a waiver from following all portions of the Act so they can implement innovative ways to deliver care.[32] For example, under Section 1115 of the Social Security Act ("1115 waiver") the Secretary of Health and Human Services has authority to approve experimental, pilot, or demonstration projects that promote the objectives of the Medicaid and CHIP programs.[33] This has allowed states to use federal funds, not normally allowed under the Act or PPACA, to create their own demonstration projects that improve access, quality, and efficiency of health care delivery in their state.[34] Before PPACA, a number of states implemented 1115 waivers to expand coverage to childless adults who were not otherwise eligible under federal rules.[35] Now that PPACA expands Medicaid coverage to childless adults, the role of 1115 waivers to expand coverage significantly changes.[36] Although the dissent in *National Federation of Independent Businesses v. Sebelius* criticized the demonstration waiver as "spend[ing] government money on. . . the study of how to spend less government money," these waivers have been used innovatively to control spending.[37] One way states have been trying to control health care costs through 1115 waivers is by combining it with Section 1915(b) Managed Care Waivers, which allow states to apply for waivers to provide services through managed care delivery systems, and thus allowing states to innovatively expand their Medicaid managed care

31. *Waivers*, MEDICAID.GOV, http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/Waivers.html (last visited Nov. 29, 2015).

32. *See* 42 U.S.C. §1315(a) (2014).

33. *Id.*

34. *Five Key Questions and Answers About Section 1115 Medicaid Demonstration Waivers*, KAISER FAMILY FOUND. 1 (June 2011) [hereinafter *Five Key Questions*], *available at* https://kaiserfamilyfoundation.files.wordpress.com/2013/01/8196.pdf (providing basic information on 1115 waivers in the style of a frequently asked questions forum).

35. *The ACA and Recent Section 1115 Medicaid Demonstration Waivers*, KAISER FAMILY FOUND. 5 (Feb. 2014), *available at* https://kaiserfamilyfoundation.files.wordpress.com/2014/02/8551-the-aca-and-recent-section-1115-medicaid-demonstration-waivers.pdf (explaining the ways 1115 waivers were used in the past and how states are implementing them after the passage of PPACA).

36. *Id.*

37. Nat'l Fed'n of Indep. Bus. v. Sebelius, 132 S. Ct. 2566, 2675 (2012).

programs.[38] The use of these waivers has allowed states, such as Illinois, to set up Medicaid managed care organizations to transition from a more costly, traditional fee-for-service model to a service-driven model.[39]

In a Medicaid managed care system, state agencies contract with MCOs who form a network of health care providers and medical facilities.[40] MCOs are able to provide care for beneficiaries at a reduced cost due to a narrowed network, payment incentives, and integrated care initiatives.[41] Although the patient is restricted to services by in-network providers, the MCOs accept a prospective payment rate, often through capitated payments, in exchange for a guaranteed steady flow of patients saving taxpayer money.[42] Capitation is a payment method in which the MCO is paid the same amount of money per member per month regardless of how much care the patient receives.[43] While the goal is that providers will be more efficient with the care they provide (e.g. by not ordering unnecessary tests), there is also a negative incentive to provide less care to patients to keep costs down.[44] Although managed care plans often have systems in place to improve and review the quality of care provided, the government's reimbursement scheme pressures providers to contain costs, which may lead to delay or denial of necessary care.[45]

The goal of managed care is to manage cost, utilization, and quality by coordinating care of its members so that care is more efficiently and effectively provided.[46] By fixing the monthly fees paid to MCOs for providing care, the MCO is incentivized to minimize costs by only delivering necessary care.[47] MCOs are also incentivized to provide adequate preventive services.[48] By reducing the risk of debilitating illness through preventive care, the MCO is investing in its members' health, which costs them less in the future.[49] MCOs encourage their members to use preventive care by promoting greater utilization of primary care physicians who often treat unmet needs and are encouraged to prescribe preventive care and by reducing out-of-pocket expenses for preventive care services.[50] The demonstration

38. *Five Key Questions*, *supra* note 34; 42 U.S.C. §1396n(b).

39. *Delivery Systems*, MEDICAID.GOV, http://www.medicaid.gov/medicaid-chip-program-information/by-topics/delivery-systems/delivery-systems.html (last visited Oct. 1, 2015) [hereinafter *Delivery Systems*].

40. *Managed Care*, *supra* note 2.

41. *Id.*

42. *Id.*

43. *Id.*

44. Freund & Lewit, *supra* note 12.

45. *See id.* at 100.

46. *Managed Care*, *supra* note 2.

47. Freund & Lewit, *supra* note 12.

48. *Id.* at 100.

49. *Id.* at 99.

50. *Id.* at 100.

waivers provide an opportunity for states to innovate to reduce healthcare spending and integrate patient care to increase quality.[51]

IV. THE MEDICAL-LEGAL PARTNERSHIP MODEL

A Medical-Legal Partnership is an inter-professional collaboration aimed at identifying and addressing social and legal issues that negatively affect the health of low-income individuals.[52] It allows for doctors to refer their patients to a lawyer to resolve the legal issue that is exacerbating the patients' health.[53] The MLP model inserts the legal team into the health care setting to work with health care providers to resolve patient needs.[54] One benefit of this collaboration is that legal issues impacting a patient's health can be resolved more quickly than in a crisis-driven legal aid setting.[55] Another benefit is that both professions work together to detect systemic problems and inform healthier public policies.[56] As a response to the surge of health care laws and regulations over the last several decades, MLPs offer an innovative change in health care delivery to improve access to the benefits and protections these laws sought to guarantee.[57] Primary care providers are often unable to adequately address the social factors that influence health, such as adequate nutrition, safe and affordable housing, and disability income, but are more equipped to do so in a MLP team because the MLP team consists of professionals from health care and legal backgrounds who are trained to approach problems in very different ways.[58] With a MLP team assisting a patient, they can effectively solve a problem by working together.

The MLP model aims at resolving the causes of poor health conditions by addressing the source.[59] For example, a MLP team would be useful in a situation where a physician sees a patient who has a high readmission rate to the hospital due to repeated severe asthma attacks.[60] Doctors will oftentimes

51. *See generally Five Key Questions*, *supra* note 34.
52. *FAQ*, *supra* note 17.
53. *Id.*
54. *Id.*
55. *Id.*
56. *Id.*
57. Megan Sandal, et al., *Medical-Legal Partnerships: Transforming Primary Care By Addressing The Legal Needs of Vulnerable Populations*, 29 HEALTH AFF. 1697, 1697 (Sept. 2010) (describing how MLPs can change clinical systems and recommending their integration into federal health care programs).
58. *Id.*
59. *FAQ*, *supra* note 17.
60. *See generally Reducing Asthma Admissions by "Hotspotting" Housing Code Violations*, NAT'L CTR. FOR MED.-LEGAL PARTNERSHIPS (Oct. 1, 2013), http://medical-legalpartnership.org/hotspotting-story/ (telling a success story about how a MLP helped a number of tenants whose health was suffering because of the poor housing conditions of several building owned by the same landlord).

treat the patient by prescribing inhalers or the use of nebulizers, but whatever is exacerbating the asthma may not be resolved with medication alone.[61] If, after speaking with the patient, the team discovers that a poor housing condition in a rented unit is aggravating the asthma, the legal team can support the patient in getting a landlord to remedy the problem.[62] With training on detecting legal issues and counsel from a legal team, the partnership can both treat the symptoms and fix the cause of a health condition to ensure healthier patients.[63] While working together, both professionals can also spot trending systemic problems and advocate for policy changes that can improve the delivery of care in the future.[64]

The legal issues in which civil legal aid attorneys spend significant portions of their time—safety, domestic violence, housing, and income maintenance—are indivisibly linked to the health of their low-income clients.[65] Although addressing civil legal needs has not been widely recognized as a way to improve health outcomes,[66] addressing the social determinants of health is widely recognized as a way to improve health outcomes because they often cause poor health.[67]

The most common social determinants of health are income, housing and utilities, education and employment, legal status, and personal and family stability.[68] When a patient lacks resources to meet his or her daily needs, the likelihood of the patient suffering from malnutrition, diabetes, and high blood pressure increases because of the inability to consistently purchase healthy foods.[69] This can cause poor health and chronic conditions that are painful for the patient and expensive to maintain.[70] To prevent conditions exacerbated by poor health, the patient's primary care physician can refer the patient to the legal team, which can help that patient become more economically stable by assisting in the application or appeal of food stamps,

61. *Id.*
62. *Id.*
63. *Id.*
64. *Id.*
65. *FAQ*, *supra* note 17.
66. *Id.*
67. Deborah Bachrach et al., *Addressing Patients' Social Needs: An Emerging Business Case For Provider Investment*, COMMONWEALTH FUND 8 (May 2014), *available at* http://www.commonwealthfund.org/~/media/files/publications/fundreport/2014/may/1749_bachrach_addressing_patients_social_needs_v2.pdf (discussing how new models are creating economic incentives for providers to incorporate social interventions into their approach to health care).
68. *How Civil Legal Aid Helps Health Care Address SDOH*, NAT'L CTR. FOR MED.-LEGAL PARTNERSHIPS, http://medical-legalpartnership.org/mlp-response/how-civil-legal-aid-helps-health-care-address-sdoh/ (last visited Oct. 8, 2015) [hereinafter *How Civil Legal*].
69. *Id.*
70. *Id.*

cash benefits, and disability benefits.[71] If the patient lives in unstable or substandard housing conditions that are causing poor health, the legal team can help prevent eviction, secure housing subsidies, improve substandard conditions, or prevent utility cut-offs.[72] Stable housing reduces the risk of emergency room visits related to homelessness, and reliable utilities can save refrigerated medication and ward off cold-weather illnesses such as pneumonia.[73] A legal team could also help a patient secure education services or prevent employment discrimination, which can limit a person's access to opportunity and resources enabling the patient to live a more economically stable life.[74] Patients could also receive help with veteran discharge status or clearing a criminal or credit record.[75] Help with legal status impacts health because legal status can affect a patient's access to public benefits and economic opportunity.[76] Finally, a legal team can assist a patient in cases of domestic violence by securing restraining orders and assisting in custody and guardianship matters for children.[77] Securing stable family relationships limits the need for costly emergency room visits due to violence and reduces stress, creating a healthier living environment for an entire family.[78] These are all examples of ways that a MLP can assist in working on the most pressing need of the individual, and by providing civil legal aid to patients when they access their primary care physicians, this model has the potential of preventing illness and improving long-term health outcomes.

Thus, by integrating the MLP model into a Medicaid managed care model whose members are low-income and suffer disproportionately from the social determinants of health, the MCO could improve the health of its members by taking a preventive, holistic approach to improving health outcomes.

V. MCOs AND MLPs WORKING TOGETHER TO INTEGRATE CARE

Since the cost of health care is higher than ever and is rising faster than the median household income, it is important now more than ever for MCOs to improve health at a reduced cost.[79] To provide care at a reduced cost, we must innovate the way care is delivered.

Since the passage of PPACA and the reforms it encourages, MCOs have

71. *Id.*
72. *Id.*
73. *Id.*
74. *Id.*
75. *Id.*
76. *Id.*
77. *Id.*
78. *Id.*
79. Cathy Schoen et al., *State Trends in the Cost of Employer Health Insurance Coverage, 2003–2013*, COMMONWEALTH FUND (Jan. 2015), http://www.commonwealthfund.org/~/media/files/publications/issue-brief/2015/jan/1798_schoen_state_trends_2003_2013.pdf.

been granted the opportunity to innovate the way they provide care to keep costs down.[80] Some MCOs have done so by incorporating more preventive care in their package of services, recognizing the need to offer a service whose utilization could cost them less in the long run.[81] For example, MCOs have innovated the way they provide care by offering programs to help individual behavior and improve access to health services.[82] In Illinois, the Family Health Network plan offers a free Weight Watchers membership and Meridian Health Plan offers help quitting smoking in their New Beginnings program to help improve their members' individual behavior.[83] Also in Illinois, the Blue Cross Community Family Health Plan offers transportation to the pharmacy, medical equipment provider and Woman, Infants and Children (WIC) food assistance sites for its members.[84]

In addition to health services to improve health outcomes, MCOs should consider incorporating MLPs into their network of health care delivery. MLPs are proven to be a cost-effective approach to address the social determinants of health that would otherwise go untreated by a conventional health care delivery system.[85] By increasing access to legal services for Medicaid beneficiaries, a legal team could help resolve the legal issues that cause a patient's poor health.[86] MLPs have proven to address the legal needs of the most vulnerable populations, resulting in improved health outcomes, increased workforce efficiency, and reduced health care cost.[87] Among its successes, in 2014 MLPs resolved legal issues that were affecting the health of over 60,000 patients nationwide and trained over 15,000 health care workers in recognizing social determinants of health.[88] Also, a MLP study at Lancaster General Health in Pennsylvania showed that overall health care costs decreased by forty-five percent once a legal team addressed the legal issues in the highest-utilizing patients, ninety-five percent of whom had two to three legal issues each.[89]

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80. *Managed Care*, *supra* note 2.
81. Freund & Lewit, *supra* note 12.
82. *Client Enrollment*, *supra* note 9.
83. *Id.*
84. *Id.*
85. Bachrach et al., *supra* note 67.
86. *How Civil Legal*, *supra* note 68.
87. *Impact At A Glance*, NAT'L CTR. FOR MED.-LEGAL PARTNERSHIPS, http://medical-legalpartnership.org/mlp-response/impact/ (last visited Nov. 29, 2015) (providing current resources and data that demonstrate the quantifiable impacts of Medical-Legal Partnerships).
88. *Id.*
89. Jeffrey Martin et al., *Health Affairs: Treating High-Utilizing Patients with MLP*, NAT'L CTR. FOR MED.-LEGAL PARTNERSHIPS, Apr. 22, 2015, http://medical-legalpartnership.org/health-affairs-treating-high-utilizing-patients-with-medical-legal-partnership/ (republishing a blog post from Health Affairs which reported on a cost benefit study of the MLP model).

More people are recognizing the importance of incorporating strategies to address the social determinants of health, including the federal government.[90] For example, in 2014 the U.S. Health Resources and Services Administration ("HRSA") explained that civil legal aid may be included in the range of "enabling services," that HRSA-funded federally qualified health centers (FQHCs) provide.[91] Enabling services are non-clinical services—such as health education and case management—that aim to increase access to health care and improve health outcomes.[92] By HRSA allowing for civil legal aid to be included as an enabling service that FQHCs provide to meet the primary care needs of the population and communities they serve under Section 330 of the Public Health Services Act, the federal government authorizes FQHCs to use grant money to pay for in-house legal aid and civil legal aid services to their patients. [93] This demonstrates that the federal government recognizes civil legal aid as a method to improve health outcomes.[94] Low-income people have poor access to legal aid even when the legal problem causes or exacerbates a health condition.[95] By providing legal aid services to members in a MCO, the members' health outcomes as well as their access to justice would be improved.

Integrating the MLP model into a Medicaid managed care network would be effective because states have increasingly moved toward the managed care delivery system and away from the fee-for-service model to cut down costs.[96] Also, the very nature of the managed care delivery system is to integrate care in a holistic way to reduce health care spending, thus it would be intuitive to add civil legal aid services to the list of enabling services that managed care organizations are trying to provide.[97] Meeting patients' social needs to improve their health outcomes is already part of many MCO models and those social needs can be met most effectively through MLPs.[98]

Currently, a MCO called AmeriHealth Caritas District of Columbia is partnering with a MLP at the Children's Law Center to test this model in Washington, D.C.[99] Under Market President Karen M. Dale, the MCO and

90. *Making the Case for Investment*, NAT'L CTR. FOR MED.-LEGAL PARTNERSHIPS, http://medical-legalpartnership.org/resources/investment/ (last visited Nov. 29, 2015) [hereinafter *Making the Case*].

91. *Id*.

92. *Program Requirements*, HRSA, http://bphc.hrsa.gov/programrequirements/index.html (last visited Oct. 13, 2015).

93. *Making the Case*, *supra* note 90*; see also* Health Services Act of 1996, Pub. L. No. 104-299, § 330, 110 Stat. 3626, 3626 (1996) (codified in scattered sections of 42 USC § 254b).

94. *Making the Case*, *supra* note 90.

95. *Id*.

96. *Delivery Systems*, *supra* note 39.

97. *Managed Care*, *supra* note 2; *see also Client Enrollment*, *supra* note 9.

98. Bachrach et al., *supra* note 67.

99. Telephone Interview with Karen M. Dale, Market President, AmeriHealth Caritas

the MLP are working together to address the legal needs that are negatively impacting the health of its members.[100] AmeriHealth is evaluating the health outcomes and the cost of providing civil legal aid to its members to determine if the model is in fact adding value by generating savings due to avoidable medical costs.[101] Based on the results of the study, the MCO will determine how to reimburse the MLP for the civil legal aid services.[102] The study is promising and may have important implications for innovative quality health care delivery.

VI. BARRIERS AND PROMISES TO INTEGRATING MLPS INTO MCOS

Because the income eligibility requirements for Medicaid are set so low, Medicaid beneficiaries represent the country's poorest populations.[103] Depending on the state and the program, income limits for the adult Medicaid programs range from 0% to 138% of the Federal Poverty Level.[104] Medicaid populations are poor, and poorer communities tend to have poorer health.[105] Due to the social determinants of health prevalent among poor communities, the delivery of care to Medicaid recipients must be capable of addressing a myriad of socioeconomic, cultural, and logistical barriers to care faced by their particularly vulnerable populations to improve their health.[106]

The promises to integrating MLPs into MCOs are numerous. In an ideal world, integrating MLPs into MCO networks would reduce Medicaid spending, improve access to justice for thousands, and improve the quality of care delivered to low-income individuals. However, there are challenges in the current political and economic climate of the United States, and a cultural shift is necessary for this model to work. The current economic and political climate makes it difficult to implement such a program. Many state budgets are currently in crisis, making many legislators cautious of changing laws that affect public programs because of pressure to cut government spending.[107] Policy-makers and innovators must recognize the need to

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District of Columbia (Oct. 22, 2015).

100. *Id.*

101. *Id.*

102. *Id.*

103. Julia Paradise, *Medicaid Moving Forward*, KAISER FAMILY FOUND. (Mar. 2015), http://kff.org/health-reform/issue-brief/medicaid-moving-forward/ (discussing the coverage and financing of the Medicaid program).

104. *Medicaid Eligibility for Adults as of January 1, 2014*, KAISER FAMILY FOUND. 2 (Oct. 2013), *available at* http://kff.org/medicaid/fact-sheet/medicaid-eligibility-for-adults-as-of-january-1-2014/.

105. *Cycle of Poverty*, *supra* note 15.

106. Silow-Carroll & Rodin, *supra* note 16.

107. Mark Niquette, *For Many American States, It's Like the Recession Never Ended*, BLOOMBERG (May 19, 2015), http://www.bloomberg.com/news/articles/2015-05-20/six-years-into-recovery-u-s-states-struggle-to-balance-budgets

improve health and implement preventive solutions in order to reduce spending on Medicaid.

While this model could potentially reduce Medicaid spending in the long run, convincing MCOs to implement the model may be a challenge. Without current data showing success in having a MLP as part of a MCO, MCOs may be cautious to experiment with this model. However, the pending results of AmeriHealth's evaluation of its partnership with the Children's Law Center may prove promising for MCOs who may be skeptical that MLPs improve health outcomes and reduce costs. MCOs may be primarily concerned with the cost of providing civil legal aid to its members. Furthermore, there may not be incentives for a MCO to provide civil legal aid to members if the member will not likely remain with their plan for years to come. However, there is data that shows MLPs have improved health and reduced health care costs when implemented with primary care physicians; thus, it is possible that it could work for a MCO as well whose model is centered around primary care. Also, if there are incentives provided to members to remain with plans for several years, such as offering the members legal assistance, the members may be more likely to stay with those plans in the future.

VII. CONCLUSION

To improve health outcomes while reducing cost to taxpayers, innovation is needed. The time to innovate the delivery of health care more efficiently and cost-effectively has never been so crucial because health care spending is at a historical high and on the rise.[108] Without innovation, we will continue to do the same things expecting different results.

108. *How Much Is*, *supra* note 29.

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ACOs Face the Demographics Dilemma of Managed Care

*Matthew Meidell**

I. INTRODUCTION

The enactment of the Patient Protection and Affordable Care Act ("ACA") in 2010 has introduced numerous innovations attempting to lower the cost of and increase access to health care, and improve patient outcomes.[1] One of the most talked about innovations is the Accountable Care Organization ("ACO") model for delivery of care. Proponents of the ACO model believe that if providers focus on the quality of care they are providing, as opposed to simply the quantity of services provided, overall healthcare quality will improve and healthcare costs will decrease.[2] On their most basic level, ACOs consist of healthcare providers across the care continuum that are all responsible for the health of a patient population.[3] The U.S. Department of Health & Human Service's ("HHS") goal is for ACOs to be reimbursed through value-based payments in order to financially incentivize providers that are part of an ACO to control costs by allowing the providers to retain money received from insurers that was not spent on care.[4] Further, ACOs may receive additional Medicare payments if certain quality measures are met, thereby incentivizing entities to not sacrifice quality of care.[5] Through this payment model the ACA motivates ACOs to push the healthcare system away from the fee-for-service model in which providers are paid for each service they provide.[6] Under the fee-for-service system, providers are incentivized to perform as many procedures and order as many services as they can regardless of whether the procedures or services actually improve

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1. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010).

2. Michaelle Gady & Marc Steinberg, *Making the Most of Accountable Care Organizations*, FAMILIES USA, (2012), http://familiesusa.org/sites/default/files/product_documents/ACO-Basics.pdf.

3. *Id.*

4. ROBERT J. KANE & LAWRENCE E. SINGER, THE L. OF MED. PRAC. IN ILL. § 18:70 (3d ed. 2015).

5. *Id.*

6. Gady & Steinberg, *supra* note 2, at 2.

or benefit the patient's health.[7] While the ACO model certainly seeks to reimburse providers differently than the fee-for-service system, the question remains as to whether healthcare organizations can survive under the ACO model.

This article will argue that only health organizations responsible for favorable patient populations (i.e., healthy, younger, educated, and economically-advantaged) under the ACO model will be able to remain financially sound in the long run. Many parallels can be drawn between Health Maintenance Organizations ("HMO") and ACOs; therefore, this article will begin by examining the initial success HMOs experienced throughout the late 1980s and early 1990s. This success will then be contrasted with what many consider to be the initial failure of the Pioneer ACOs. Finally, this article will conclude by addressing two of the most commonly touted differences between HMOs and ACOs and discuss why these differences will not help ACOs control healthcare costs any more effectively than HMOs.

II. THE HMO MODEL AND KAISER PERMANENTE'S SUCCESS

In 1970, Paul Ellwood, the executive director of the American Rehabilitation Foundation at the time, was the first to suggest the HMO concept to senior officials in the U.S. Department of Health, Education, and Welfare.[8] Ellwood viewed Kaiser Permanente's ("Kaiser") prepaid group practice ("PGP"), now referred to as an HMO, as a prototype for "HMOs that would encourage prevention, timely primary care, and economical use of resources."[9] In response to the rapidly rising Medicare and Medicaid costs, President Richard Nixon signed the Health Maintenance Organization Act ("HMO Act") into law in 1973.[10]

For decades, the Kaiser HMO has "delivered strong care coordination" and "care management" that ACOs are now looking to replicate.[11] Looking at Kaiser's approach to health care over the years reveals how it has been able to do this all while controlling costs.[12] The organization now known as Kaiser Permanente began at the height of the Great Depression when Sidney Garfield, M.D., borrowed money to start a hospital and began treating

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7. *Id.*

8. HISTORY AND HEALTH POLICY IN THE UNITED STATES: PUTTING THE PAST BACK IN 318 (Rosemary A. Stevens et al. eds., 2006).

9. *Id.* at 317-18.

10. *Id.*

11. *Accountable Care Organizations: Frequently Asked Questions and Research Summary*, COUNCIL OF ACCOUNTABLE PHYSICIAN PRACS. 3 (Jan. 31, 2013), http:// c0024345.cdn1.cloudfiles.rackspace cloud.com/LegislativeDownload.pdf.

12. DOUGLAS MCCARTHY ET AL., KAISER PERMANENTE: BRIDGING THE QUALITY DIVIDE (Joris Stuyck ed., 2009).

thousands of workers who were building the Colorado River Aqueduct Project.[13] Using the advice of an insurance agent, Dr. Garfield created a prepayment system where insurance companies would pay the hospital a fixed amount upfront for each worker.[14] With thousands of workers enrolling in the prepayment system, and the hospital receiving payment immediately, the hospital became a financial success.[15] After the Colorado River Aqueduct Project was completed, Dr. Garfield successfully replicated the prepayment model by recruiting physicians to work in a PGP that covered 6,500 workers who were building the Grand Coulee Dam.[16] After successfully replicating the PGP model a third time during World War II with shipyard workers in Richmond, Virginia, Kaiser Permanente opened to the public in 1945.[17]

Under the HMO Act of 1973, all employers with twenty-five or more employees were required to offer at least one PGP-based HMO if an HMO was available in the area.[18] This provision encouraged the development of HMOs within the context of employer/employee contracts. The number of patients enrolled in HMO plans in the U.S. skyrocketed from 3 million to 80 million from 1970 to 1999.[19] However, HMOs were "distributed unevenly across geographical areas and segments of the population."[20] In fact, many populations with a disproportionate share of poor and elderly patients did not have access to HMOs.[21] This uneven distribution resulted from the inability of HMOs to lessen the concentration of health care expenditures caused by these costly populations.[22] Kaiser was no exception to this trend. By the mid-980s, Kaiser had HMOs in Northern and Southern California, Oregon, Hawaii, Texas, Washington D.C., Connecticut, and Ohio.[23] Kaiser entered these regions with an eye towards obtaining national corporate accounts.[24] With these favorable demographics of "working-age" patients, Kaiser

13. *Our History*, KAISER PERMANENTE, http://share.kaiserpermanente.org/article/history-of-kaiser-permanente/ (last visited Sept. 30, 2015).

14. *Id.*

15. *Id.*

16. *Id.*

17. *Id.*

18. Daniel P. Gitterman et al., *The Rise and Fall of a Kaiser Permanente Expansion Region*, 81 MILBANK Q. 567, 569–70 (2003).

19. MARTIN MARKOVICH, THE RISE OF HMOS 4 (2003), http://www.rand.org/pubs/rgs_dissertations/ RGSD172.html.

20. Ellen M. Morrison & Harold S. Luft, *Health Maintenance Organization Environments in the 1980s and Beyond*, 12 HEALTH CARE FIN. REV. 81, 81 (1990).

21. *Id.*

22. Mark W. Stanton, *The High Concentration of U.S. Health Care Expenditures*, AGENCY FOR HEALTHCARE RES. & QUALITY 6 (June 2006), http://meps.ahrq.gov/mepsweb/data_files/ publications/ra19/ra19.pdf.

23. Gitterman et al., *supra* note 18, at 569.

24. *Id.*

controlled a less expensive population.[25] Gaining an early foothold in these markets proved to be crucial; as the number of HMOs increased, price competition stiffened.[26] In 1987, half of all existing HMOs had been in operation for less than three years.[27] However, from 1988 to 1990, seventy-six HMOs closed and sixty-one either consolidated or merged with other HMOs.[28] With so many HMOs failing after only a few years, Kaiser serves as a model of how managed care organizations must operate in order to remain profitable under a value-based care model.[29]

III. THE ACO APPROACH

Kaiser's focus on favorable demographics stands in stark contrast to the approach taken by modern day ACOs. The Pioneer ACO model serves as a prime example of this difference. The Department of Health and Human Services ("HHS") selected thirty-two organizations, out of over eighty applicants, to participate in the Pioneer ACO model beginning in 2012.[30] HHS selected organizations based on their "experience offering coordinated, patient-centered care, and operating in ACO-like arrangements."[31] In its Request for Applications form, the Center for Medicare and Medicaid Services ("CMS") specifically stated it would not place "limitations on applicants based on geographic region, [. . .] geographic type, or size of health system."[32] While this increased the number of eligible applicants, it also increased the type of patient populations that would be covered due to the level of variance between regional healthcare markets.[33] Therefore, certain eligible organizations would have a disproportionate share of an unhealthier and more expensive patient population.[34] This affects not only an organization's financial performance, but also its quality performance.[35]

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25. Stanton, *supra* note 22, at 2.

26. Marsha R. Gold, *HMOs and Managed Care*, 10 HEALTH AFFAIRS 189, 196 (1991).

27. *Id*.

28. Gold, *supra* note 26.

29. Yevgeniy Feyman, *Where Is the Value in Health Care?*, FORBES.COM (July 21, 2014, 12:01 AM), http://www.forbes.com/sites/theapothecary/2014/07/21/where-is-the-value-in-health-care/.

30. *HHS Names 32 Pioneer ACOs*, ADVISORY BD. CO. (Dec. 19, 2011), https://www.advisory.com/daily-briefing/2011/12/19/pioneer-aco.

31. *Selected Participants in the Pioneer ACO Model*, MODERN HEALTHCARE 1 (Dec. 19, 2011), http://www.modernhealthcare.com/assets/pdf/CH768851219.pdf [hereinafter *Participants in ACO*].

32. *Bundled Payments for Care Improvement Initiative: Request for Application*, CTR. FOR MEDICARE & MEDICAID INNOVATION 29 (Aug. 22, 2011), http://innovation.cms.gov/Files/x/Bundled-Payments-for-Care-Improvement-Request-for-Applications.pdf.

33. MARK MCCLELLAN ET AL., HEALTH POLICY ISSUE BRIEF: HOW TO IMPROVE THE MEDICARE ACCOUNTABLE CARE ORG. (ACO) PROGRAM 2 (Brookings Inst. 2014).

34. *Id*.

35. *Id*.

In response to this issue with unfavorable demographics, the Pioneer ACO Model calculates a risk adjustment to raise the financial benchmark set by CMS for certain organizations that are covering costly populations, and to pay bonuses to ACOs that keep costs below their financial benchmarks and who meet certain quality measures.[36] Even with these risk adjustments and bonuses based on quality measures, many ACOs cannot support the model, as evidenced by the fact that only sixteen of the original thirty-two Pioneer ACOs selected at the end of 2011[37] remained as of November 2015.[38] After dropping out of the Pioneer ACO program last year, the CEO of Genesys PHO remarked, "We improved utilization, we improved quality and we lowered our costs but we couldn't make the economic model work."[39] While Genesys saved Medicare more than $20 million, those savings still did not meet CMS's benchmark and, therefore, Genesys had to absorb a loss.[40] Genesys's experience with the Pioneer Model was not atypical. Another former Pioneer ACO, Sharp Healthcare, announced it was dropping out of the Pioneer ACO program because the ACO model was "financially detrimental."[41] While a number of ACOs shared $445 million of the $817 million in saved Medicare spending through 2013, three-quarters of ACOs received nothing because they failed to meet their financial benchmarks.[42] The economic model of the ACO also seems to be adversely affecting Medicare spending because in 2014 the Medicare trust fund suffered a net loss of $2.6 million under the Pioneer ACO program and the Medicare Shared Savings program.[43] Healthcare organizations participating in the Pioneer ACO model and the Medicare Shared Saving program are having difficulty keeping their costs below the financial benchmarks set by CMS even with risk adjustment.[44]

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36. *Id.*

37. *Participants in ACO*, *supra* note 31, at 1–2.

38. Melanie Evans, *More Pioneer ACOs Exit as New CMS Model Emerges*, MODERN HEALTHCARE (Nov. 4, 2015), http://www.modernhealthcare.com/article/20151104/NEWS/151109941

39. *More to the Story: A Look at ACOs Under the ACA*, AMERICAN HEALTHLINE (Oct. 13, 2014), http://www.americanhealthline.com/analysis-and-insight/features/more-to-the-story.

40. *Id.*

41. Gabriel Perna, *Sharp Healthcare Becomes Latest to Depart Medicare Pioneer ACO Program*, HEALTHCARE INFORMATICS (Aug. 29, 2014), http://www.healthcare-informatics.com/news-item/sharp-becomes-latest-depart-medicare-pioneer-aco-program.

42. Melanie Evans, *Medicare's Pioneer Program Down to 19 ACOs after Three More Exit*, MODERN HEALTHCARE (Sept. 25, 2014), http://www.modernhealthcare.com/article/20140925/ NEWS/309259938.

43. *Id.*

44. Jennifer Bresnick, *Will Inadequate Metrics Doom the Accountable Care Organization?*, HEALTHIT ANALYTICS (Oct. 20, 2015), http://healthitanalytics.com/news/will-inadequate-metrics-doom-the-accountable-care-organization.

A. A Closer Look at Genesys's Patient Demographics

The economic model of the ACO did not work for organizations such as Genesys because their patient populations could not support the model. As a Pioneer ACO, the Genesys PHO hospital network covered the Greater Flint community in Genesee County, Michigan.[45] According to the 2012 Genesys Health System Community Health Needs Assessment ("CHNA"), 15% of the residents in Genesee County earned less than $15,000 annually, and the county's unemployment rate was 11.4%.[46] The CHNA concluded that Genesee County experiences poor health, giving Genesee County a "ranking of 78 out of 82 (82 being the worst) health ranking for overall health outcomes" in 2011.[47] Without adequate risk adjustment that reflects the demographics and overall health status of ACO patient populations, ACOs are incentivized to avoid costly populations such as Genesee County.[48]

B. Favorable Demographics

Dr. Elliot Fisher, the director of the Dartmouth Institute for Health Policy and Clinical Practice, is credited with helping create the ACO concept and was instrumental in getting the ACO model into the ACA.[49] In a 2006 Medicare Payment Advisory Commission meeting, Dr. Fisher proposed the ACO concept as a solution to the rising costs of health care that could be implemented and viable for both physicians and Medicare beneficiaries nationwide.[50] However, in 2013, researchers from the Dartmouth Institute for Health Policy and Clinical Practice looked at where ACOs were actually being formed and discovered that ACOs were not being distributed evenly across the country.[51] Based off the locations of 227 ACOs, the Dartmouth researchers concluded that ACOs were less likely to form in high poverty and

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45. *2012 Genesys Health System Community Health Needs Assessment*, GENESYS HEALTH SYS. 1 (June 6, 2012), http://www.genesys.org/GRMCWeb.nsf/CHNA%20and%20GHS%20Implementation%20Plan.pdf.

46. *Id.*

47. *Id*. at 6.

48. S. Lawrence Kocot et al., *The Revised Medicare ACO Program*, HEALTH AFFAIRS (June 16, 2015), http://healthaffairs.org/blog/2015/06/16/the-revised-medicare-aco-program-more-options-and-more-work-ahead/.

49. Mark T. Morell & Alex T. Krouse, *Accountability Partners: Legislated Collaboration for Health Reform*, 11 IND. HEALTH L. REV. 225, 243 (2014).

50. Kip Sullivan, *The History and Definition of the "Accountable Care Organization,"* PHYSICIANS FOR A NAT'L HEALTH PROGRAM CAL. (OCT. 2010), http://pnhpcalifornia.org/2010/10/the-history-and-definition-of-the-%E2%80%9Caccountable-care-organization-n%E2%80%9D/.

51. *Market, Demographic Factors in Forming ACOs; Study Find First Empirical Evidence of External Market Forces at Play*, SCIENCE DAILY (Oct. 8, 2013), http://www.sciencedaily.com/releases/2013/10/131008165405.htm [hereinafter *Demographic Factors in Forming ACOs*].

rural regions.[52] As such, the study confirmed that ACO formation is driven by the demographics of patient populations.[53]

The high level of concentration and consumption of health care expenditures in the U.S. may be pushing ACOs towards favorable populations.[54] A mere ten percent of the U.S. population in 2009 accounted for sixty-five percent of healthcare expenditures.[55] The individuals included in this ten percent group tend to be aged sixty-five and older and in fair or poor health—the two lowest health rankings in a report issued by the Medical Expenditure Panel Survey.[56] As noted above, the ACO model as developed by Dr. Fisher was focused on controlling healthcare costs of this population.[57] However, as of January 2015, the Medicare ACO programs cover only 7.8 million Medicare beneficiaries.[58] This number pales in comparison to the 15.7 million patients covered by commercial ACOs or Medicaid ACOs.[59] Two maps of the U.S. prepared by the Leavitt Partners Center for Accountable Care Intelligence illustrating the percentage of the U.S. population that is covered by an ACO give a clear picture of not only the uneven distribution of ACOs across the country but also within each state.[60] There are a number of Hospital Referral Regions ("HRR") where over twenty percent of the patient population is enrolled in an ACO.[61] These HRR's include Eugene, Medford, and Bend, Oregon; Bismarck, North Dakota; Des Moines and Sioux City, Iowa; Traverse City, Michigan; and Bangor and Portland, Maine.[62] The four states with the largest percentage of its

52. *Id.*

53. *Id.*

54. *The Concentration and Consumption of Health Care Dollars in the United States*, EXCELLUS 1 (2012), https://www.excellusbcbs.com/wps/wcm/connect/7238a37f-e7b4-4a0a-b7877af0b7b4c121/Concentration+and+Consumption+FS-EX+FINAL+FALL+2012.pdf?MOD=AJPERES&CACHEID=7238a37f-e7b4-4a0a-b787-7af0b7b4c121 [hereinafter *Consumption of Health Care Dollars*].

55. *Id.* at 3.

56. Steven B. Cohen & William Yu, *The Concentration and Persistence in the Level of Health Expenditures over Time*, AGENCY FOR HEALTHCARE RES. & QUALITY 4 (Jan. 2012) http://meps.ahrq.gov/mepsweb/data_files/ publications/st354/stat354.pdf; *Consumption of Health Care Dollars*, *supra* note 54, at 3.

57. Sullivan, *supra* note 50.

58. David Muhlestein, *Growth and Dispersion of Accountable Care Organizations in 2015*, HEALTH AFFAIRS (Mar. 31, 2015), http://healthaffairs.org/blog/2015/03/31/growth-and-dispersion-of-accountable-care-organizations-in-2015-2/.

59. *See id.* (stating that 23.5 million people total are covered by ACOs and those not covered by Medicare ACO programs are covered by commercial or Medicaid ACOs).

60. *See id.* (showing the estimated percentage of the population covered by an ACO per state in Figure 5, and the estimated percentage of the population covered by an ACO per hospital referral region in Figure 6).

61. *Id.*

62. *Id.* (Figure 6); *The Dartmouth Atlas of Health Care*, DARTMOUTH INST. FOR HEALTH POL'Y & CLINICAL PRAC., http://www.dartmouthatlas.org/data/region/ (last visited Nov. 3,

population covered by an ACO include Oregon, Maine, Iowa, and Connecticut.[63] Looking at the U.S. Census data for these states shows that each of these states has a significantly lower percentage of persons living below the poverty level compared to the U.S. average.[64] Each of these states also outpaces the U.S. average in persons aged twenty-five or older with at least a high school degree.[65] Therefore, it is clear that regions with the largest ACO coverage tend to have favorable demographics, such as low levels of poverty and higher average education levels.

Moving hospitals away from fee-for-service reimbursement to value-based reimbursement under the ACO model forces hospitals to be accountable for the care they provide.[66] This movement requires hospitals to either take on the risk of up-front value-based payments or face the potential financial penalties under the Medicare ACO programs, which are designed to mimic the risks of true value-based care.[67] To lessen the blow of assuming this new risk, many ACOs, like HMOs in the 1980s and 1990s, have and will continue to gravitate to favorable populations.[68] Already many of the organizations that have dropped out of the Pioneer ACO have moved to the MSSP[69] because the MSSP allows organizations to completely avoid downside risk under track one.[70] However, the financial viability of ACOs under the MSSP are not much more encouraging given that only twenty-two percent of ACOs in the MSSP received shared saving payments in the first year.[71]

IV. AVOIDING THE SHORTCOMINGS OF HMOS

Despite this fundamental issue with the economic model of ACOs, some experts point to a number of differences between ACOs and HMOs as

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2015) (displaying an interactive map with the names of hospital referral regions across the U.S.).

63. Muhlestein, *supra* note 58 (Figure 5).

64. *State & County Quick Facts*, U.S. CENSUS BUREAU, http://quickfacts.census.gov/qfd/index.html (accessed by clicking the states of Alaska, Iowa, Massachusetts, Maine, and New Hampshire) (last updated Oct. 14, 2015).

65. *Id*.

66. Gady & Steinberg, *supra* note 2, at 1, 3.

67. KANE & SINGER, *supra* note 4.

68. *Demographic Factors in Forming ACOs*, *supra* note 51.

69. *10 of 32 ACOs Have Now Dropped Out of the Program*, THE ADVISORY BOARD CO. (Aug. 27, 2014), https://www.advisory.com/daily-briefing/2014/08/27/10-of-32-pioneer-acos-have-dropped-out [hereinafter *ACOs Have Dropped Out*].

70. AM. ACAD. OF ACTUARIES, FACT SHEET: MEDICARE SHARED SAVINGS PROGRAM & THE PIONEER ACO PROGRAM 1 (Am. Acad. Of Actuaries 2012), http://actuary.org/files/ACO_Fact_Sheet_FINAL_ 121912.pdf.

71. TIANNA TU ET AL., THE IMPACT OF ACCOUNTABLE CARE: ORIGINS & FUTURE OF ACCOUNTABLE CARE ORGS. 7 (2015), http://www.brookings.edu/~/media/research/files/papers/2015/05/12-aco-paper/impact-of-accountable-careorigins-052015.pdf.

evidence that ACOs will not suffer the same fate as HMOs.[72] Proponents of ACOs note that the designers of ACOs are aware of the HMO bust and are intent on not repeating the past.[73] Further, these proponents point to the fact that ACOs do not require patients to obtain care within their ACO.[74] Under the HMO model, generally, patients were restricted from obtaining care outside their HMO network of hospitals and physicians.[75] Current ACO legislation does not require ACO patients to obtain care from hospitals and physicians who are part of the patient's ACO.[76] CMS favors this provision as it aims to avoid the consumer backlash that occurred when HMO patients could not obtain care outside their HMO.[77] However, removing this restriction from the ACO model appears to thwart the entire purpose of ACOs—making providers accountable for their patient's health.[78] How can healthcare providers be held responsible for a patient's health outcome if providers cannot control who cares for the patient?

As stated at the beginning of this article, the ACO model seeks to move the nation's healthcare system away from the fee-for-service model towards a value-based model where payment is directly connected to the quality of care provided.[79] The purpose of tying payment directly to the quality of care patients receive is that providers will be incentivized to improve the quality of care patients receive as opposed to simply performing services to be billed.[80] The problem is that providers will have difficulty controlling the quality of care given to patients outside of their ACO system.[81] Kaiser, often referred to as the gold standard of value-based care, employs a closed group

72. Greg Freeman, *Are ACOs Really Different from HMOs?*, HEALTHLEADERS MEDIA (Nov. 27, 2013), http://healthleadersmedia.com/page-3/hep-298746/Are-ACOs-Really-Different-from-HMOs.

73. *Id.*

74. DEP'T OF HEALTH & HUMAN SERVS., CTRS. FOR MEDICARE & MEDICAID SERVS., SUMMARY OF FINAL RULE PROVISIONS FOR ACCOUNTABLE CARE ORGS. UNDER THE MEDICARE SHARED SAVINGS PROGRAM 3 (2014), *available at* https://www.cms.gov/medicare/medicare-fee-for-service-payment/sharedsavingsprogram/downloads/aco_summary_factsheet_icn907404.pdf [hereinafter SUMMARY OF FINAL RULE PROVISIONS].

75. *PPO vs. HMO*, HEALTHINSURE.ORG, http://www.healthinsure.org/ppo-vs-hmo/ (last visited Nov. 3, 2015).

76. SUMMARY OF FINAL RULE PROVISIONS *supra* note 74, at 3.

77. Austin Frakt, *Limiting Choice to Control Health Spending*, N.Y. TIMES (Sept. 15, 2014), http://www.nytimes.com/2014/09/16/upshot/limiting-choice-to-control-health-spending-a-caution.html?abt=0002&abg=1&_r=1.

78. S. Lawrence Kocot & James Colbert, *Improving Communication with ACO Patients*, BROOKINGS INST. (July 14, 2014, 10:16 AM), http://www.brookings.edu/blogs/up-front/posts/2014/07/14-medicare-aco-patient-communication.

79. Richard G. Stefanacci, *Accountable Care – But the Patient Isn't Accountable*, MANAGED CARE MAG. (July 2011), http://www.managedcaremag.com/archives/1107/1107.acos.html.

80. *Id.*

81. *Id.*

model where patients generally receive care from Kaiser physicians who facilitate effective care coordination.[82] A recent study published in the Journal of the American Medical Association "found that over a two-year period, only sixty-six percent of Medicare ACO patients are consistently assigned to the same ACO."[83] This difficulty can arise because treatments or tests performed by one provider are often unavailable or not trusted by another provider.[84] Furthermore, government studies indicate that the fragmentation of care "leads to multiple incompatible formats for medical records."[85] Moreover, communication between providers within an ACO is preferable when coordination of care plays such a significant role in efficient and effective care.[86] Allowing patients to seek care outside of their assigned ACO hinders the organization's ability to effectively coordinate care.[87]

CMS has developed thirty-three quality measures to track and incentivize quality outcomes produced by ACOs.[88] Proponents of ACOs consider quality measurement to be an essential piece of managed care that was missing from the HMO model: "HMOs talked a lot about quality but did little to measure it."[89] CMS made the thirty-three quality measures a priority for providers by requiring quality measure reporting in both the Pioneer and MSSP ACO model.[90] The ACOs enrolled in the MSSP are even allowed to receive shared saving payments as long as the ACO successfully report its quality measures in its first year—meeting quality benchmark standards are not required during the first year.[91] CMS places great importance on quality measures due to the widely held belief that "improving quality saves money."[92] The idea is that dollars will be saved by not having to re-treat a patient or remedy ineffective services previously provided.[93] However, highly effective care is often expensive, and the healthcare industry does not know what efficiencies will save costs in the long run and how much will be

82. MCCARTHY, *supra* note 12.
83. Kocot & Colbert, *supra* note 78.
84. EINER ELHAUGE, THE FRAGMENTATION OF U.S. HEALTH CARE 4 (2010).
85. *Id.*
86. Stefanacci, *supra* note 79.
87. Kocot & Colbert, *supra* note 83.
88. Freeman, *supra* note 72.
89. *Id.*
90. RTI INT'L, ACCOUNTABLE CARE ORG. 2015 PROGRAM QUALITY PERFORMANCE STANDARDS NARRATIVE MEASURE SPECIFICATIONS (2015).
91. AVALERE ANALYSIS: NO CORRELATION BETWEEN QUALITY & COST-EFFECTIVENESS AMONG MEDICARE ACOS, AVALERE HEALTH 1 (2014), http://avalere.com/expertise/life-sciences/insights/avalere-analysis-most-medicare-acos-earning-shared-savings-payments-were-be [hereinafter AVALERE ANALYSIS].
92. Frank Diamond, '*High Quality Saves Money,' or So the Story Goes*, MANAGED CARE MAG., http://www.managedcaremag.com/archives/1105/1105.costs.html (last visited Nov. 3, 2015).
93. *Id.*

saved.[94] Mark V. Pauly, PhD, Professor of Insurance and Risk Management at Wharton, argues that improved outcomes can reduced costs in some cases, though not all, although most credible economists may be reluctant to state this.[95] More empirical studies are needed to affirmatively state that improving quality yields a positive return on investment.[96] In looking at the effect of quality measures on ACOs, a recent analysis of the MSSP performed by Avalere Health Center for Payment and Delivery Innovation concluded that there is "no correlation between quality and cost-effectiveness among Medicare ACOs."[97] Multiple ACOs that have dropped out of the Pioneer program have remarked that despite their strong quality scores, they were unable to meet their benchmarks for reducing costs.[98]

V. CONCLUSION

Many ACOs will not be able to withstand the test of time because their patient populations have put them at a disadvantage. Successful managed care programs, such as the Kaiser Permanente HMO, created a viable economic model by focusing on relatively healthy and employed populations.[99] Organizations seeking to move away from the fee-for-service payment model under the Medicare ACO programs are taking on new amounts of risk by agreeing to pay penalties for keeping their costs below certain benchmarks or by receiving up-front value-based payments.[100] A number of ACOs, Medicare and commercial, are finding it difficult to thrive under this new payment model while covering costly populations such as Medicare beneficiaries, less educated patients, and economically disadvantaged patients. While preliminary studies indicate that ACOs are forming where the demographics are more favorable,[101] just as HMOs did, supporters of ACOs argue there are differences between ACOs and HMOs that will prevent ACOs from suffering the same fate as HMOs.[102] Giving patients the freedom to obtain care outside of their assigned ACO may avoid the patient backlash that HMOs faced, but it will also be detrimental to the premise of ACOs—holding providers accountable for the care they supply

94. *Id.*

95. *Id.*

96. *Id.*

97. AVALERE ANALYSIS, *supra* note 91, at 1.

98. *ACOs Have Dropped Out*, *supra* note 69; *see, e.g.*, Evans, *supra* note 42 (Franciscan Alliance participated in the Pioneer ACO program, and while it received a quality score rating of 83.7%, it did not meet its financial "benchmark for reducing the costs of patient care.").

99. *See generally Our History*, *supra* note 13 (looking the history of Kaiser Permanente reveals a clear focus of providing health care for employed populations).

100. KANE & SINGER, *supra* note 4.

101. *Demographic Factors in Forming ACOs*, supra note 51.

102. Freeman, *supra* note 72.

and the overall health of their patients.[103] Also, empirical evidence has yet to show that the ACO quality measures are helping to reduce the costs of health care.[104] Under the ACO model, organizations that do not cover favorable populations are likely to follow in the footsteps of failed HMOs.[105]

103. Kocot & Colbert, *supra* note 78; Stefanacci, *supra* note 79.
104. AVALERE ANALYSIS, *supra* note 91.
105. Freeman, *supra* note 72.

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A for Effort, I for Innovation: Hospital Readmissions Reduction Program and Its Positive Progress

*Xavier Vergara**

I. INTRODUCTION

As one of many efforts to decrease costs while maintaining or increasing the quality of health care, Section 3025 of the Patient Protection and Affordable Care Act ("ACA") established the Hospital Readmissions Reduction Program ("HRRP").[1] This program required Centers for Medicare and Medicaid Services ("CMS") to find a method to reduce payments to Acute Inpatient Payment System hospitals with excessive readmission rates.[2] The program originally provided that CMS enforce a penalty when a patient, originally hospitalized for one of three conditions (acute myocardial infarction, congestive heart failure, and pneumonia), was readmitted within thirty days of being discharged.[3] Other conditions were subsequently added to the list, including chronic obstructive pulmonary disease ("COPD") and total hip arthroplasty/total knee arthroplasty ("THA/TKA").[4] In order to carry out the program, CMS calculates a 'readmissions adjustment factor' for Acute Care Hospital Inpatient Prospective Payment System ("IPPS") hospitals.[5] The final rule contains policies aiming to shift Medicare payments from volume-based to value-based.[6] These expected rates are then compared

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1. Patient Protection and Affordable Care Act (ACA), Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified in part as 42 U.S.C.A § 3025)

2. *Id.* (codified in part as 42 U.S.C.A § 280j-3 (2010) (covering the ACA's readmission reduction program)).

3. Karen E. Joynt & Ashish K. Jha, *A Path Forward on Medicare Readmissions*, 368 NEW ENG. J. MED. 1175, 1175 (2013).

4. Bobbi Brown, *How to Survive CMS's Most Recent 3% Hospital Readmissions Penalties Increase*, HEALTH CATALYST, https://www.healthcatalyst.com/healthcare-data-warehouse-hospital-readmissions-reduction (last visited Oct. 29, 2015).

5. Jim Hoffman & Mary Cronin, *The True Financial Impact of Hospital Readmissions*, HEALTHCARE FIN. MGMT. 68, 69 (2015), *available at* http://www.kellogg.northwestern.edu/faculty/gurvich/personal/hrrp.pdf.

6. *eMRB InforAlert – Highlights and Impacts of the FY 2016 IPPS Final Rule*, ENCORE (Aug. 25, 2015), http://encorehealthresources.com/emrb-infoalert-highlights-and-impacts-of-the-fy-2016-ipps-final-rule/ ("The Administration has set measurable goals and a timeline to move the Medicare program, and the health care system at large, toward paying providers

with actual readmission rates.[7] If the readmission rates are above the projected rate, Medicare fines the hospital.[8]

While the program has in many ways achieved the overall goal of lowering readmission rates, it has met opposition from the medical community.[9] Hospitals have pushed Medicare and Congress to consider different factors when addressing readmission rates, such as a patient's socioeconomic background or situations where a patient's reason for re-admittance differs from that of the original admission.[10] Nevertheless, the program has jolted hospitals to not only take notice of high readmission rates, but to also create innovative and cost-effective methods of achieving lower readmission rates.[11]

This article argues that CMS is properly responding to concerns of high readmission rates by continuing to lower such rates in hospitals. Although the HRRP is not without fault, the policy contributes to widespread innovation and collaboration among providers and entities in the healthcare field. This article will begin by examining the negative implications of high hospital readmission rates and acknowledge the positive data associated with recent studies of the HRRP. The article will then move to an analysis of the perceived failures of the HRRP by addressing commonly voiced complaints and the backlash from the medical community. Next, the article will distinguish the commonly voiced complaints by highlighting the program's success in recent years and prove that the HRRP is accomplishing exactly what it was intended to do—lower readmission rates. The final section will expound on the success of the HRRP as creating and inviting an environment for innovation and collaboration to achieve better quality in health care. Moreover, this section will examine how innovations such as the HRRP are affected by legal, regulatory, or economic challenges, and how the program will be primed to answer those challenges while continuing to successfully

based on the quality, rather than the quantity of care they give patients. The final rule includes policies that advance that vision.").

7. Hoffman & Cronin, *supra* note 5, at 69.

8. *Id.*

9. Akin Demehin & Michael Ward, *The Readmissions Reduction Program*, TRUSTEE, May 2015, at 25, 25, *available at* http://www.trusteemag.com/display/TRU-newsarticle.dhtml?dcrPath=/templatedata/HF_Common/NewsArticle/data/TRU/Magazine/2015/May/EB readmissions-reduction-program-reassess.

10. Jordan Rau, *Senators Offer Bill to Ease Readmission Penalties on Some Hospitals*, KAISER HEALTH NEWS (June 19, 2014), http://khn.org/news/senators-offer-bill-to-ease-readmission-penalties-on-some-hospitals/; *CMS Urged to Work with Congress on HRRP Concerns*, AM. HOSP. ASS'N NEWS (June 13, 2014), http://news.aha.org/article/cms-urged-to-work-with-congress-on-hrrp-concerns.

11. *See* Colleen K. McIlvennan et al., *Hospital Readmissions Reduction Program*, 131 CIRCULATION 1796, 1798 (2015) ("The HRRP has helped forge collaborative relationships – within hospitals, between medical institutions, and in surrounding communities – that focus on improving the overall patient experience through hospitalization and beyond.").

lower readmission rates in the future.

II. IMPLICATIONS OF HIGH READMISSION RATES AND THE FIRST YEARS OF THE HRRP

The HRRP's creation arose out of concern for the high percentage of adults readmitted after hospitalization, oftentimes in situations that appeared to be discretionary or avoidable through improvements in care.[12] In addition to signaling poor quality or inefficient care, readmissions are also associated with hospital complications, functional decline, and death.[13] According to CMS, about one in five Medicare patients discharged from a hospital is readmitted within thirty days.[14] High readmission rates contribute to avoidable health expenditures in the inpatient and post-acute care setting – contributing to sixteen percent of all hospitalization expenditures.[15] In fact, a single preventable return trip to the hospital more than doubles the cost of care for Medicare patients.[16]

In only three years of the program, national readmission rates have dropped.[17] In 2013, Medicare levied the maximum penalty against 276 hospitals.[18] The average penalty amounted to an estimated $125,000 per hospital.[19] Nonetheless, CMS estimated that hospital readmissions declined by a total of 150,000 from January 2012 to December 2013 – "a substantial improvement."[20] Furthermore, for 2015, eighty-three percent of Medicare

12. Teryl K. Nuckols, *County-Level Variation in Readmission Rates: Implications for the Hospital Readmission Reduction Program's Potential to Succeed*, 50 HEALTH SERVICES RESEARCH 12, 12-13 (2015).

13. *Id*. at 13.

14. Julia James, *Medicare Hospital Readmissions Reduction Program*, HEALTH AFFS. (Nov. 12, 2013), http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_102.pdf.

15. Nuckols, *supra* note 12, at 13; *see also* Andrew S. Boozary et al., *The Medicare Hospital Readmissions Reduction Program Time for Reform*, 314 JAMA 347, 347 (2015) ("[P]atients are still being readmitted too often, potentially costing Medicare more than $26 billion annually. According to the Centers for Medicare & Medicaid Services (CMS), an estimated $17 billion of that expenditure is related to readmissions that could have been avoided.").

16. Bobbi Brown, *The Best Way to Run a Hospital Readmissions Reduction Program*, HEALTH CATALYST, https://www.healthcatalyst.com/healthcare-data-warehouse-hospital-readmissions-reduction (last visited Oct. 8, 2015) ("Medicare pays, on average, $15,000 for an episode of care without a readmission incident, but that number increases to $33,000 for a single readmission.").

17. Jordan Rau, *Most U.S. Hospitals Hit with Medicare Readmission Penalties*, PHILLY.COM (Aug. 4, 2015, 1:09AM), http://www.philly.com/philly/health/hospitals/20150804_Most_U_S__hospitals_hit_with_Medicare_readmission_penalties.html.

18. Brown, *supra* note 16.

19. *Id*.

20. Brown, *supra* note 4 ("While CMS will continue to administer fines, hospitals are seeing significant declines in readmission rates.").

patient admissions are projected to be in hospitals receiving either no readmission penalty or penalties of less than one percent.[21] These rates suggest that hospitals are beginning to work with the HRRP and find successful methods for lowering readmission rates.

III. PERCEIVED FAILURES OF THE HRRP

Despite declining readmissions, concerns about fairness and long-term sustainability arise from the HRRP penalty process.[22] A commonly voiced issue with the HRRP is the lack of risk adjustment for key sociodemographic factors that influence the likelihood of readmission.[23] Individuals with lower socioeconomic status have higher readmission rates due to a number of factors, such as language and cultural barriers, failure to comply with discharge instructions, lack of resources to purchase medications, and fewer options for post-discharge care.[24] The issues surrounding socioeconomic factors suggest that hospitals serving larger numbers of low-income patients are twice as likely to receive penalties than hospitals serving fewer poor patients.[25]

Another criticism of the HRRP is the presence of numerous factors that are outside of a hospital's control that translate into penalties.[26] Readmission rates are not only affected by providers' actions but also by a number of clinical and nonclinical factors beyond provider control.[27] Readmissions that occur a few days after discharge may reflect poor care coordination or inadequate recognition of post discharge instructions;[28] however, readmissions four weeks later are far more likely due to the underlying severity of a patient's disease.[29]

Furthermore, unavoidable readmissions contribute to the high rates adversely affecting hospitals.[30] Many argue CMS should not hold hospitals accountable for unplanned, unrelated admissions because they are

21. Cristina Boccuti & Giselle Casillas, *Aiming for Fewer Hospital U-turns: The Medicare Hospital Readmission Reduction Program*, KAISER FAMILY FOUND. (2015), http://kff.org/medicare/issue-brief/aiming-for-fewer-hospital-u-turns-the-medicare-hospital-readmission-reduction-program/.

22. Demehin & Ward, *supra* note 9, at 25.

23. *Id.*

24. *See* James, *supra* note 14, at 4.

25. *Id.* at 3-4.

26. Dehemin & Ward, *supra* note 7, at 26.

27. *Id.* ("For example, Medicare beneficiaries with six or more chronic conditions have a readmission rate of 25 percent, compared with 9 percent for those having only one or no chronic condition.").

28. Joynt & Jha, *supra* note 3, at 1177.

29. *Id.*

30. Dehemin & Ward, *supra* note 9, at 25 ("Many readmissions are unavoidable due to the natural progression of disease, accepted treatment protocol or a patient's preference.").

unpredictable and not typically preventable; however, these readmissions are included in the HRRP penalty.[31] While the list of the HRRP's perceived faults extends past the few examples given here and there are undoubtedly economic and social issues that must be addressed, the HRRP has achieved its intended objective of lowering hospital readmission rates across the nation in the few years since its implementation.[32]

IV. ACHIEVING THE INTENDED OBJECTIVE

Decreasing readmission rates for many patients translated to an estimated 150,000 fewer hospital readmissions between January 2012 and December 2013.[33] Even though it may be argued that external factors attribute to this decline in readmissions, the HRRP demonstrates either through direct or indirect effects that it is achieving its intended purpose.[34]

The program is intended to impose incentives (and a sense of pressure) on hospitals to improve performance by avoiding preventable readmissions through various methods.[35] However, the public may perceive success in policy making or the political success of a program differently.[36] Many different ways to measure the success of the HRRP exist. One could measure success by asking whether the program achieved outcomes in line with its stated objectives, whether the program benefitted a specific subgroup, whether the program achieved economic success, or whether the program was an efficient use of resources.[37]

The HRRP arguably achieves all four measures of success. The program has achieved economic success by encouraging hospitals to take measures to reduce their readmission rates lest they face a financial penalty.[38] Jim Hoffman, COO of Besler Consulting, and Mary Cronin, Director of Product Development at Besler Consulting, looked to answer the question of whether

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31. *Id.* at 26.

32. McIlvennan et al., *supra* note 11, at 1797 ("According to recently released U.S. Department of Health and Human Services data, from 2007 to 2011, the all-cause 30-day readmission rate among Medicare beneficiaries held relatively constant at nineteen percent to nineteen and a half percent; in 2012 and 2013, this rate fell to eighteen and a half percent and seventeen and a half percent, respectively.").

33. *Id.*

34. *Id.* ("Although these favorable trends may reflect any number of other changes occurring over this period, the temporal relationship argues that the HRRP may be meeting its intended purpose, to reduce hospital readmissions and to decrease CMS spending.").

35. Kathleen Carey & Meng-Yun Lin, *Readmissions to New York Hospitals Fell for Three Target Conditions from 2008 to 2012, Consistent with Medicare Goals*, 34 HEALTH AFFS. 978, 979 (2015).

36. Nuckols, *supra* note 12, at 13 ("Success in the policy making process and political success are both based on perceptions by the public; therefore, policies can perform poorly on these dimensions despite being programmatic success and vice versa.").

37. *Id.*

38. Hoffman & Cronin, *supra* note 5, at 73.

the readmissions penalty exceeds or is lower than the revenue received from readmission after the cost of those admissions is taken into consideration.[39] In reviewing publicly available nationwide claims, cost-to-charge ratios, and readmission penalty data, Hoffman and Cronin found positive results for the HRRP.[40] In 2014, 2,225 facilities were penalized for excessive readmissions.[41] Of those facilities, 502 would have generated at least $100,000 more if they had eliminated readmission rates.[42] Other hospitals would have had a smaller positive financial impact but no hospital in the country would have been negatively impacted for eliminating excess readmission.[43] The statistics show that the HRRP and the cost of lowering readmission rates does in fact outweigh the cost of a possible penalty under the program.

The HRRP also achieves operational success because it is implemented in accordance with other objectives apart from lowering readmission rates.[44] For the HRRP, operational success could be defined as whether hospitals respond in a manner consistent with the underlying motivations of improving quality of care and reducing costs.[45] This does not mean the program cannot grow and change with each year.[46] To the contrary, this leads to innovation and achievement of other types of success, such as working not to harm specific subgroups like hospitals that primarily serve low-income populations.[47]

Another favorable study conducted by Kathleen Carey, Professor at Boston University School of Public Health and Meng-Yun Lin, Research Data Analyst in General Internal Medicine at the Boston Medical Center, investigated the intended impact of the HRRP.[48] The study examined changes in thirty-day readmissions before and after the HRRP's introduction by comparing three groups: Medicare patients admitted for three conditions targeted by the HRRP in New York State; Medicare patients with other conditions; and patients with private insurance.[49] They found that Medicare thirty-day readmissions fell for the three conditions targeted by CMS –

39. *Id.* at 72 ("Is excess readmission revenue, minus the variable cost related to those admissions, greater or less than the readmissions penalty?").

40. *Id.* at 71-72.

41. *Id.*

42. *Id.* at 73.

43. *Id.*

44. Nuckols, *supra* note 12, at 13.

45. Nuckols, *supra* note 12, at 14 ("In terms of improving quality, a recent meta-analysis of randomized trial found that interventions designed to prevent readmissions tended [sic] be moderately effective.").

46. *Id.* at 16.

47. *Id.*

48. Carey & Lin, *supra* note 35.

49. Carey & Lin, *supra* note 35, at 980.

consistent with the goals of the program.[50] They also found that although reductions were not as great for the target group, the Medicare comparator group's readmission rate dropped considerably.[51]

Through the analysis of the HRRP and the data yielded to date, many signs point to the program not only meeting its intended objectives but also promoting and influencing innovation throughout the healthcare field.

V. GRADING HIGH FOR INNOVATION

Another strong implication of the HRRP has been its influence in the medical field by pushing for innovation and collaboration between all players involved. By understanding the negative implications of high readmission rates combined with the perceived issues of the program in its few years, it is evident that hospitals, nurses, pharmacies, legislators, and even researchers have found ample motivation for suggesting and promoting innovative solutions.[52] Such examples come from hospitals that look to promote more collaborative 'Care Transitions' addressing issues surrounding medication for patients.[53] Such issues include when patients leaving a hospital fail to fill their prescriptions, feel too ill to travel, or simply do not understand the importance of immediately beginning medication.[54] To combat these issues, certain pharmacy departments enacted strategies to reduce readmission by focusing on medication-related targets.[55] For example, Barnes-Jewish Hospital in St. Louis, Missouri implemented bedside prescription transactions to enable patients to leave the hospital with their medication as opposed to getting it for themselves later.[56] The hospital pharmacy at Einstein Medical Center in Philadelphia, Pennsylvania developed a multidisciplinary initiative - Reconciliation, Education, Access, Counseling, Healthy Patient at Home ("REACH") - which cut its number of readmissions within thirty days by thirty percent in high-risk heart patients.[57] In this extensive program, a

50. *Id.* at 983.

51. *Id.*

52. *See generally* Jo Ann Brooks, *Reducing Hospital Readmissions: A Closer Look at the Medicare Hospital Readmissions Reduction Program*, 115 AM. J. OF NURSING 62, 64 (2015) ("Improving information sharing among care providers, patients, and families during care transitions may improve patient outcomes, keep patients safer at home, and prevent unplanned readmissions.").

53. *Improving Care Transitions to Reduce Readmissions*, HEALTHCARE FIN. MGMT. ASS'N 1, 1 (2014) ("Given that many patients, especially those with chronic conditions, use more than one pharmacy and take medications prescribed by more than one physician, the room for error between hospital and after-care setting abounds.").

54. *Id.* at 2.

55. Kelly A. Green Boesen et al., *Hospital Readmissions Reduction Program: Implications for Pharmacy*, 72 AM. J. HEALTH SYS. PHARMACY 237, 240 (2015).

56. *Id.*

57. *Id.*

patient's prescriptions are compared at arrival and departure and the staff verifies dosages and checks for missing or duplicative items.[58] Hospital staff meet with patients in their rooms before discharge, review each medication, and provide pictures of each medication and instructions for use.[59] Hospitals send patients home with medications even if it means billing patients later or pursuing insurance claims at a later date.[60] After discharge, a follow-up phone call is made within three days and another is made after one month.[61] The Einstein Medical Center believes that doing all of the above leads to healthy patients at home who are at low risk of being readmitted.[62]

Additionally, evaluating the effect the number of nurses staffed at a hospital has on readmission may help improve both readmission rates and health care quality.[63] "Nurses who work in well-staffed hospitals have the time and the resources to more effectively execute the care processes that influence readmissions. They are also better equipped than other nurses to monitor for complications and adverse events that increase readmission risk."[64] In a 2013 study, researchers found that hospitals with higher nurse staffing had a twenty-five percent lower chance of being penalized than hospitals with less nursing staff.[65] In addition to increasing the nursing staff, some hospitals have assigned nurses to visit recently discharged patients at home to prevent the need for readmission by ensuring the patients are properly taking care of themselves.[66]

In remediating these regulatory and social issues, healthcare providers are not the only ones who must act. Between March and June of 2014, both the Senate and House of Representatives introduced bipartisan-backed bills that would revise the HRRP to adjust for certain socioeconomic and health factors that increase the risk of a patient's readmission.[67] A replacement bill

58. *Id.* (the "Reconciliation" prong of REACH).

59. *Id.* (the "Education" prong of REACH).

60. *Id.* (the "Access" prong of REACH).

61. *Id.* (the "Counseling" prong of REACH).

62. *Id.* (the "Health Patient at Home" prong of REACH).

63. Matthew D. McHugh et al., *Hospitals with Higher Nurse Staffing Had Lower Odds of Readmissions Penalties Than Hospitals with Lower Staffing*, 32 HEALTH AFFS. 1740, 1740 (2013) ("It is known, however, that when nurses work inadequately staffed environments, the delivery of these care processes is hampered.").

64. *Id.* at 1740-41.

65. *Id.* at 1742 ("Among a national sample of hospitals, we found that even after closely matching on hospital and patient population characteristics, hospitals with better registered nurse staffing levels were significantly less likely to be penalized under the CMS HRRP than otherwise similar hospitals that were less well staffed."); *see id.* at 1744.

66. Jordan Rau, *Medicare Fines 2,610 Hospitals in Third Round of Readmission Penalties*, KAISER HEALTH NEWS (Oct. 2, 2014), http://khn.org/news/medicare-readmissions-penalties-2015/.

67. *A Bill That Deals with Unfair HRRP Penalties*, AM. HOSP. ASS'N NEWS, Mar. 2014, at 1; Rau, *supra* note 10.

introduced in March 2015, the "Establishing Beneficiary Equity in the Hospital Readmission Program Act" would require CMS to reevaluate the HRRP and improve overall quality of care, increase accountability for all inpatient hospitals, and further reduce preventable Medicare readmissions.[68] This is an example of the environment the HRRP constantly invites to address the program's negative ramifications.

Perhaps the strongest display of incentivized innovation through the HRRP is the new Enterprise Data Warehouse (EDW) mainframes that hospitals are beginning to incorporate in order to join the digital age and track numbers of patients and readmissions faster than ever.[69] EDWs can help solve reporting burdens by enabling users to access integrated views of financial, clinical, and operational data from throughout the enterprise and data from inpatient and outpatient settings, as well as generating automatic reports to ensure that data gets to the correct audience at the right time.[70] Beyond reporting, another benefit includes business intelligence tools that allow hospitals to drive real cost and quality improvement initiatives such as computed baseline for all quality measures, tracking success in certain interventions or improvements, and ensuring the ability to measure and sustain results over the long term.[71] In fact, at one large health system results have been impressive.[72] In just six months after implementing an EDW, the health system achieved twenty-one percent seasonally-adjusted reduction in thirty-day heart failure readmissions, a fourteen percent seasonally-adjusted reduction in ninety-day heart failure readmissions, and a sixty-three percent increase in post-discharge medication reconciliation.[73]

CMS has not circumvented the call to innovation and improvement of the program. They too have instituted a number of programs in accordance with the HRRP to further prevent and reduce readmissions.[74] The Hospital Compare website provides an online database on hospital readmission rates; CMS Innovation Center has new payment and service delivery models as well as funding grants known as the Health Care Innovation Awards; and the Partnership for Patients launched a variety of public-private partnerships with more than 3,700 hospitals to improve patient safety and care transitions.[75]

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68. *Report, Hospital Leaders Make a Case for Revamping Readmissions Penalties*, AM. HOSP. ASS'N NEWS (Mar. 20, 2015), http://news.aha.org/article/a-bill-that-deals-with-unfair-hrrp-penalties ("S. 688/H.R. 1343 will 'greatly improve the fairness of readmission penalties by taking into account both the proportion of the hospital's patients eligible for both Medicare and Medicaid and the patients' sociodemographic status.' ").

69. Brown, *supra* note 16.

70. *Id.*

71. *Id.*

72. *Id.*

73. *Id.*

74. Brooks, *supra* note 52, at 64.

75. *Id.*

Through cutting edge technological improvements, all players involved in health care, including pharmacies, nurses, hospitals, and even Congress can increase the quality of health care while lowering readmission rates.

VI. CONCLUSION

In its few years, the HRRP has been a strong example of how a penalty-based incentive program can jolt healthcare providers into taking a closer look at their practices and care.[76] The broadest goal of the ACA was to promote efficiency and quality health care in all sectors and the HRRP facilitates that goal.[77] Despite some pushback such as concern over the program's unintended effect on certain (low-income patient based) hospitals,[78] the ACA charged CMS with an overarching goal—to address and lower readmission rates. Through many interventions, CMS, hospitals, and other healthcare providers have answered the call.[79] Moreover, the HRRP has promoted an environment of cooperation and teamwork among all providers that cultivates growth and innovation, which only furthers the progress made in reducing readmission rates. Notwithstanding the growing pains that any pilot program certainly will have, the steady decline in readmission rates along with the response in learning how to avoid penalties demonstrates that the HRRP can continue to succeed.

76. Rau, *supra* note 66 ("The program was popular among nurses and doctors, with one saying we 'understand, we know the importance of it,' that 'in order to get a response from administration, you have to penalize.'").

77. Sara Rosenbaum, *The Patient Protection and Affordable Care Act: Implications for Public Health Policy and Practice*, 126 PUBLIC HEALTH REP. 130, 130 (2011) ("A third aim is to improve health-care value, quality, and efficiency while reducing wasteful spending and making the health-care system more accountable to a diverse patient population.").

78. Boozary et al., *supra* note 15, at 347.

79. McHugh et al., *supra* note 63 (discussing the positive effects of a hospital's high nurse staff on readmission rates); *see* also Boesen, *supra* note 55, at 240.

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The Sunshine Act: Casting a Shadow on Health Care Innovation

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I. INTRODUCTION

The Physician Payment Sunshine Act ("Sunshine Act")[1] was enacted with the Patient Protection and Affordable Care Act in 2010.[2] The Sunshine Act was proposed in 2007 by two senators who sought to promote honesty and full disclosure of the financial relationships pharmaceutical companies enter into with physicians.[3] In short, the Sunshine Act requires all "applicable manufacturers" to report any payments or transfers of value to physicians or teaching hospitals,[4] the hope being that this required disclosure will deter any corrupt financial influences on research, education, and physicians' clinical judgment.[5] The Sunshine Act takes a different approach to transparency by relying on self-reporting mechanisms, which shift the burden from whistleblowers and government investigations to the organizations themselves.[6] The Sunshine Act considerably impacts the business of

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1. The Act was officially "rebranded" the Open Payments Program but is colloquially referred to as the Sunshine Act. *See* Shirley Chen, *A Review of the Sunshine Act's Open Payments Program: Are Patients Still in The Dark?*, 27 LOY. CONSUMER L. REV. 358, 360 (2015).

2. Igor Gorlach & Genevieve Pham-Kanter, *Brightening Up: The Effect of the Physician Payment Sunshine Act an Existing Regulation of Pharmaceutical Marketing*, 41 J.L. MED. & ETHICS 315, 317 (2013).

3. Alexandros Stamatoglou, *The Physician Payment Sunshine Act: An Important First Step in Mitigating Financial Conflicts of Interest in Medical and Clinical Practice*, 45 J. MARSHALL L. REV. 963, 976 (2012); Paul R. Lichter, *Implications Of The Sunshine Act – Revelations, Loopholes, and Impact*, 122 OPHTHALMOLOGY 653, 653, (2015) ("Senator Grassley intended to shine light on companies that made payments to physicians and on the amounts of money that physicians and other providers received from industry; he hoped this would influence more cost-effective practice patterns.")

4. *See* Scott A. Memmott & Jennifer L. Clarke, *The Proposed Rule on Transparency Reports: Shedding Light on The Sunshine Act*, 14 J. HEALTH CARE COMPLIANCE 13, 13 (2012), (explaining that an applicable manufacturer is an entity that manufactures drugs, devices, biologicals, and medical supplies covered by Medicare, Medicaid, or the Children's Health Insurance Program).

5. *Fact Sheet for Physicians: Open Payments*, CTRS. FOR MEDICARE & MEDICAID SERVS., at 1, http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Downloads/Physician-fact-sheet.pdf.

6. Joshua E. Perry et al., *Trust and Transparency: Patient Perceptions of Physicians'*

manufacturers and physicians, and its proponents hope to change the way patients approach their healthcare decisions.[7] Despite its underlying noble intentions, the Sunshine Act is unexpectedly affecting physicians who dedicate themselves to advancing the healthcare industry through research and development. The Act is casting a negative shadow on the relationships with industry that make innovation possible. This article will argue the Sunshine Act has caused physicians to refrain from participating in beneficial industry relationships because of their fear that public response to the required disclosures will be misguided and result in misinterpretation of the data. Further, this article will argue that the physician response may be unfounded and an unnecessary hindrance to innovation and advancement because patients will not take the necessary steps to access, thoughtfully consider, and then confront their physicians regarding their financial ties to industry actors.

II. BACKGROUND

The Sunshine Act requires all applicable manufacturers to report to the Centers for Medicare and Medicaid Services ("CMS") on three broad categories: (1) general payments or transfers of value, (2) research payments,[8] and (3) "ownership and investment interests in manufacturers held by physicians as well as their immediate family members."[9] Manufacturers are required to report their annual data to CMS by the ninetieth day of each calendar year.[10] CMS then aggregates this data and posts it on the CMS Open Payments website.[11] Penalties for failing to report could be severe—an unreported payment could incur penalties ranging from $1,000 to $10,000 per indiscretion, with a maximum of up to $150,000 per year.[12] Manufacturers are subject to even more severe penalties if they

*Financial Relationships With Pharmaceutical Companie*s, 42 J.L. MED. & ETHICS 475, 475 (2014).

7. *The Sunshine Act: Increasing Transparency or Opening Pandora's Box*, SHYFT ANALYTICS (June 28, 2012), http://shyftanalytics.com/shyft-insights/the-sunshine-act-increasing-transparency-or-opening-pandoras-box, ("[I]t is hoped that this mandate will elevate public concern that their patient care is being compromised by manufacturer-physician conflicts-of-interest.").

8. *See* Elizabeth Richardson, *Health Policy Brief: The Physician Payments Sunshine Act*, HEALTH AFF., 2 (Oct. 2, 2014), http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=127, (explaining these payments will be reported in a separate section so it does not appear that individual physicians are profiting the entire amount of a research grant).

9. *Id.*

10. Memmott & Clarke, *supra* note 4.

11. *See The FACTS About Open Payments Data*, CMS, https://openpaymentsdata.cms.gov (last visited Oct. 23, 2015).

12. Stamatoglou, *supra* note 3, at 978.

knowingly fail to report penalties.[13] Manufacturer penalties range from $10,000 to $100,000, with a maximum of up to $1 million per year.[14] Certain types of value transfers are excluded from the reporting requirement, including free drug samples intended for patient use and payments for products that are still in the course of development.[15] Reporting must be done with specificity, designating both the nature and form of the payment made.[16] The hope is that these disclosures will improve "health care quality, [lower] health care costs, and [engage] consumers in decision making about their health care."[17]

III. FINANCIAL TIES AND THEIR PLACE IN THE INDUSTRY

It is no secret that drug manufacturers use incentive-based programs to market their products to physicians, but are these relationships necessarily a bad thing?[18] This gift-giving relationship can be beneficial to the healthcare industry because the collaboration between physicians and manufacturers can bring about swifter improvements in patient care.[19] However, proponents of the Sunshine Act cite to physicians' impaired medical judgment as the main driving force behind the need for transparency.[20] Financial incentives and gifts have the potential to influence physicians to prescribe certain manufacturers' products more frequently than they would have otherwise.[21]

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13. *Id.*

14. *Id.*

15. Richardson, *supra* note 8, at 2-3; *See* 42 C.F.R. § 403.904(h) for a full list of excluded payments.

16. Memmott & Clarke, *supra* note 4, at 15.

17. Chen, *supra* note 1, at 358-59 (quoting Ruth E. Granfors, *The Open Payments Program: Enforcing Transparency Under the Sunshine Law*, HEALTH CARE LAW ENFORCEMENT & COMPLIANCE 23, 26 (2014)).

18. Audrey B. Uknis, *President's Perspective: Will the Physician Payment Sunshine Act Shed Light on Conflicts of Interest?*, THE RHEUMATOLOGIST (Jul. 1, 2013), http://www.the-rheumatologist.org/article/presidents-perspective-will-the-physician-payment-sunshine-act-shed-light-on-conflicts-of-interest/?singlepage=1 ("It is also true that relationships between physicians and manufacturers are often helpful in advancing the science of discovery and facilitating the lifesaving and quality of life-enhancing changes to our medical practices that we often have seen in the past two decades.").

19. *See* Perry, *supra* note 6, at 475 ("The Institute of Medicine described in its 2009 report that these relationships have the potential to produce positive collaborations that improve patient care and public health.").

20. Stamatoglou, *supra* note 3, at 977; *see* Allison M. Whelan, *Partly Cloudy: Why the Physician Payment Sunshine Act Will Not Result in More Informed Patients*, 9, http://www.mnbar.org/docs/default-source/sections/partly-cloudy-why-the-physician-payment-sunshine-act-will-not-result-in-more-informed-patients.pdf?sfvrsn=6 (last visited Oct. 31, 2015) (explaining that "transparency is meant to allow patients to identify potential physician conflicts of interest and influences on their physician's medical judgment").

21. *See* Chen, *supra* note 1, at 361 (explaining that those who accepted free meals from drug companies were more likely to request that the companies' drugs be added to a hospital formulary).

Often, as a patient's sole source of information and advice, physicians are depended on to make judgments that are "wholly loyal to the patient's therapeutic needs and unaffected by other interests."[22] It is the violation of this duty that has sparked the perceived need for more transparency.[23]

The Sunshine Act places a heavy burden on manufacturers to provide accurate data of their financial interactions with physicians and teaching hospitals.[24] The Sunshine Act discourages manufacturers from pursuing beneficial relationships with physicians by means of imposing burdensome reporting measures and severe penalties for noncompliance.[25] However, it appears that the Sunshine Act may provide the most deterrence due to physician concern for their public perception. The threat of public backlash from disclosing financial ties is enough incentive for many physicians to scale back their efforts in promoting research, innovation, and advancement in their field.[26]

In addition to manufacturers and physicians, patients also play a significant role under the Sunshine Act. The Sunshine Act assumes patients will thoughtfully consider the disclosures and will thus deter dishonest influence on physicians.[27] However, it is unclear whether patients will actually access and consider this information in any meaningful manner, making the threat of public backlash an unnecessary inhibition to the sharing of knowledge and expertise.[28]

IV. PHYSICIANS CONCERNED OVER POTENTIAL MISUNDERSTANDINGS OF THEIR FINANCIAL TIES TO INDUSTRY

The Sunshine Act has raised real concerns amongst physicians across every specialty, even though it does not require any direct participation on

22. Stamatoglou, *supra* note 3, at 967.

23. Uknis, *supra* note 18 ("As physicians, we are duty bound to remain free from conflict of interest that may influence our patient care decisions. There is no question that a conflict of interest may serve to undermine the trust that is essential to the therapeutic doctor-patient relationship. The critical issue on which we should focus is that transparency should help to maintain this essential trust.").

24. Richardson, *supra* note 8, at 4.

25. *See The Impact of Health Care Reform on Academic Cancer Centers*, NAT'L COMPREHENSIVE CANCER NETWORK, http://www.nccn.org/professionals/meetings/oncology_policy_program/pdf/2014_health_care_reform_ summit_summary.pdf (last visited Nov. 29, 2015).

26. Richardson, *supra* note 8, at 5.

27. Perry et al., *supra* note 6, at 477 ("[T]he promise of increased transparency includes an additional potential benefit beyond improved levels of trust between the patient and physician. Open Payments aim to improve levels of sophistication and awareness among patients, in an effort to further educate and empower health care consumers consistent with so-called market-driven approaches to health care.").

28. *See* Lichter, *supra* note 3, at 654, for a discussion that evidence exists that the public does not use existing health-related databases to help their healthcare decision.

their part. Physicians are encouraged, but not required, to register on the CMS Open Payments website so they may review the data published about them and check for accuracy.[29] A survey done after the website launched in September 2014 found that forty-six percent of the physicians surveyed visited the CMS website to ensure accuracy of the data.[30] Of the physicians who did visit the website, sixty-two percent of them found inaccuracies in the data regarding their financial ties with manufacturers.[31] CMS recommends that physicians keep a record "of all payments and transfers of value received from industry" so the physicians may reconcile with the reporting entities any discrepancies the reporting entities find.[32] The Sunshine Act allows forty-five days for physicians to review and confirm accuracy of the data reported before it is released to the public via the Open Payments Website.[33] Physicians' concerns over the potential negative reception of their financial relationships with the industry may be heightened by the frequency of inaccuracies in the data; however, for busy physicians, forty-five days may not be enough time to carefully review data submitted for the previous twelve months.[34] Physicians are put in a difficult position because of the fear that consumers may perceive inaccurate data in an unfavorable way, yet they have very little time to correct inaccuracies.[35]

A study published by BBC disclosed that of "the world's ten largest pharmaceutical companies, nine of them spent more on sales and marketing than they did on research and development in 2013," with the majority of these marketing efforts focused on physicians.[36] Despite this statistic, a majority of physicians take the view that accepting items from manufacturers, such as free drug samples or consulting agreements, does not

29. *Fact Sheet for Physicians: Open Payments*, *supra* note 5, at 1.

30. Chen, *supra* note 1, at 366.

31. *Id.* at 365.

32. Peter Loftus, *Doctors Face New Scrutiny Over Gifts*, WALL ST. J. (Aug. 22, 2013, 7:57 PM), http://www.wsj.com/articles/SB10001424127887323455104579014812178937016.

33. *Fact Sheet for Physicians: Open Payments*, *supra* note 5, at 4.

34. Richardson, *supra* note 8, at 4; Chen, *supra* note 1, at 365.

35. Peter Frost et al., *Obamacare Sunshine Act Sheds Light on $3.5B Paid to Doctors*, CHI. TRIB. (OCT. 1, 2014), http://www.chicagotribune.com/business/ct-sunshine-act-1001-biz-20141001-story.html (stating that the data published is "significantly incomplete, and physician and industry groups have raised concerns about accuracy and context."); *Bracing for the Physician Payment Sunshine Act*, THE ADVISORY BOARD CO.: HEALTH CARE INDUS. COMM., at 1, https://www.hunton.com/files/Publication/f6ff11b1-a9e9-4321-a6ea-340044695e59/Presentation/PublicationAttachment/5d21979f-4295-4448-9f01-3f2a7e47fb13/Physician_Payment_Sunshine_Act.pdf, ("Some physicians have expressed concerns that their reputations could be damaged by inaccurate public reporting about the payments they have received from manufacturers.").

36. Chen, *supra* note 1, at 359 ("[I]n 2012, while $3 billion was spent in the United States marketing to consumers, a whopping $24 billion was targeted at physicians.").

violate their ethical responsibilities.[37] Further, most of these physicians also deny that any kind of incentive from the industry influences prescribing habits, yet years of data suggests otherwise.[38] While incentives influence physicians in varying degrees, data collected over a thirty-year span indicates that physician-industry relationships can compromise a physician's objectivity and judgment.[39] These financial relationships can have such a negative impact on a physician's judgment that they could "compromise patient care and jeopardize public trust."[40] The Sunshine Act seeks to remedy this behavior.[41] While this is certainly a noble notion, the practical effects may not yield the intended results.

Physicians have grave concerns over the effect of the required reporting in relation to their public perception and the shadow cast over industry relationships as a whole.[42] The effectiveness of the Sunshine Act relies on the active participation of patients to seek out the information being reported and to improve their knowledge about potential physician biases.[43] Physicians worry patients may not be able to easily "distinguish compensation for research-related services from payments of a more promotional nature."[44] Patients may misunderstand certain arrangements and assume that a physician's judgment is compromised because of his or her financial interests.[45] For example, a surgeon who helped invent a certain product and thereby holds patents on that product may appear to have high levels of compensation from a manufacturer.[46] Such data may give a patient the impression that a physician has a financial incentive to use a certain

37. Perry et al., *supra* note 6, at 475 (citing to M.A. Morgan et al., *Interactions of Doctors with the Pharmaceutical Industry*, 32 J. OF MED. ETHICS 559, 562 (2006) ("However, while physicians are adamant in their denial that financial relationships inappropriately influence their personal medical decision making, studies consistently show that physicians believe these relationships may cause *other* physicians to be biased in their prescribing behavior." (emphasis added)).

38. *Id.* at 477.

39. *Id.*

40. *Id.* at 475.

41. Stamatoglou, *supra* note 3 at 976.

42. *Id.* at 476.

43. *See generally* Whelan, *supra* note 20 at 13 ("[Disclosure laws] place great—and perhaps excessive—responsibility on patients, and essentially require patients to police their doctors' behavior and determine the impact of industry relationships on their doctors' medical judgments.").

44. Perry et al., *supra* note 6, at 476.

45. *Id.*

46. *See* Elizabeth Hofheinz, *Do Sunshine Act Disclosures Hurt Ortho Innovation?*, ORTHOPEDICS THIS WEEK (Oct. 27, 2014), http://ryortho.com/2014/10/do-sunshine-act-disclosures-hurt-ortho-innovation-holy-grail-of-registries-ramping-up-and-more/ (expressing concern by an orthopedic surgeon over the reporting category entitled "General Non-Research Related Payments" under which his compensation resulting from the patent he holds on popular implant technologies and products is reported).

product, when in actuality the physician does not get paid to use that company's product.[47]

Physicians are also concerned that sensationalized reporting by the media may inaccurately influence their public perception.[48] The CMS Open Payments website practically gives journalists leads on stories by explicitly disclosing which physicians are receiving the highest compensation from which manufacturers.[49] Physicians have expressed concern that their names may end up in a headline one day, even if resulting from a legitimate financial arrangement.[50] For instance, Stephen S. Burkhart, an orthopedic surgeon, found himself at the top of the list in an article published by the *Wall Street Journal* listing the top paid surgeons based on consulting fees and royalties.[51] The article suggested that there may be a "dark side" to physicians receiving these top payments when in fact, Dr. Burkhart simply held twenty-eight patents for which the manufacturer had been assigned the intellectual property rights.[52] The payments received by Dr. Burkhart were for legitimate innovation and advancement in patient care, yet the media skewed the story to make it appear that something less than ethical was occurring.[53] The media's vilification of physicians who receive royalty payments for products they have developed discourages innovators from pursuing relationships with the industry in order to develop their products.[54] Physicians are concerned that the disclosure of their financial ties with manufacturers may damage the public's trust in the medical community through patient misunderstanding, as well as misguided reporting in the media.[55]

V. FEAR OF BEING PUBLISHED ON THE OPEN PAYMENTS WEBSITE IS DETERRING PHYSICIANS FROM PARTICIPATING IN CRITICAL RELATIONSHIPS AND LEARNING OPPORTUNITIES

The negative picture painted by the Sunshine Act's required disclosures has led many physicians to reconsider their relationships with manufacturers

47. The physician does not receive royalties when he personally uses the device he helped invent, thereby preventing any financially-driven decisions to use his own product. *Id.*

48. *Id.*

49. *See* Niam Yaraghi, *Pharma Pays $825 Million to Doctors and Hospitals, ACA's Sunshine Act Reveals*, BROOKINGS (Oct. 23, 2014, 7:30 AM), http://www.brookings.edu/blogs/techtank/posts/2014/10/23-open-payments-cms.

50. *Id.*

51. Hofheinz, *supra* note 46.

52. *Id.*

53. *Id.*

54. Laura Dyrda, *Post Sunshine Act: How Spine Surgeon Relationships With Industry Are Evolving*, BECKER'S SPINE (June 10, 2014, 3:07 PM), http://www.beckersspine.com/spine/item/21107-post-sunshine-act-how-spine-surgeon-relationships-with-industry-are-evolving.html.

55. Hofheinz, *supra* note 46.

and potentially scale back on activities that could lead to innovation and advancement within the health care industry.[56] Yet these are the physicians who have the greatest opportunity to recognize gaps in knowledge and procedures and "to innovate and to perform basic and clinical research related to the development of new. . .devices."[57] Physicians are crucial to the advancement of medicine and oftentimes do not possess the funding or the time to "develop, produce, and distribute innovative medical and surgical products independently."[58] Funding is difficult to secure from sources other than pharmaceutical and device companies.[59] The federal government does offer limited grants, and certain specialty organizations attempt to contribute; however, these resources are not enough to fund a majority of the trials occurring today.[60] Without physicians' relationships with manufacturers, these innovations would be extremely delayed and potentially impossible in some circumstances.[61]

Physicians are not only wary of contributing to the research and development of products for fear of public backlash, but also of participating in educational opportunities to share knowledge and research, whether this be speaking at an event or simply attending one.[62] Speaking engagements are a big source of income for many physicians who are considered experts in their fields and research leaders.[63] However, the required reporting of Continuing Medical Education ("CME") related payments may lead some physicians to forgo these learning opportunities in an effort to prevent what could appear to be influential compensation from companies sponsoring these programs.[64] An update to the final rule for the Sunshine Act eliminated a previous exception to reporting for indirect CME payments.[65] Specifically,

56. Loftus, *supra* note 32.

57. Hofheinz, *supra* note 46.

58. *Id.*

59. Dyrda, *supra* note 54; Stamatoglou, *supra* note 3, at 972-73.

60. Dyrda, *supra* note 54.

61. Hofheinz, *supra* note 46.

62. Loftus, *supra* note 32.

63. *See* Charles Ornstein & Ryann Grochowski Jones, *Double Dip: Doctors Paid to Advise, Promote Drug Companies That Fund Their Research*, PROPUBLICA (Mar. 25, 2014, 12:00AM), http://www.propublica.org/article/double-dip-doctors-paid-to-advise-promote-drug-companies-that-fund-research (explaining that an infectious disease specialist was paid $51,000 for research he performed, $13,000 for consulting, and $125,000 for speaking arrangements).

64. Anne L. Finger, *Sunshine Act Expands, Creates More Thorny Issues*, MEDSCAPE, (Aug 11, 2014) http://www.medscape.com/viewarticle/829691 (explaining that the required reporting of CME payments may deter speakers and attendees due to the perceived tainted nature of the event).

65. Larry Husten, *Continuing Medical Education Payments to Physicians Will Be Exposed to Sunshine*, FORBES (Dec. 16, 2014, 8:02 PM), http://www.forbes.com/sites/larryhusten/2014/12/16/continuing-medical-education-payments-to-physicians-will-be-exposed-to-sunshine/ ("The new rule will not go into effect until 2016. The first reports will

prior to this update CME payments did not need to be reported if the CME program met certain certification standards and the applicable manufacturer did not directly select or pay the speaker.[66] However, this exclusion has since been eliminated and any indirect payments made by an applicable manufacturer in support of CME programs must be reported if the applicable manufacturer eventually learns of the speaker's identity, regardless of whether they knew of the speaker's identity at the time the payment was made.[67] The Sunshine Act is effectively dwindling the pool of expert speakers who are willing to provide "teaching and experience to many health care providers."[68] Not only are physicians becoming less willing to speak at these engagements, they are also hesitant about even attending these events where they may be subject to having their name appear on the CMS Open Payment website.[69]

Another interesting effect of the spotlight on disclosure is that a trend is evolving amongst young physicians attempting to keep their records "squeaky clean."[70] It appears that the recent focus on the negative impact of ties to industry has bred an unwillingness of newer physicians to participate in any significant way, including many CME opportunities.[71] Seasoned physicians have taken notice of this trend, commenting that the relationship between young colleagues and manufacturers appears to be "more standoffish" and may potentially get in the way of innovative concepts and commercialization of new ideas.[72] This unwillingness to enter into relationships with manufacturers will only become a stronger sentiment within the industry as increasing amounts of young physicians enter the workforce.

Physicians have expressed real concern over the potential tarnishing of their integrity as a result of the Sunshine Act. Physicians across the country

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then appear in 2017.").

66. Jason B. Caron et al., *CMS Finalizes Proposal to Remove Continuing Education Exclusion from Sunshine Act Regulations*, MCDERMOTT, WILL, & EMERY, (Nov. 12, 2014), http://www.mwe.com/CMS-Finalizes-Proposal-to-Remove-Continuing-Medical-Education-Exclusion-from-Sunshine-Act-Regulations-11-12-2014/.

67. *See CMS Implements Final Rule Changes for Open Payments*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/OpenPayments/About/Law-and-Policy.html; *see also* Husten, *supra* note 65 (quoting Daniel Carlat, the former director of the Prescription Project at Pew Charitable Trusts, "It would be almost unimaginable for a case where the company did not learn the identity of the physicians speaking."); *see also The Impact of Health Care Reform on Academic Cancer Centers*, *supra* note 25 ("[R]eporting of indirect payments is more challenging and companies are being cautious as they are liable for accurate information.").

68. Loftus, *supra* note 32.

69. *Id.*

70. *The Impact of Health Care Reform on Academic Cancer Centers*, *supra* note 25.

71. *Id.*

72. Dyrda, *supra* note 54.

have vowed they are becoming more cautious in their interactions with the industry "and what they will accept from industry representatives."[73] Those physicians with genuine intentions to promote innovation and education are having their relationships with industry come under close scrutiny because of a handful of physicians who may be allowing compensation from manufacturers to cloud their judgment. But how will this play out moving forward?

VI. SUNSHINE ACT DISCLOSURES WILL NOT SERVE THEIR INTENDED PURPOSE BUT RATHER FACILITATE THE UNINTENDED CONSEQUENCE OF PHYSICIAN UNWILLINGNESS TO CONTRIBUTE KNOWLEDGE AND INNOVATION TO THE INDUSTRY

The crux of the Sunshine Act is the assumption that patients will access and thoughtfully evaluate the information provided on the CMS Open Payment website and hopefully, in effect, deter those "bad apple" arrangements from forming or continuing.[74] However, will these new disclosures even serve their purpose in mitigating conflicts of interest?[75] With no way to decipher biases, there is no guarantee these disclosures will serve their purpose of thinning out the relationships causing undue influence on physicians' medical judgment.[76] Further, patients may not have a solid grasp on what is and what is not fair market value for certain services or any means of determining which payments are ethical in nature or potentially too influential on a physician's medical decision making.[77] What is guaranteed is that enough physicians are taking precautions against these potential backlashes that healthcare advancement and innovation is going to suffer.

Despite findings from multiple studies that patients view some financial

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73. Loftus, *supra* note 32.

74. *See* Gorlach, *supra* note 2, at 319 ("If the public and media can, based on the disclosed information, discriminate well between payments made solely for marketing purposes and those made for services that are helpful for innovation, the net effect of data accessibility will be positive; if the disclosed information paints all payments, including those that foster innovation and improve public welfare, with a broad negative brush, data accessibility may curtail some useful kinds of payments.").

75. *See* Richardson, *supra* note 8, at 5 ("[E]ven those who champion the program agree that simple disclosure is not sufficient to address financial conflicts of interest."); Whelan, *supra* note 20, at 17 (Even CMS recognizes that "disclosure is not sufficient to differentiate beneficial, legitimate financial relationships from those that create a conflict of interest or are otherwise improper.").

76. Frost et al., *supra* note 35 ("The open payments program does not identify which financial relationships are beneficial and which could cause conflicts of interest"); *See* Uknis, *supra* note 18 for a discussion on the need for a "user's manual" to understand the data reported on the Open Payments website.

77. *See* Richardson, *supra* note 8, at 4-5 (expressing concern that "it may be difficult to distinguish payments that inappropriately influence prescribing from payments made for services that are helpful for innovation or clinical practice.").

relationships in a positive light and even indicators of prestige on the part of their physician,[78] physicians are still treading cautiously when it comes to entering into financial arrangements with manufacturers.[79] The Sunshine Act purports to advance an important ideal, but the negative shadow cast on the physician-industry relationship will certainly hinder those physicians with a true desire to bring innovation and development to the healthcare industry.

VII. WILL PATIENTS ACTIVELY SEEK AND CONSIDER THE INFORMATION REPORTED BY THE SUNSHINE ACT?

Studies have concluded that patients are not necessarily invested in this type of information as to spark them to inquire further into these relationships past whatever is reported by the media.[80] Patients appear to trust the government and the regulations and standards the government enforces to hold actors in the healthcare industry accountable.[81] In response to these findings, one of the goals of the Sunshine Act is to encourage patients to take the time to look at the data that has been reported and make informed choices as to their health care provider and course of treatment,[82] the intent being that by providing this information in one convenient location patients will be more likely to take an interest in this type of information and open the line of communication with their physicians.[83] The problem is that the Open Payments website has not been a convenient source of information where patients can easily find the specific data for which they are searching.[84]

A study published in the Journal of Law, Medicine, & Ethics in 2013 sought to examine the way payments made to physician affected consumer perception.[85] This study concluded that patients found physicians who did

78. Dyrda, *supra* note 54; Perry et al., *supra* note 6, at 484.

79. *Bracing for the Physician Payment Sunshine Act*, *supra* note 35 ("There is a real concern that the new disclosure requirements will have the effect of dissuading physicians from joining efforts to develop and test new products.").

80. Chen, *supra* note 1, at 358.

81. *Id.*

82. Perry et al., *supra* note 6, at 476; Kelly M. Cleary, *Physician Payment Sunshine Act: How Hot Could It Get in the Sun*, BNA (Apr. 17, 2013), http://www.bna.com/physician-payment-sunshine-act-how-hot-could-it-get-in-the-sun/ ("This transparency initiative, as theory goes, will allow patients to better understand the financial relationships their doctors may have with the drug and device industry, question whether financial relationship might negatively affect their course of treatment, and, ultimately, make better informed decisions.").

83. Stamatoglou, *supra* note 3, at 988 (discussing the likelihood that patients will not have the courage to bring this topic up with their physician due to the traditional roles in the patient-physician relationship despite the Act's intent "to encourage conversations between patients and their physicians by allowing patients to broach the subject with their physicians").

84. *How Will The Sunshine Act Affect Physician Access?*, ARTCRAFTHEALTH (Dec. 4, 2014), http://www.artcrafthealth.com/blog/professional-challenges/how-will-the-sunshine-act-affect-physician-access/.

85. Perry et al., *supra* note 6, at 477.

not accept any payments or who only accepted free drug samples more trustworthy than physicians who accepted payments or owned stock in pharmaceutical companies.[86] However, patients also perceived these physicians as potentially being inexperienced or professionally isolated.[87] Almost across the board, patients interpreted a physician ownership interest in a company as negative and many assumed that "bias and dishonesty flowed from [the physician's] personal financial interest in the drug company."[88] However, patients perceived consulting payments as a legitimate payment, and physicians who accepted these payments were viewed as having a higher level of expertise.[89]

Based on such findings, it would appear the Sunshine Act would be successful in serving its purpose because different types of payments to physicians do seem to illicit different reactions in patients.[90] The Sunshine Act requires that manufacturers report the nature of the payment made and requires a high degree of specificity.[91] Ideally, this requirement will allow patients to decipher what types of payments they find acceptable and what types they do not and thereby make an informed decision about whether to see that particular physician. However, this will require that patients have the ability to access the CMS Open Payments website and actually take the time to thoughtfully process and understand this information.[92]

This reliance on patient participation is what will keep the Sunshine Act from achieving its intended purpose.[93] Not only will patients need to care enough to look up their physician on the CMS Open Payments website, they must also be able to understand what kind of data they are viewing. The confusing way in which payments are reported exacerbates the potential for misunderstanding amongst patients.[94] According to a publication by ProPublica, the Open Payments website has been called an "organizational nightmare" on which even patients who are very comfortable using

86. *Id.* at 481, 484-85.

87. *Id.* at 484-85.

88. *Id.* at 483.

89. *Id.* at 484.

90. *Id.*

91. *Id.* at 488.

92. Patients must be able to access this website and use it efficiently. Whelan, *supra* note 20, at 11-12. ("According to the United States Census Bureau, in 2010 54.3% of Americans fifteen and older connected to the internet at home, with the elderly having the lowest rate at 29.8%."). Furthermore, more vulnerable populations, namely minorities and low income citizens, are even less likely to have internet access at home. *Id.*

93. *Id.* at 28 (explaining that the Sunshine Act is unlikely to achieve its goal because patients are unlikely to "access the information, understand the information, and/or know how to appropriately use the information").

94. *Id.* at 17 ("The potential for interpretation difficulties is further exacerbated by the different "forms" and "natures" of payments that must be reported, some of which represent more legitimate payments than others").

computers may have trouble locating data with ease.[95] If patients are unable, or unwilling, to understand these disclosures, the Sunshine Act is deterring ethical physicians from pursuing beneficial relationships with industry because of a misguided assumption that patients will view that financial arrangement in a negative light.[96]

The primary concern physicians have with the Sunshine Act is the public's perception of the reported financial relationships, whether by patients or the media.[97] Physicians fear that patients may not understand the information presented and have no way of distinguishing the good from the bad when it comes to payments.[98] Physicians' concern over patients misinterpreting financial relationships and potentially assuming tainted judgment on behalf of the physician has resulted in a trend of "doctors . . . increasingly opting out of attending or speaking at [teaching programs]."[99] Despite findings that patients may be unlikely to actually access the information reported, physicians are still put off by the methods of the Sunshine Act and intimidated by the potential for adverse reactions to their financial relationships.[100] This hesitancy physicians have over their names appearing on the CMS website is unnecessarily inhibiting innovation in the healthcare industry.

VIII. CONCLUSION

While the intention of the Sunshine Act is to shed light on the financial ties physicians may have with industry actors, the fear of being scrutinized has pushed physicians in the direction opposite of progress.[101] Many

95. *How Will the Sunshine Act Affect Physician Access?*, *supra* note 84.

96. Whelan, *supra* note 20, at 16 ("[S]imply posting a dollar amount next to a physician's name does not tell the whole story and will often be misleading and suggest that all physician-industry relationships are unethical or at least suspect.").

97. However, patients and the media may not be the only two sources of criticism. Cleary, *supra* note 82 ("Other groups likely to tap into this data include law enforcement entities charged with ferreting out fraud and abuse, lawmakers critical of physician-industry ties, and whistleblowers looking to make a profit.").

98. Whelan, *supra* note 20, at 16-18 (explaining even those with industry knowledge may have a difficult time discerning the payments reported on the Open Payment website; without the proper context there is a greater likelihood of the data being misconstrued or misunderstood.).

99. Loftus, *supra* note 32.

100. Amaka Uchegbu, *Open Payments Law Unlikely to Affect Doctor-Patient Relationships*, YALE DAILY NEWS (Oct. 30, 2014), http://yaledailynews.com/blog/2014/10/30/open-payments-law-unlikely-to-affect-doctor-patient-relationships/ ("Even if the act has little effect, industry experts conceded that most medical professionals are not overwhelmingly supportive of the act because they believe it can lead to ambiguous interpretations.").

101. *See Bracing for the Physician Payment Sunshine Act*, *supra* note 35, at 1, for a discussion about why some feel the Sunshine Act will dissuade "physicians from joining efforts to develop and test new products."

physicians are unwilling to take a chance on their reputation being compromised by having their name reported on the CMS Open Payment website.[102] The relationship between physicians and industry manufacturers has historically been crucial in research, development, and education.[103] However, despite this necessary relationship, many physicians believe the Sunshine Act will "result in fewer clinical studies, conferences, research publications, and scientific advisory board meetings associated with manufacturers."[104] Physicians are treading lightly until it is empirically proven whether patients will actually take the time to make thoughtful decisions based on the relationships that are reported on the CMS website. The potential backlash of the Sunshine Act's disclosures has intimidated physicians enough to dissuade them from actively participating in the development and advancement of the health care industry – a detrimental consequence to all those involved.

102. *Id.*
103. Dyrda, *supra* note 54.
104. SHYFT ANALYTICS, *supra* note 7.

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Uniting All Interests: Law and Regulation Must Facilitate Pharmacogenomic Development

*Melvin Gaddy**

I. INTRODUCTION

Legal and regulatory developments in the health care field must drive technological innovation. Merely resolving bioethical ambiguity with backward-looking policy is not enough.[1] This is due to health and health law's tendency to be reactive, as opposed to proactive.[2] This article will propose a framework for how health law and regulations can proactively facilitate pharmacogenomic innovation.

Pharmacogenomics is the study of how our genetic traits affect individuals' responses to prescription medications, while intersecting pharmacology with the newer field of genomics.[3] At present, prescription drugs are developed with the understanding that each and every drug must be a "one size fits all" model.[4] For example, every person should be able to take a blood pressure medication for high blood pressure and experience similar results. Similarly, every person should be able to take a thyroid medication and experience similar results. Despite the fact that genetics affect efficacy rates, absorption rates, and countless other factors that affect how prescription drugs work in the human body, drug companies develop drugs to treat all people identically and without regard to consumer's genetic variation.[5]

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1. *See generally* Roger S. Magnusson, *The Changing Legal and Conceptual Shape of Health Care Privacy*, 32 J.L. MED. & ETHICS 680, 680 (2004) (providing a general overview of health privacy law's multivariate limitations and challenges that result from backward-looking policies and their application to novel technological innovation).

2. *See id.* at 683 ("Privacy laws tend to be reactive.").

3. *Id*. at 687.

4. *What Is Pharmacogenomics?*, U.S. NAT'L LIBRARY OF MED. http://ghr.nlm.nih.gov/handbook/genomicresearch/pharmacogenomics (last visited Jan. 18, 2016) [hereinafter *What Is Pharmacogenomics?*].

5. *See* Sillon Guillaume, *An Ethical and Legal Overview of Pharmacogenomics: Perspectives and Issues*, 27 MED. & L. 843, 844 (2008) ("Knowledge of an individual's genetic sensitivity to certain medication will allow health care professionals to tailor treatment to the genotype profile by either decreasing the dosage of a medication, or prescribing a

Pharmacogenomics, in contrast, promises movement beyond this model of pharmaceutical development.[6] Essentially, pharmacogenomics is to pharmaceuticals what Savile Row is to bespoke suits: the means to "custom fit" or "tailor make" prescriptive medications, developing medication for each individual according to their genetic profile. However, unlike Savile Row, pharmacogenomic medication must be available to general consumers.

Through its very nature, pharmacogenomics exists in the tension between individual privacy and societal or global interests in medical advancement since it requires access to individual patient genetic information.[7] Despite the fact that individual patients' privacy is made more precarious by the type of information necessary to advance pharmacogenomic research, individual action is necessary to realize pharmacogenomic advancement.[8] Specifically, individual patients must undergo genetic testing from their medical providers and convey the same to public or private researchers.[9]

If public and private researchers have sufficient access to aggregated patient genetic information from across the general population, that access will facilitate advancement towards a "personalized medicine" health care model.[10] Consequently, regulation must be oriented to create conditions where individuals have access to genetic testing, and where public and private researchers have access to the results of those tests. By extension, because pharmacogenomic advancement is in every individual's interest, privacy concerns should yield to genetic and pharmacogenomic research when in conflict to the extent that doing so does not expose individual consumers to unreasonable harm or risk. Lastly, Congress should make every effort to reduce the costs of genetic testing because of the often impermissibly high costs of genetic testing. Two ways Congress could reduce consumer costs of genetic testing, thereby making such testing more readily accessible include: consumer tax credits to offset the costs associated with genetic testing; and requiring Medicare and/or Medicaid coverage, or insurance coverage of the same.

II. BACKGROUND

A reasonable understanding of pharmacogenomic research's potential

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different one.").

6. *What is Pharmacogenomics?*, *supra* note 4.

7. Magnusson, *supra* note 1, at 681.

8. Alexandra E. Shields, *Ethical Concerns Related to Developing Pharmacogenomic Treatment Strategies for Addiction*, 32 ADDICTION SCI. & CLINICAL PRACTICE 33 (July 2011).

9. Magnusson, *supra* note 1, at 688.

10. *See generally* Teresa Kelton, *Pharmacogenomics: The Re-Discovery of the Concept of Tailored Drug Therapy and Personalized Medicine*, 19 HEALTH LAW 1, 1 (2007) (explaining that pharmacogenomics is the scientific foundation of what is described as "personalized medicine").

requires situating it in the context of American health care. Specifically, this section will address four major background areas: (a) private insurance; (b) the pharmaceutical industry; (c) genomics and pharmacogenomics in general; and (d) regulatory challenges associated therewith.

A. Private Insurance

In the United States, Health Management Organizations ("HMOs") function as conduits between many companies that provide insurance benefits as part of their employee's compensation packages, and the healthcare industry.[11] HMOs monitor which entities consume the most healthcare resources, which enables them to calculate the relative risk of extending insurance to large groups.[12] Thus, patient information relating to health care is transmitted, in these cases, from their health providers to those administrative entities and beyond.[13] This means a medium already exists by which individual information may be transmitted from healthcare providers to researchers, through insurance companies, but this medium simultaneously presents a host of regulatory and ethical challenges.[14] Yet, if genetic information is available to researchers and administrators, an epidemiological aggregation of individual genetic profiles may be possible, but not without considerable risk to individual privacy.[15]

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11. Magnusson, *supra* note 1, at 683.

12. *Id.*

13. *Id.*

14. For example, suppose that private health insurance companies obtained information relating to a person's genetic profile and calculated their insurance rate based on that information. For those blessed with good genes, this would not present an issue. Alternatively, for those predisposed to heart failure, brain tumors, certain cancers, and the like, it is not unreasonable to assume an insurance company may adjust individual rates on that unique predisposition. Therefore, regulation would be necessary to prevent private insurance companies from using individual health information to consumers' detriment, much in the same way that the Affordable Care Act mandated that preexisting conditions be covered. For a discussion of what impact the Affordable Care Act had on preexisting condition coverage, *see generally* Nat'l Fed'n of Indep. Bus. v. Sebelius, 132 S. Ct. 2566, 2585 (2012) ("[T]he Affordable Care Act. . .addressed the problem of those who cannot obtain insurance coverage because of preexisting conditions . . . through the Act's "guaranteed-issue" and "community-rating" provisions [which] prohibit insurance companies from denying coverage to those with such conditions or charging unhealthy individuals higher premiums than healthy individuals."); *see also* Kathryn C. Kokoczka, *Less Than Perfect: Health Care Coverage in Spite of Preexisting Conditions*, 20 ANNALS HEALTH L. ADVANCE DIRECTIVE 86, 92-93 (2010) (arguing that by eliminating the preexisting condition limitation that insurance companies used to deny coverage to individuals who suffered from certain health problems prior to obtaining their insurance policy, the Affordable Care Act at once eliminated arbitrary power exercised by private insurance companies, and created a "sense of security and comfort" for those with "less than perfect health").

15. *See* Sarah Fendrick, *The Role of Privacy Law in Genetic Research*, 4 I/S: J.L. & POL'Y FOR INFO. SOC'Y 803, 803 (2009) (discussing generally the tension between heightened privacy protections specific to genetic research and the potential benefits of such research).

B. The Pharmaceutical Industry

The pharmaceutical industry, in general, operates in an effort to create drugs that treat all patients' medical conditions with similar levels of effectiveness.[16] This is because the medical and research landscape creates conditions where adverse drug reactions are more likely to occur than they should, since not all people's bodies respond to prescription drugs in the same way.[17] Presently, "gaping holes" on the state regulatory level permit both public and private research, which results in appropriating individuals' health information without the consent of those individuals.[18] Despite states' efforts to remediate those deficiencies, the states' health privacy laws are generally inconsistent, and that inconsistency results in the misuse of genetic information.[19] The potential explosion of information related to the genetic makeup of specific individuals underscores the need for better national standards for genetic testing.[20]

C. Genomics and Pharmacogenomics, Generally

Genetics lies at the foundation of nearly all human medical conditions, and in that, the study of genomics entails the study of what role our unique genetic makeups have on diseases such as cancer, diabetes, cardiovascular disease and others.[21] Medical advancement in this field presents enormous promises in combating many of the most common health problems from which Americans suffer.[22] To the extent that such information can be amassed,

16. *What Is Pharmacogenomics?*, *supra* note 4.

17. *Id.*

18. Fendrick, *supra* note 15, at 820 ("Federal legislation should be amended to specifically identify genetic material as PHI, but should not impose stricter regulations for genetic material. Amending the legislation in this manner will reach a balance that protects genetic privacy while still allowing research to progress for the benefit of humanity.").

19. *Id.*

20. *See generally* Daniel Schlein, *New Frontiers for Genetic Privacy Law: The Genetic Information Nondiscrimination Act of 2008*, 19 GEO. MASON U. C.R.L.J. 311, 311 (2009) (discussing the scope, extent and imminence of technological advances in such areas as the human genome project, the reduced costs associated with genetic testing and individual genetic sequencing, etc.).

21. Genetics and genomics are not the same thing. Genetics is the study of heredity, whereas genomics is the study of how genes function in the body. Specifically, genomics seeks to understand how individual genes impact the human body. Thus, the main difference between genetics and genomics is that genetics attempts to understand the structure and effect of particular genes and how they are passed through generations by the process of reproduction, whereas genomics attempts to understand how all genes relate to one another and affect an individual organism's biological functioning. *WHO Definitions of Genetics and Genomics*, WORLD HEALTH ORG., http://www.who.int/genomics/geneticsVSgenomics/en/ (last visited Jan. 3, 2016).

22. *See A Brief Guide to Genomics: DNA, Genes and Genomes*, NAT'L HUMAN GENOME RESEARCH INST. NAT'L INST. OF HEALTH (Aug. 27, 2015), https://www.genome.gov/18016863 ("Genome-based research is already enabling medical researchers to develop improved

aggregated, and organized, it will be possible in the near future to classify individuals into discrete genetic categories, based on their phenotype.[23]

Genetics may account for twenty to ninety-five percent of a patient's response to pharmacological treatments.[24] Examples of genetics' impact on pharmacological efficacy are many: First, in statin therapy (which is used for cholesterol reduction) two specific types of genetic variations were linked with the reduced efficacy of pravastatin therapy.[25] Second, in using selective serotonin re-uptake inhibitors ("SSRI") for treating psychological disorders (e.g. depression, panic and obsessive compulsive disorders, and social phobias), genetic variation among individuals may determine whether individuals will respond positively, negatively, or not at all to such treatments due to generic variants which impact serotonin receptors and drug metabolization rates.[26] Drug metabolization differences caused by genetic variants, similarly, affect the efficacy of "antiarrhythmic, reninangiotensin, beta-blocker, lipid-lowering, and antithrombotic classes" of pharmacological treatments for cardiovascular diseases.[27]

Pharmacogenomics lends considerable hope in the areas of personalized, predictive, and targeted medicine with respect to oncology and prenatal care or screening.[28] Ideally, pharmacogenomics will solve the current deficiencies

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diagnostics, more effective therapeutic strategies, evidence-based approaches for demonstrating clinical efficacy, and better decision-making tools for patients and providers.").

23. *See* GENOMICS AND WORLD HEALTH: REPORT OF THE ADVISORY COMMITTEE ON HEALTH RESEARCH, WORLD HEALTH ORG. 116 (2002) (discussing generally the projected goal of the Estonian Genome Project, which was intended to create a database collating genotype and phenotype for nearly three-quarters of Estonia's population, showing the potential for popular genetic classification) [hereinafter GENOMICS AND WORLD HEALTH].

24. Ramón Cacabelos, *Pharmacogenomics and Therapeutic Prospects in Dementia*, 258 EUR. ARCHIVES PSYCHIATRY & CLINICAL NEUROSCI. 28, 28 (2008).

25. Daniel I. Chasman et al., *Pharmacogenetic Study of Statin Therapy and Cholesterol Reduction*, 291 JAMA 2821, 2821 (2004).

26. Dalu Mancama & Robert W. Kerwin, *Role of Pharmacogenomics in Individualizing Treatment with SSRIs*, 17 CNS DRUGS 143, 143 (2003).

27. J.L. Anderson et al., *Cardiovascular Pharmacogenomics: Current Status, Future Prospects*, 8 J. CARDIOVASCULAR PHARMACOLOGY & THERAPEUTICS, 71, 71 (2003).

28. *See* Robert Pearl, *Genomics: What You Should Know,* FORBES (Dec. 4, 2014), http://www.forbes.com/sites/robertpearl/2014/12/04/genomics/ (discussing generally pharmacogenomics impact on medicine today in the fields of oncology, prenatal screening, and pharmacology); *see also* James Fallows, *When Will Genomics Cure Cancer?,* ATLANTIC (Jan./Feb. 2014) http://www.theatlantic.com/magazine/archive/2014/01/when-will-genomics-cure-cancer/355739/ (illustrating pharmacogenomics' potential utility in cancer research and treatment); *see also* Alison M. Hill, Comment, *Ambiguous Regulation and Questionable Patentability: A Toxic Future for in Vitro Companion Diagnostic Devices and Personalized Medicine?*, 2013 WIS. L. REV. 1463, 1464–66 (2013) (explaining that "the future of patient treatment lies in personalized medicine," which "proposes customizing health care to each individual patient's needs" for the purpose of maximizing treatment efficacy, while explaining how market and regulatory limitations for specific medical devices are insufficiently suited to realize that potential in the context of in vitro companion diagnostic devices).

of pharmacological research, with regard to pharmaceutical development.[29] Presently, the majority of prescriptive medications were developed under the "one size fits all" model, which rests on the premise of, and are prescribed according to, the idea that medications will generally produce identical effects in all people.[30] This approach is insufficient, however, because individuals' unique genetic makeup can and does affect how patients respond to prescriptive medications.[31]

Pharmacogenomics' promises are many. First, personalized medicine will increase prescriptive medications' efficacy.[32] Second, pharmacogenomic advancement will reduce adverse drug reactions, and eliminate the waste associated—especially in the context of prescriptive medications that are purposed to treat ongoing medical conditions like Alzheimer's, cancer, HIV/AIDS, or Diabetes—with pharmaceutical "trial and error."[33] Basically, to the extent individuals are classified by their unique genetic makeup, more powerful and effective medications will be developed because they will be tailored to each individual on the basis of their genetic profiles, rather than

29. *See* Pearl, *supra* note 28 (explaining the current limitations to pharmacological research due to the "one size fits all" model of drug development, and showing how pharmacogenomic research can solve those problems); *see also* Fallows *supra* note 28 (explaining the current limitations to cancer research and treatment, and showing how pharmacogenomic research can improve the overall efficacy of such treatment).

30. Fallows, *supra* note 28; *see also* Pearl, *supra* note 28 (describing the "one size fit's all" model, which is the pharmaceutical industry's current drug development model).

31. *See Pharmacogenomics*, AM. MED. ASSOC., http://www.ama-assn.org/ama/pub/physician-resources/medical-science/genetics-molecular-medicine/current-topics/pharmacogenomics.page? (last visited Sept. 29, 2015) ("The most common variations in the human genome are called single nucleotide polymorphisms (SNPs). There is estimated to be approximately 11 million SNPs in the human population, with an average of one every 1,300 base pairs. An individual's response to a drug is often linked to these common DNA variations. In a similar manner, susceptibility to certain diseases is also influenced by common DNA variations. Currently, much of the research in the field of pharmacogenomics is focused on genes encoding either metabolic enzymes that can alter a drug's activity or defective structural proteins that result in increased susceptibility to disease.") [hereinafter "*Pharmacogenomics*"].

32. Cacabelos, *supra* note 24, at 28; Chasman et al., *supra* note 25, at 2821; Mancama & Kerwin, *supra* note 26, at 143.

33. "Trial and error" refers to a scheme whereby patients and their doctors attempt to figure out specifically which drug from a host of available options is best suited for them. *See Pharmacogenomics*, note 31. (explaining that current methods rely on an individual patient's weight and age rather than an individual's genetics of how they process medicine); *see also* Dov Greenbaum, *Incentivizing Pharmacogenomic Drug Development: How the FDA Can Overcome Early Missteps in Regulating Personalized Medicine*, 40 RUTGERS L.J. 97, 113 (2008) ("Pharmacogenomics offers to look at particular mutations or polymorphisms or just general genetic differences between individuals or groups to understand why one drug may work well in one population and not another. Eventually a greater understanding of pharmacogenomics could lead to the creation of genome-specific drugs—i.e. drugs that are tweaked to optimize their interaction with a particular polymorphic protein.").

treating everyone identically without regard to their genetic type.[34] This will result in better and safer prescriptive medications, which minimize the potential for both side effects and adverse reactions.[35]

D. Regulatory Challenges

Current federal law permits the use of pharmacogenomic evidence in clinical trials for expedited approval of drugs used to treat life-threatening conditions.[36] The effect of such regulation, however, is considerably limited, and it is generally accepted that current laws and regulations are insufficient to create the requisite conditions for the benefits of such research to be realized, no matter how the challenged pharmacogenomics are framed.[37] The nature and extent of the regulatory challenges associated with pharmacogenomic research surface from the pharmacogenomic research process's complexity.[38] That process involves amassing the information necessary for such research to take place, as well as transmitting, aggregating, organizing, and analyzing it to categorize individuals according to their genetic types or profiles.[39] Essentially, individual patients must first undergo

34. Hill, *supra* note 28, at 1463; *see Pharmacogenomics*, *supra* note 31 (explaining the limitations of the current pharmacological model with regard to how new drugs are developed).

35. *Id*.

36. *See* 21 U.S.C.A. § 356(c)(1)(B) ("The evidence to support that an endpoint is reasonably likely to predict clinical benefit under subparagraph (A) may include epidemiological, pathophysiological, therapeutic, pharmacologic, or other evidence developed using biomarkers, for example, or other scientific methods or tools.").

37. For example, the intersection between personalized medicine and intellectual property law presents considerable challenges. Matthew Herder, *Patents & the Progress of Personalized Medicine: Biomarkers Research as Lens*, 18 ANNALS HEALTH L. 187, 189 (2009); Nusrat Khaleeli, & Dennis Fernandez, *Patent Prosecution in Pharmacogenomics*, 88 J. PAT. & TRADEMARK OFF. SOC'Y 83, 89 (2006).

38. *See generally* Jonathan Hsu, Student Note, *Genetic Testing: Balancing Preventative Medicine with Privacy and Nondiscrimination*, 6 I/S: J. L. & POL'Y FOR INFO. SOC'Y 557 (2011) (identifying and generally explaining the differences between the three broad categories of genetic testing—diagnostic, nondiagnostic, and pharmacogenomic—and articulating the regulatory challenges and extant legal framework associated therewith, particularly regarding the potential implications such tests pose to both patient privacy and discrimination). However, not all genetic testing is created equally; different tests reveal different things, and such tests require regulation according to various factors, including their function and intended user. As such, a "single standard" is not appropriate. *See* Rebecca Antar Novick, Note, *One Step at a Time: Ethical Barriers to Home Genetic Testing and Why the U.S. Health Care System Is Not Ready*, 11 N.Y.U. J. LEGIS. & PUB. POL'Y 621, 621–22 (2008).

39. Novick, *supra* note 38, at 624–26 (explaining the broad-based utility of various kinds of genetic tests that individuals may utilize as well as how such tests may be utilized, generally: (a) "[f]or individuals with symptoms of certain genetic diseases, some genetic tests can confirm the diagnosis"; and (b) "[t]ests can also predict one's propensity to develop a particular disease in the future by identifying genes that increase the chance of getting a disease" such as an "increased propensity to develop certain . . . breast cancer and colon cancer" and providing that different kinds of genetic tests offered, as well as "pharmacogenetic

genomic screening.[40] Then, the results of that testing must be obtained, and collected by individual healthcare providers or third parties.[41] The results of such tests must be transmitted to public and/or private researchers, who will then analyze it.[42] Thereafter, pharmaceutical companies may use genetic information to design prescriptive medications that are tailored to individuals' genetic profiles.[43] Thus, it is generally recognized that pharmacogenomic advancements are only possible to the extent that genetic information from a large, diverse population sample is available to researchers.[44]

The sheer scale and quantity of data implicates individual privacy concerns on a macro scale.[45] Some have argued that current privacy laws are insufficient to address the new and dynamic problems that pharmacogenomics presents.[46] Specifically, privacy concerns arise on the

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testing," which can "predict an individual's reaction to particular drugs" by determining how an individual's genes would affect a particular drug's efficacy for individual persons; and, subsequently noting the means by which the results of such tests may be collected and used by research institutions, within the scope of current regulations).

40. *Id*. at 624–25.

41. Food & Drug Admin., Dep't of Health & Human Servs., *Guidance for Industry: Pharmacogenomic Data Submissions* (2005), 3–12, http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126957.pdf (last visited Feb. 1, 2016).

42. *Id*. at 8–16.

43. *Id*.; *see also* Mikyung Kim, *Pharmacogenomics and Pharmacologic Class Effect in Drug Safety Management*, 69 FOOD & DRUG L.J. 603, 603–05 (2014) (explaining that even though there have been considerable improvements in premarket testing and approval, patients and medical providers remain in a precarious position; criticizing premarket studies to the extent that the process requires insufficient information to ensure patient safety; and suggesting that pharmacogenomics may remediate that deficiency).

44. *See* Amanda Tessmer, *Pharmacogenomics and the Genetic Information Nondiscrimination Act of 2008: Legislation Limitations and Its Impact on Pgx Research and Clinical Opportunity*, 3 ST. LOUIS U.J. HEALTH L. & POL'Y 153, 182 (2009) (explaining that the efficacy of pharmacogenomic research is contingent upon the availability of genetic information from "increases in research participation and public interest among diverse racial, ethnic, and genetic backgrounds"). Tessemer's paper is generally oriented towards an explication of the extent to which the Genetic Information Nondiscrimination Act of 2008 serves to ameliorate the potential risk of discrimination in pharmacogenomic research on several salient fronts, as may advance the goals of pharmacogenomic research. Tessemer adroitly identifies the risks of discrimination so presented, although discussion of such risks is beyond the scope of this article. *See also* Gail Henderson et al., *Great Expectations: Views of Genetic Research Participants Regarding Current and Future Genetic Studies*, 10 GENETICS MED. 193, 193 (2008) (explaining that "participants were 'very positive' (63%) or 'positive' (32%) about genetic research").

45. Hsu, *supra* note 38, at 572–75 (discussing the breadth of privacy concerns regarding genetic testing).

46. *See* Berrie Rebecca Goldman, *Pharmacogenomics: Privacy in the Era of Personalized Medicine*, 4 NW. J. TECH. & INTELL. PROP. 83, 99 (2005) ("New legislation must be passed to enhance the privacy laws already in place. This legislation must be federal and must include specific provisions for databases containing genetic material, as well as for collection, use, and distribution of information derived from an individual's genetic profile.").

issue of informed consent.[47] Informed consent issues manifest in three areas: first, the use of individual genetic information for an individual's benefit; second, the use of genetic information for public or private research; and third, the scope and extent of the risks of transmitting individuals' genetic information to the people and entities who will use that information for the general advancement of public health and good.[48]

However, even if current privacy laws are insufficient to address the novel regulatory challenges presented by pharmacogenomic research,[49] privacy concerns should yield to common public welfare where the harms that privacy laws are intended to protect can be ameliorated by regulations. For example, enjoining health and life insurance companies from accessing and using individual genetic information to harm their interests would reduce the risk of insurance companies discriminating against patients based on their genetic profiles in the same way that the Affordable Care Act provided a sense of security to those with preexisting health conditions.[50]

III. ANALYSIS: REGULATION AND PHARMACOGENOMIC RESEARCH'S ADVANCEMENT

There are three main groups of interests implicated in pharmacogenomic research: individual or private interests; corporate or industrial interests; and societal or collective interests in advancing overall public good.[51] This paper argues that individual privacy rights should defer to the interests of pharmacogenomic advancement unless doing so would result in inadvertent or intentional disclosures of individuals' genetic information to third parties, which could harm individual interests. This balance would advance individual and corporate interests in service of overall public good.

Federal law and other regulations should facilitate researcher's collection of non-identifying genetic information for the purpose of aggregating,

47. *Id.*

48. *See* Hsu, *supra* note 38, at 572–75 (discussing general ethical concerns and balancing individual interests with interests that are properly regarded as societal or collective interests); *see also* Goldman, *supra* note 46, at 84–95 (explaining individual privacy concerns).

49. Barbara J. Evans & Eric M. Meslin, *Encouraging Translational Research Through Harmonization of FDA and Common Rule Informed Consent Requirements for Research with Banked Specimens*, 27 J. LEGAL MED. 119, 162 (2006) ("Current FDA regulations predate the widespread use of banked specimens in biomedical research and they are outdated in their failure to acknowledge that unidentified, unlinked, coded, and identified specimens present varying levels of privacy concerns that require nuanced standards of protection.").

50. *See* Kokoczka, *supra* note 14, at 86, 92-93 (arguing that removing insurance companies' ability to discriminate on the basis of a patient's preexisting condition removes from insurance companies an "unfair and unnecessary power," which would have the salutary effect of providing "security and comfort to those with the misfortune of having less than perfect health").

51. *See generally*, Guillaume, *supra* note 5 (providing a legal and ethical overview of the relevant interests at stake with regard to pharmacogenomic research).

organizing and classifying individuals into genetic "types" according to their genetic profile. Specifically, national regulation should standardize genetic testing regulation, and create the types of conditions where private and public researchers could use such information to advance pharmacogenomic research. Likewise, such regulation should enable the private sector to utilize such research to an extent that products and services may be introduced to consumer markets, to get personalized prescriptive medications to consumers.

Essentially, this regulatory framework unites individual, commercial, and societal interests. However, individuals must be able to inexpensively undergo genetic testing,[52] the results of those tests must be transmitted to researchers, and researchers must be able to classify patients according to their genetic type or profile. That way, those who are predisposed to genetically-linked diseases may receive uniquely tailored prophylactic care. Additionally, those who require prescriptive medications of any kind may only be prescribed medications that are maximally conducive—or at least not adversely linked—to their genetic profile. Finally, national regulation must ensure that patient rights are not adversely affected by pharmacogenomic research through the implementation of consumer safeguards.

A. Individual/Private Risks

Naturally, there are risks associated with pharmacogenomic research.[53] For example, certain genetic tests may be inferior, inadequate, or "outright scams."[54] Consumer protection laws, more than privacy laws, must ensure that genetic tests are what they purport to be, and do what they purport to do.[55] Additionally, there are risks associated with the kind of genetic information obtained from such tests.[56] Potential risks include misinterpretation, improperly handling, or improper or inadvertent disclosure to third parties.[57] It will be almost certainly necessary to require that patients

52. *See "What Is The Cost of Genetic Testing, and How Long Does It Take to Get the Results?"*, NAT'L LIBR. MED. (Oct. 19, 2015), http://ghr.nlm.nih.gov/handbook/testing/costresults (discussing the present costs of genetic testing as a barrier to public utilization of the same) [hereinafter *What Is The Cost of Genetic Testing*].

53. Gabrielle Z.A. Kohlmeier, *The Risky Business of Lifestyle Genetic Testing: Protecting Against Harmful Disclosure of Genetic Information*, 2007 UCLA J.L. & TECH. 1, 1, 6 (2007).

54. *Id.*

55. *See*, Novick, *supra* note 38, 621–22 (explaining the general lack of regulatory standardization with various kinds of genetic tests, and how that lack of standardization creates problems for consumers as there are insufficient regulations currently in place to ensure that many kinds of genetics tests are useful and effective).

56. *See* Kohlmeier, *supra* note 53, at 18 ("Misinterpretation includes both misperceptions and misunderstandings. . .even if the data are accurate. Genetic determinism. . .is one of the most deleterious forms of misunderstandings.").

57. The importance of pharmacogenomic research and the collective advancement of

are informed of precisely what testing they are undergoing, the purpose of the test, how and by whom that information will be used, and for what purposes their genetic information will be used or not used.[58] Patients also must be given the opportunity to "opt out" of such testing, if after being "informed,"[59] they do not consent.[60]

To advance the objectives of pharmacogenomic research, the implications of patient nonparticipation should be explained to patients as concretely as the implications of participation.[61] Specifically, patients should be informed that in not participating, their actions limit the advancement of pharmacogenomic research.[62] This is necessary because informed consent requires more than just simplistic communication; medical providers must provide patients with enough information to make an informed choice.[63] Only when patients are properly informed of both the individual and collective ramifications of their actions may they properly make decisions where both individual and collective interests are at stake.[64]

B. Financial Barriers

The cost of genetic testing, and low initial return value of undergoing the

individual interests served by it, must be presented to patients as well as a discussion of the risks associated with genetic testing. *See* Kohlmeier, *supra* note 53, at 6 (explaining that risks to patients include misinterpretation, improperly handling, or improper/inadvertent disclosure to third parties).

58. *What Is Pharmacogenomics?*, *supra* note 4.

59. *See generally* Cruzan v. Dir., Mo. Dep't of Health, 497 U.S. 261, 269 (1990) (explaining that informed consent is generally required for medical treatment by state statutes and the common law, because, as the Supreme Court has recognized, every adult has the "right to determine what should be done with [his or her] own body").

60. *See id.* at 270 ("The logical corollary of the doctrine of informed consent is that the patient generally possesses the right not to consent, that is, to refuse treatment.").

61. *See generally*, GENOMICS AND WORLD HEALTH, *supra* note 23, at 116 (providing that the Estonian Genome Project's success or failure, and subsequent potential pharmacogenomic advancements, which could be gleaned from that research intended to create a database collating genotype and phenotype, depended on popular participation).

62. *See, e.g., id.* (as was the case with Estonia's assembling an aggregation of Estonian's genetic profiles, substantial public participation would be required in the United States to classify individuals based on their phenotype, for the purpose of furthering pharmacogenomic research).

63. *See Opinion 8.08 – Informed Consent*, AMERICAN MEDICAL ASSOCIATION, http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion808.page? (last accessed Feb 3, 2016) ("The patient's right of self-decision can be effectively exercised only if the patient possesses enough information to enable an informed choice. The physician's obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient's care and to make recommendations for management in accordance with good medical practice. Informed consent is a basic policy in both ethics and law that physicians must honor, unless the patient is unconscious or otherwise incapable of consenting and harm from failure to treat is imminent.").

64. *See generally*, Kohlmeier, *supra* note 53 (describing certain information that would be necessary to disclose to patients).

same, may presently discourage consumers from undergoing such testing.[65] Ethical and regulatory concerns notwithstanding, pharmacogenomic research's advancement will be stymied if the consumer cost of genetic testing is not reduced.[66] Therefore, Congress should make every effort to reduce the cost of accessing genetic testing, (e.g. by offering tax credits to offset the costs of privately obtained genetic tests where results of the same are made available to researchers).[67] One potential means to this end would include, for example, passing federal legislation requiring private insurers to expand policy coverage to include genetic testing if a patient voluntarily elected to undergo it, in addition prophylactic or diagnostic purposes.[68]

California Clinical Laboratory Association v. Secretary of Health and Human Services ("*CCLA*") is one of the few cases where a court discusses pharmacogenomic testing.[69] In *CCLA*, an unnamed plaintiff ("Doe") was an 82-year-old Medicare recipient in Virginia who was a registered nurse.[70] Doe claimed she was diagnosed with various chronic conditions requiring the prescription of certain drugs, some of which caused "very serious adverse reactions."[71] Doe undertook to understand her reaction to these medications, and her physician ordered pharmacogenomic testing from a laboratory that provided such services in Virginia.[72] The costs of such services were not reimbursed.[73] Medicare Part B did not reimburse her.[74] The stakes of such determinations are substantial:

> In the event that a MAC makes an initial coverage determination denying Medicare coverage for a particular claim, the provider that submitted the claim typically bears financial responsibility for the items or services at issue, unless the provider has previously given the Medicare beneficiary or

65. The costs of genetic testing may exceed $2,000 per test, depending on the nature and complexity of the test. *What Is The Cost of Genetic Testing*, *supra* note 52.

66. *See id*. (describing the high cost of genetic testing to consumers).

67. *See id*. (suggesting that costs of genetic tests may present a barrier to consumers).

68. Because of the high costs associated with genetic testing, requiring private insurers to cover the up-front costs of that testing for both prophylactic and diagnostic purposes would reduce the economic barriers to undergoing such tests, as well as increase the frequency with which such testing was available for coverage. *Id.* Presently, health insurance plans cover the costs of genetic testing, but only upon a doctor's recommendation. *Will Health Insurance Cover the Costs of Genetic Gesting?*, NAT'L LIBR. MED. (Jan. 25, 2016), http://ghr.nlm.nih.gov/handbook/testing/insurancecoverage.

69. Cal. Clinical Lab. Ass'n v. Sec'y of Health & Human Servs., No. 14-CV-0673, 2015 WL 2393571, at *1 (D.D.C. May 20, 2015).

70. *Id*.

71. *Id*.

72. *Id*.

73. *Id*. at *2.

74. *Id.* Medicare Part B is a medical insurance program whose purpose it is to cover medical goods and services not covered under Part A which are "reasonable and necessary" as determined by the Secretary of Health and Human Services.

> enrollee (who are generally referred to throughout this opinion as "Medicare recipients") an "advance beneficiary notice" or "ABN" stating "that Medicare will likely deny payment for the service or item to be furnished." . . .The ABN is, in essence, a cost-shifting mechanism: if the provider gives a Medicare recipient such advance notice, then instead of the provider bearing the cost of the denial of the service, the recipient "is held liable for the denied services or items…[75]

CCLA was dismissed on procedural grounds.[76] However, the case presents a compelling example of the regulatory deficiencies associated with public access to the kind of testing that would enable individuals to benefit from the fruits of pharmacogenomic advancements.[77] Specifically, *CCLA* is important because it illustrates how many individuals like Doe—perhaps even those who would most benefit from pharmacogenomic advancements—lack access to genetic testing.[78] Thus, Congress must act to lower the consumer costs of genetic testing, at the very least. Congress might likewise advance pharmacogenomic research (1) by requiring these types of genetic testing to be covered by Medicare and Medicaid, and (2) requiring private insurance companies to cover the costs of such testing on an elective basis, in the same way that it requires coverage of preexisting conditions.[79]

IV. CONCLUSION

The benefits of pharmacogenomic research are settled. The question now: "How do we create the types of conditions where the future of personalized medicine may be realized?" Accomplishing this objective requires creating

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75. *Id.* at *3 (internal citations omitted).

76. *Id.* at *6 ("[T]he Court has concluded that Doe is not a proper plaintiff because Plaintiffs have failed to demonstrate that she has suffered, or imminently will suffer, an injury-in-fact that is traceable to the action she seeks to challenge."); *but see* Jack E. Urquhart, *The Duty to Use Pharmacogenetics and Pharmacogenomics to Reduce the Risk of Idiosyncratic Drug-Induced Liver Injury*, 1 ANDREWS EXPERT & SCI. EVIDENCE LITIG. REP. 16, 16 (2004) (explaining that drug manufacturers do not have a legal duty to use pharmacogenomic or like research to reduce the risk of drug-induced injury).

77. Cal. Clinical Lab. Ass'n v. Sec'y of Health & Human Servs., No. 14-CV-0673, 2015 WL 2393571, at *2 (D.D.C. May 20, 2015) (because Medicare Part B is something like a 'catch-all' medical insurance program whose purpose it is to cover medical goods and services not covered under Part A, and genetic testing is not necessarily even covered under Part B, this case provides an example of federal regulatory access barriers to genetic testing as may facilitate pharmacogenomic advancement).

78. *Id.* at *1.

79. Kokoczka, *supra* note 14, at 92-93. While beyond the scope of this paper, it is possible that this kind of investment in public health would improve the overall efficiency of our health care system, generally, by reducing wasted healthcare resources, because the economic costs of creating and marketing "one size fits all" drugs would be reduced or eliminated. In theory, this could translate into net consumer benefits by reducing the cost of drug development in the long term. However, further research would be needed to assess that potentiality.

laws and policies that aligns all relevant interests. Individual, corporate or private, and public or societal interests are aligned when individual access to genetic testing is maximized, and laws—especially privacy laws—related to that access facilitate pharmacogenomic research's advancement. Laws related to individual access to genetic testing facilitate pharmacogenomic research's advancement when systemic (i.e. privacy and economic) barriers to pharmacogenomic research are remediated. In that way, we move toward a world in which we collectively benefit from personalized medicine, by reforming policy laws and reducing consumer economic barriers to genetic research to facilitate pharmacogenomic development.

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Analyzing Recent Trends in the Debate Over Gene Patents: United States and Australia

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I. INTRODUCTION

The scope of patentable subject matter for genome modifications is a hotly contested and ever-evolving area of intellectual property law both domestically and internationally.[1] In particular, many debate the moral, economic, and scientific implications of granting patents to isolated genetic material of humans.[2] Many countries, such as Canada, Japan, and European Union member states maintain an expansive view of patentable subject matter, arguing that isolated genes are patent-eligible.[3] The United States ("U.S.") and Australia, on the other hand, have recently scaled back the scope of patentable subject matter by excluding isolated genes, turning back their own decades-long jurisprudence.[4]

This article is a reaction to the High Court of Australia's decision in *D'Arcy v. Myriad Genetics, Inc.* ("*D'Arcy*") and argues that the High Court's holding should be broadly interpreted – narrowing the scope of patentable subject matter.[5]

Section II of this article provides a brief overview of modern biotechnology giving particular attention to the underlying gene patent

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1. *See generally* Adam Mosoff, *Why History Matters in the Patentable Subject Matter Debate*, 64 FLA. L. REV. FORUM 23 (2012) (cautioning against the assumption that the American patent system was born fully formed and complete); Cynthia M. Ho, *Global Access to Medicine: The Influence of Competing Perspectives*, 35 FORDHAM INT'L L. J. 1 (2011) (discussing the competing perspectives inherent in patent law within a social science framework).

2. *See generally* Donna M. Gitter, *International Conflicts over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption*, 76 N.Y.U. L. REV. 1623, 1628-29 (2001) (providing a comprehensive survey of the gene patent debate, both domestically and abroad).

3. Emma Barraclough, *What Myriad Means for Biotech*, WIPO MAGAZINE, Aug. 2013, at 21, *available at* http://www.wipo.int/export/sites/www/wipo_magazine/en/pdf/2013/wipo_pub_121_2013_04.pdf.

4. Molly Jamison, *Patent Harmonization in Biotechnology: Towards International Reconciliation of the Gene Patent Debate*, 15 CHI. J. INT'L. L. 688, 696 (2015).

5. D'Arcy v. Myriad Genetics Inc. [2015] HCA 35 (Austl.).

controversy.[6] Section III (A) provides historical context for gene patent jurisprudence beginning with the Supreme Court's landmark decision in *Diamond v. Chakrabarty* ("*Chakrabarty"*).[7] Section III (B) highlights the recent shift toward a narrowed interpretation of patentable subject matter as seen in *Association for Molecular Pathology v. Myriad Genetics* ("*Myriad*"), while Section III (C) concludes with a discussion of the fallout from *Myriad* and its influence abroad.[8] Section IV discusses the Australian High Court's decision in *D'Arcy* by providing a brief historical overview of Australian gene patent jurisprudence and then contemplating the early consequences of *D'Arcy.*[9] Finally, Section V argues for a broad interpretation of the High Court's decision to make isolated genetic material patent-ineligible using the U.S. Supreme Court's decision in *Myriad* and Australia's international treaty obligations as backdrop.[10]

II. BIOTECHNOLOGY AND THE DEBATE OVER GENE PATENTS

The word "biotechnology" is an amalgam of "biology" and "technology"; aptly, biotechnology is technology based on biology.[11] Humans have used biotechnology in one form or another for over 6,000 years.[12] Today, it is a source of breakthrough products that "combat debilitating and rare diseases, reduce our environmental footprint, feed the hungry, use less and cleaner energy, and have safer, cleaner, and more efficient industrial manufacturing processes."[13] More concretely, there are over 250 biotechnology healthcare products and vaccines available, which have reduced the rates of previously untreatable diseases.[14] Through advancements in biotechnology, researchers are now able to create tailor-made medicines based on proteins, enzymes, and ribonucleic acid ("RNA") molecules that are associated with specific genes and diseases.[15] These advancements, although immeasurably valuable, are not free from controversy, especially with regard to gene patents.[16]

Gene patents are patents on particular sections of deoxyribonucleic acid

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6. *See infra* pp. 2-4.
7. *See infra* pp. 5-6.
8. *See* Section III (B) *infra* pp. 6-8; Section III(C) *infra* pp. 8-10.
9. *See* Section IV *infra* pp. 10-12.
10. *See* Section V *infra* pp. 12-15.
11. *What is Biotechnology?*, BIOTECHNOLOGY INDUS. ORG., https://www.bio.org/articles/what-biotechnology (last visited Sept. 28, 2015).
12. *Id.*
13. *Id.*
14. *Id.*
15. *Id.*
16. *Why Are Gene Patents Controversial?*, ECONOMIST (Apr. 18, 2013, 11:50 PM), http://www.economist.com/blogs/economist-explains/2013/04/economist-explains-why-gene-patents-controversial.

("DNA") rather than the entire sequence (the human genome).[17] Since biotechnology can be costly to develop,[18] a substantial investment of money and time is needed before a safe and effective product can be made available to the general public.[19] As such, biotech companies protect their investments through patents and other intellectual property rights.[20] After a biotech company isolates genetic material or a mutation, such as the material that detects the risk of breast and ovarian cancers, the company then seeks to recoup its research and development costs by patenting the material or mutation.[21]

However, because patents are government-sanctioned monopolies, the importance of carefully and clearly crafting the scope of patentable subject matter is of great importance.[22] On the one hand, a patent gives its owner, such as a biotech company, the right to exclude others from making, using, selling, offering to sell, or importing what is patented.[23] In theory, this gives companies the ability to recoup their investment and perhaps incentivize further research.[24] On the other hand, a government-sanctioned monopoly allows patent holders to price its patented technology well above what the fair market would dictate.[25] As a result, a biotech company can take

17. Gitter, *supra* note 2, at 1628-29.

18. *See* Christopher P. Adams & Van V. Brantner, *Estimating the Cost of New Drug Development: Is It Really $802 Million?*, 25 HEALTH AFF. 420, 420 (2006) (estimating $868 million, and varying between $500 million and $2 billion by drug type and company).

19. *Id.* at 427.

20. Richard A. Epstein & F. Scott Kieff, *Questioning the Frequency and Wisdom of Compulsory Licensing for Pharmaceutical Patents*, 78 U. CHI. L. REV. 71, 72 (2011) ("Patents are praised as a spur to innovation, which is only made possible with the predictable enforcement of rights of Exclusion for the patented technology.").

21. Kristen L. Burge, *Personalized Medicine, Genetic Exceptionalism, and the Rule of Law*, 8 WASH. J.L. TECH. & ARTS 501, 513 (2013). There are four categories of gene patents. *Id.* First, there are patents on the gene itself, either in whole or in part, which includes claims to isolated nucleotide sequences. *Id.* The second category includes patents on proteins (and their function within the organism) encoded by the genes. *Id.* Third, patents may issue to vectors, which are DNA molecules used to artificially transfer foreign genetic material from one organism to another where it can be replicated and/or expressed. *Id.* Finally, patents may be issued to genetically modified cells or organisms, the processes used for the making of genetically modified products, and the uses of genetic sequences or proteins for genetic testing. *Id.*

22. *See* Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 730-31 (2002) ("The patent laws 'promote the Progress of Science and useful Arts' by rewarding innovation with a temporary monopoly." (quoting U.S. CONST. art. I, § 8, cl. 8.)).

23. 35 U.S.C. § 271 (2010).

24. *See* Jamison, *supra* note 4, at 709 (arguing that uneven patent enforcement and legal uncertainty about the patentability of isolated genetic material could "dampen innovation because of uncertainty about recouping the high costs of [research and development]").

25. *See* Cydney A. Fowler, Comment, *Ending Genetic Monopolies: How the TRIPS Agreement's Failure to Exclude Gene Patents Thwarts Innovation and Hurts Consumers Worldwide*, 25 AM. U. INT'L L. REV. 1073, 1093 (2010) (arguing that allowing gene patenting closes access to the market and forecloses competition, which, in turn, allows genetic

advantage of patent rights to price a potentially life-saving product out of the reach of people in need.[26] For over thirty years, courts around the world have wrestled with deciding where to draw the line; to date, the international community remains in disaccord about what should be patentable.[27]

III. *CHAKRABARTY* TO *MYRIAD*: THE GENESIS OF THE SCOPE OF PATENTABLE SUBJECT MATTER AND GENES IN THE UNITED STATES

In the U.S., Congress established a framework for the scope of patentable subject matter.[28] The U.S. Patent Act of 1952 § 101 ("§ 101") provided that "whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent . . . "[29] For most technology this is an easy test to apply.[30] However, for genetic material, courts have struggled to clearly craft the scope of patentable subject matter, which has created a controversy since gene patents were first issued in the United States in the 1980s.[31]

A. Chakrabarty: The Explosion of Gene Patents

U.S. courts have traditionally interpreted § 101 quite broadly.[32] Patent offices and courts in developed nations typically grant patents liberally to encourage investment in biotechnology.[33] This was especially true in the U.S. when the Supreme Court decided *Chakrabarty* in 1980.[34] *Chakrabarty* involved a patent application for a genetically modified bacterium capable of breaking down multiple components of crude oil.[35] The United States Patent and Trademark Office ("USPTO") rejected the patent claims, reasoning that Congress did not intend § 101 to cover living things such as laboratory

monopolies negatively impacting both consumers and researchers).

26. *Id.*

27. Gitter, *supra* note 2, at 1624-25.

28. U.S. CONST. art. I, § 8, cl. 8.

29. 35 U.S.C. § 101 (1952).

30. *See* INTELLECTUAL PROPERTY LAW: CASES & MATERIALS 148 (Lydia P. Loren & Joseph S. Miller eds., 4th ed. 2015) ("From fluoxetine hydrochloride, the active ingredient in Prozac (U.S. Patent No. 4,314,081) to bubble wrap (U.S. Patent No. 3,142,599) to the airplane (U.S. Patent No. 821,393), practical solutions to concrete problems fall comfortably within the scope of § 101.").

31. *See* Stephen H. Schilling, *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents*, 61 Duke L.J. 731, 732 (2011) (discussing the unique issues presented by gene patents and arguing that concerns regarding gene patents, such as the concern that gene patents will restrict patient access to genetic diagnostic tests and impede research, have "engendered overreactions" by U.S. courts).

32. Jamison, *supra* note 4, at 694.

33. *Id.*

34. *Id.* at 695.

35. Diamond v. Chakrabarty, 447 U.S. 303, 305 (1980).

created microorganisms.[36] However, the Supreme Court overruled the USPTO decision, concluding that the language of § 101 is broad and that Congress intended the scope of patentable subject matter to include "anything under the sun that is made by man."[37] This sweeping approach resolved the case in favor of Chakrabarty, the named inventor.[38]

Chakrabarty immediately opened the door to the patenting of isolated gene sequences in the U.S.[39] As a result, the number of biotechnology patents issued annually increased rapidly.[40] Further, *Chakrabarty* influenced other countries to adopt an expansive view of patentable subject matter that allows for gene patents.[41] In Australia, the decisions in the lower courts in *D'Arcy* evidence the wide influence *Chakrabarty* had abroad.[42]

However, a marked shift in policy began after the year 2000: the number of gene patents issued decreased and challenges to the validity of such patents increased.[43] One such challenge, brought by the Association for Molecular Pathology and the University of Pennsylvania ("Plaintiffs"), alleged abusive enforcement of patent rights against Myriad Genetics, Inc. ("Myriad Genetics"), an American molecular diagnostic company.[44]

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36. *Id.* at 306.

37. *Id.* at 309-10.

38. *Id.* at 321-22.

39. *See* Jamison, *supra* note 4, at 695 ("In the 1980s and 1990s, the standards governing patentable subject matter expanded [as a result of the *Chakrabarty* decision], particularly in the field of biotechnology, and the issuance of biotech patents, including gene patents, increased.").

40. *See id.* (explaining that by 1998, annual biotech patents issued by the USPTO peaked at 5,977). From the years following *Chakrabarty* in the mid-1980s to the late 1990s, patent intensity, which is "the measure of patents obtained per research and development dollar," approximately doubled. Gideon Parchomovsky & R. Polk Wagner, *Patent Portfolios*, 154 U. PA. L. REV. 1, 5 (2005).

41. *See* Jamison, *supra* note 4, at 696.

42. *See* Sections IV and V *infra* pp. 10-15.

43. *See* Jamison, *supra* note 4, at 695 (noting multiple explanations for the leveling off of biotech patents and suggesting "the shift in policy seems to have been 'largely stimulated by a convergence of a general social unease, the emergence of preliminary data and literature on the possible adverse practical ramifications of gene patents, and several high-profile patent protection controversies.'" (quoting Timothy Caulfield et al., *Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies*, 24 NATURE BIOTECHNOLOGY 1091, 1091 (2006))).

44. *See* E. Richard Gold & Julia Carbone, *Myriad Genetics: In the Eye of the Public Policy Storm*, 12 GENETICS MED. 39, 61 (Supp. 2010) (noting how many in the scientific and clinical communities believed that Myriad tried to "impede basic research" and that it entered the U.S. market in an aggressive manner when, with a family of U.S. patents over the breast cancer genes and control over the diagnostics tests, it sent cease-and-desist letters to university researchers). The Plaintiffs to the suit included: the Association for Molecular Pathology, a not-for-profit scientific society; American College of Medicine Genetics, a private, non-profit voluntary organization of clinical and laboratory geneticists; the American Society for Clinical Pathology, which represents the medical specialty of pathology and laboratory medicine; the College of American Pathologists, a national medical society; and various individual plaintiffs

B. Myriad: Changing Trends in U.S. Gene Patent Law

In *Myriad,* the question before the Supreme Court was whether isolated, purified DNA molecules were patentable subject matter under the statutory language of § 101.[45] Myriad Genetics had "discovered the precise location and sequence of two human genes (BRCA1 and BRCA2 genes), mutations of which can substantially increase the risks of breast and ovarian cancer."[46] Myriad Genetics sought, and was issued, a family of patents, which the Plaintiffs felt were overly broad.[47] In fact, the patents on the BRCA1 and BRCA2 genes permitted Myriad Genetics to prevent doctors and researchers from conducting further research.[48] Neither party disputed that Myriad Genetics had not created or altered any of the genetic information encoded in the two genes or the genetic structure of DNA itself since the location and order of the nucleotides existed in nature before Myriad Genetics discovered them.[49] As such, the Supreme Court unanimously held that Myriad Genetics' claims to isolated natural DNA fell outside the scope of § 101, making them patent-ineligible.[50] The Supreme Court relied on the so-called "significantly different" standard, which in natural product cases requires that the patent-seeker add new or useful improvements to the original gene sequence.[51] The Supreme Court held that Myriad Genetics did not meet the significantly different standard.[52]

Nevertheless, the *Myriad* decision surprised the biotech industry, as well as some scholars, who believed the decision was a departure from thirty years of gene patent jurisprudence since *Chakrabarty*.[53] After all, as some scholars argued, "anything under the sun that is made by man" would seem to include genetic material that was isolated by researchers.[54] Those in the biotechnology industry, specifically research and development companies

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representing researchers from various American universities such as the University of Pennsylvania, Yale, and Columbia. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 702 F. Supp. 2d 181, 186 (S.D.N.Y 2010).

45. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013).

46. *Id.* at 2110-11.

47. Jamison, *supra* note 4, at 690.

48. Sarah E. Hagan, *DNA Real Estate: The Myriad Genetics Case and the Implications of Granting Patent Eligibility to Complimentary DNA*, 35 N. ILL. U. L. REV. 205, 221 (2014).

49. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116 (2013).

50. *Id.* at 2120.

51. *Id.* at 2117.

52. *Id.*

53. Jamison, *supra* note 4, at 696; *see also* Arti K. Rai, *Diagnostic Patents at the Supreme Court*, 18 MARQ. INTELL. PROP. L. REV. 1, 2 (2014) (discussing the Supreme Court's treatment of gene patents in light of the recent "heated public controversy over whether such patents pose an impediment to patient access and control of medical decision making").

54. Gitter, *supra* note 2, at 1641.

that rely heavily on investors, feared the market for genetic testing would suffer because investment in such research would decrease stifling innovation.[55] Alternatively, those who supported the decision hailed it as a victory for increased patient access to diagnostic testing and medicines and for patient and physician autonomy in the diagnostic process.[56] In the end, *Myriad* effectively invalidated thousands of gene patents in the U.S., leaving many to question the long-term implications of the decision.[57]

C. Myriad: Narrow Scope, Broad Implications

As noted above, the Supreme Court relied heavily on the "significantly different" test for natural product cases in rejecting the BRCA claims against Myriad Genetics.[58] However, Myriad Genetics was successful in defending against attacks on the validity of several of its other patents.[59] For example, Myriad Genetics also held patents to exclusively synthesize a strand of nucleotides referred to as complimentary DNA (cDNA).[60] Before reaching the Supreme Court, the lower court found that cDNA are naturally occurring products because they are the result of a natural splicing process.[61] Notwithstanding the decision of the lower court, the Supreme Court held that cDNA is not naturally occurring and is therefore patent-eligible, in contrast to DNA.[62] The Supreme Court reasoned that the synthesized strand does not occur as a natural phenomenon and is only producible in a lab setting, thus validating Myriad Genetics' cDNA patents.[63] While the decision left the door open to other questions such as the patentability of proteins, antibodies, or other pharmaceutical products such as new chemical entities isolated from natural resources, subsequent cases have declined to explore such questions.[64]

However, comparing the Supreme Court's decisions in *Chakrabarty* and *Myriad*, along with its interpretation of § 101 will help answer some of these

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55. Hagan, *supra* note 48, at 221.

56. Arti K. Rai, *Biomedical Patents at the Supreme Court: A Path Forward*, 66 STAN. L. REV. ONLINE 111, 111 (2013), *available at* http://www.stanfordlawreview.org/sites/default/files/online/articles/RaiSLR.pdf.

57. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 221 (S.D.N.Y. 2011).

58. *Molecular Pathology*, 133 S. Ct. at 2117.

59. *Id.* at 2119.

60. *Id.*

61. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 186-90 (S.D.N.Y. 2010).

62. *Molecular Pathology*, 133 S. Ct. at 2119.

63. *Id.*

64. Alex Boguniewicz, *Discovering the Undiscoverable: Patent Eligibility of DNA and the Future of Biotechnical Patent Claims Post*-Myriad, 10 WASH. J.L. TECH. & ARTS 35, 42 (2014).

questions — at least until the Supreme Court conclusively defines the "substantially different" standard.[65] The *Myriad* Court rejected the BRCA claims because Myriad Genetics had not made "new or useful" improvements to the original gene sequence, reasoning they were structurally the same as the genes in their natural state.[66] On the other hand, the Supreme Court held that cDNA easily met the threshold for § 101 despite the fact that the basic structure of cDNA is "dictated by nature, not by the lab technician."[67] Similarly, the *Chakrabarty* Court held that adding plasmids to the bacterium pushed the resulting product into the realm of patentability since it was the result of "human ingenuity."[68] Thus, *Myriad* seems to be a rather narrow holding.[69] After *Myriad,* determining whether a natural product meets the "substantially different" standard under § 101 could come down to the slightest variation – as long as the variation does not occur as a natural process.[70] In effect, biotech companies will likely protect the discovery of naturally occurring products by arguing the validity of the resulting product instead of the discovery itself.[71] Although *Myriad* has been construed narrowly, it is a step toward a narrowed scope of patentability; many in the scientific community argue that this will prevent biotech companies from pricing diagnostic tests and tailor-made medicines far above normal market conditions and out of the reach of patients.[72]

It remains unclear how *Myriad* will be applied to other areas of biotechnology such as proteins and antibodies or to other pharmaceutical products such as new chemical entities isolated from natural resources.[73] Nonetheless, the decision reflects a shift in Supreme Court jurisprudence toward a narrower interpretation of § 101 that excludes isolated genetic material from the scope of patentable subject matter.[74] The significance of the *Myriad* decision is evidenced by its influence abroad.[75]

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65. *Id.* at 44.
66. *Molecular Pathology*, 133 S. Ct. at 2117.
67. *Id.* at 2119.
68. Diamond v. Chakrabarty, 447 U.S. 303, 309-10 (1980).
69. Boguniewicz, *supra* note 64, at 46-47.
70. *Id.*
71. *Id.* at 47.
72. David B. Agus, Op-Ed., *The Outrageous Cost of a Gene Test*, N.Y. TIMES, May 21, 2013, at A25.
73. Boguniewicz, *supra* note 64, at 46-47.
74. Ashley Winkler, *Association of Molecular Pathology v. Myriad Genetics, Inc.: Determining the Scope of the Supreme Court's Holding for Patentable Subject Matter*, 103 KY. L. J. 147, 147-148 (2015).
75. *D'Arcy v. Myriad Genetics Inc.* [2015] HCA 35, 19 (Austl.).

IV. THE AUSTRALIAN APPROACH: *D'ARCY V. MYRIAD GENETICS*

Australian patent law is largely rooted in English law.[76] In 1852, the first formal Australian patent system was established, and by 1904 a consolidated Australian commonwealth agency called IP Australia was formed to oversee all patents.[77] IP Australia continues to administer the patent system in Australia today.[78] IP Australia's role is similar to that of the USPTO: absent clear statutory language, both IP Australia and the USPTO interpret their respective patent laws to determine the scope of patentable subject matter.[79]

The Australian counterpart to § 101, the Patents Act of 1990 ("Patent Act"), dictates that any article of manufacture is patent eligible if it is novel, useful, and not secretly used before the application date.[80] Section 101 and the Patent Act are substantially similar and traditionally have been interpreted in substantially the same way by their respective patent offices and judicial systems.[81] Not coincidentally, these similarities have led the High Court of Australia to look to U.S. patent jurisprudence.[82] In one case, the High Court noted that "United States authorities should be accepted in preference to the path apparently taken in the English decisions."[83] In biotechnology specifically, Australian courts look to U.S. patent cases as persuasive authority "because of the similarity of the systems, and the breadth of patent cases in the U.S."[84] In fact, until recently the Australian approach largely resembled the U.S. approach pre-*Myriad*; that is, Australia did not exclude isolated DNA structures from patentability.[85] However, just as in the U.S., the validity of such patents has been increasingly called into question in Australia.[86] Interestingly, a Myriad Genetics patent was also at the center of

76. Kate M. Mead, *Gene Patents in Australia: A Game Theory Approach*, 22 PAC. RIM. L. & POL'Y J. 751, 756 (2013).

77. *Id.*

78. *Id.*

79. *Id.* at 757.

80. *Patents Act 1990* (Cth) ch 1 § 18.1 (Austl.).

81. *See* Mead, *supra* note 76, at 757-58 (noting that the only difference between § 101 and the Patent Act is that the Patent Act also specifically excludes human beings, plants, and animals from the scope of patentable subject matter).

82. *Aktiebolaget Hässle v. Alphapharm* [2002] 212 CLR 411 (Austl.).

83. *Id.*

84. Mead, *supra* note 76, at 757.

85. *Patents for Biological Inventions*, IP AUSTRALIA (Mar. 4, 2014), http://www.ipaustralia.gov.au/get-the-right-ip/patents/about-patents/what-can-be-patented/patents-for-biological-inventions/.

86. Melissa Parke, a federal member of Parliament, urged the Australian Parliament to ban all human gene patents. *See* Commonwealth, *Parliamentary Debates*, Federation Chamber, 21 May 2012, 4977 (Melissa Parke, Member of the Australian Parliament for Fremantle (Austl.). The Australian Law Reform Commission asserted in its report to the federal attorney general that gene patents were problematic. *See* ALRC, Genes and Ingenuity: Gene Patenting and Human Health, ALRC Report 99 s 12, http://www.alrc.gov.au/

a controversy that pushed the Australian judicial system toward a narrower scope more reflective of the U.S. approach.[87] With the Australian High Court's 2015 decision in *D'Arcy*, Australian patentable subject matter shifted, mirroring and perhaps directly following the U.S. approach of excluding isolated genetic material from the scope of patentability.[88]

In *D'Arcy*, the Australian High Court ruled on the validity of Myriad Genetics' BRCA1 gene claim – the same gene at issue in *Myriad*.[89] The lower court – the Federal Court of Australia – unanimously ruled in favor of Myriad Genetics in 2013 and again in 2014.[90] The lower court's opinion largely mirrored the reasoning of *Chakrabarty* and affirmed the validity of patents on naturally occurring DNA sequences.[91] The lower court made clear that the manufacture test for patent-eligibility under Australian law is different from the test that applies under § 101 after *Myriad*.[92] However, in a ninety-three-page opinion, the High Court of Australia overruled the lower court's decision and revoked the BRCA1 claims of the Australian patent.[93] The High Court's opinion is laden with references to *Myriad* as persuasive authority and seems to rely heavily on the Supreme Court's reasoning in revoking the BRCA1 claims.[94] The next Section explores the scope of the holding and argues for a broad interpretation.

V. AN ECHO EFFECT: THE SCOPE OF *D'ARCY* AND THE *MYRIAD* INFLUENCE

While the full reach of *Myriad* and *D'Arcy* is not completely understood, one thing is clear: the exclusion of isolated DNA structures from the scope of patentability sets the U.S. and Australia apart from their economic rivals – namely, the European Union, Canada, and Japan.[95] Because the U.S. is a global leader on biotechnology patents, the *Myriad* holding was the impetus for change in Australia.[96] With the tide now turning against gene patents,

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publications/12-patents-and-human-genetic-research/impact-gene-patents-research.
Legislators in Parliament also introduced the Patent Amendment (Human Genes and Biological Products) Bill 2010, which sought to expressly forbid human DNA from being patent-eligible. *See* Patent Amendment (Human Genes and Biological Products) Bill 2010 (Cth.) (Austl.), http://www.comlaw.gov.au/Details/C2011B00012.

87. *D'Arcy v. Myriad Genetics Inc.* [2015] HCA 35, 1 (Austl.).
88. *Id.* at 88.
89. *Id.* at 1.
90. *D'Arcy v. Myriad Genetics Inc.* [2014] FCAFC 115 (Austl.).
91. *Id.* at 18.
92. *Id.* at 18.
93. *D'Arcy v. Myriad Genetics Inc.* [2015] HCA 35, 44 (Austl.).
94. *Id.* at 22, 33-34, 37-38, 61, 64, 66, 69.
95. *See* Barraclough, *supra* note 3 (arguing that jurisdictional differences will lead biotech companies to protect their investments through trade secret laws instead of patents, which in turn prevents disclosure, and thus hinders the advancement of the arts and sciences).
96. *See D'Arcy v. Myriad Genetics Inc.* [2015] HCA 35.

other countries may soon exclude isolated genetic material from the scope of patentable subject matter.

The *D'Arcy* decision came down in October 2015 and is the latest push toward a narrowed scope of patentability.[97] The *D'Arcy* Court began its determination of patentability by noting that "Parliament has left it to the courts to carry out a case-by-case development of a broad statutory concept according to the common law method in a representative democracy."[98] The High Court pointed out that the function of the Patent Act, much like § 101, serves the larger purpose of encouraging innovation.[99] However, the High Court said that the means to encourage such innovation should not in fact "imped[e] advances and improvements by skilled, non-inventive persons."[100] Nonetheless, the High Court relied on similar language used by the Supreme Court.[101] Specifically, the High Court held that for a claimed invention to qualify for patent protection as a "manner of manufacture," it must be something more than a mere discovery, which depends on the extent to which the product "individualizes" nature.[102] The High Court held that the BRCA claims were not sufficiently individualized from the naturally existing genes because they were "the inevitable result of that which is inherent in the DNA."[103] However, the High Court was hesitant to go further, limiting its holding to the facts of the case.[104]

Although *D'Arcy* will likely be interpreted narrowly, it nonetheless propelled the gene patent debate to the forefront once again.[105] Interestingly, the High Court went only as far as the Supreme Court, leaving in question whether patents of proteins, antibodies, and new chemical entities isolated from natural resources are permissible.[106] Despite the narrow holdings, Australian and American courts should push for a broad interpretation of the cases and for a narrowed scope of patentability. A narrowed scope of patentability will ensure that researchers, doctors, and patients will have access to affordable medicines and diagnostic testing.[107] Moreover, by setting themselves apart from their economic rivals, one may question whether the U.S. and Australia are in violation of international treaty obligations.

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97. *Id.*
98. *Id.* at 17.
99. *Id.* at 19.
100. *Id.* at 19-20.
101. *Id.* at 53.
102. *Id.*
103. *Id.* at 56.
104. *Id.*
105. Mead, *supra* note 76, at 757.
106. Winkler, *supra* note 74, at 147-149.
107. *See* Rai, *supra* note 56, at 111.

A. Other Considerations: The Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS")

Patent law is inherently diverse.[108] Variations in cultural attitudes, biases, and perspectives have led to differences in how nations define patentable subject matter.[109] Each patent system is a function of its nation's territoriality, its government's use of patent law to spur economic growth, and the cultural perspectives of its people.[110] Not coincidentally, these variations have led to differences in how nations delineate the scope of patentable subject matter.[111]

Notwithstanding these factors, patent regimes have become increasingly harmonized.[112] Due in large part to the adoption of the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS"), previously isolated and independent economies and cultures are becoming globalized.[113] Yet, while Article 27 of TRIPS "recogniz[es] the underlying public policy objectives of national systems for the protection of intellectual property," TRIPS still allows member countries flexibility.[114] Specifically, TRIPS allows member countries to "adopt measures necessary to protect public health and nutrition" or "to promote the public interest in sectors of vital importance to their socio-economic and technological development."[115] This flexibility permits countries such as the U.S. to craft the scope of patentable subject matter thereby excluding isolated DNA.[116]

Despite the flexibility inherent in TRIPS, the threat of sanctions through TRIPS has contributed to a culture of over-compliance that discourages countries from experimenting with the protected flexibility.[117] Due to the fact that the U.S. is a leader on the issue of patents, the country sits in a unique

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108. *See* Jamison, *supra* note 4, at 705 (noting that differences in how countries define patentable subject matter stems from "territoriality, government use of patent law as a tool for economic growth, and cultural factors").

109. *Id.*; *see also* Ho, *supra* note 1, at 19-29 (discussing the existence and operation of schemas, confirmation bias, and naïve realism in the context of two competing patent perspectives).

110. Jamison, *supra* note 4, at 705.

111. *Id.* at 700.

112. *Id.*

113. *Id.* TRIPS is the most comprehensive multilateral agreement on intellectual property. *Overview: The TRIPS Agreement*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm. (last visited Nov. 30, 2015). It sets out the minimum standards of protection to be provided by each member country, the procedures and remedies for the enforcement of intellectual property rights, and establishes dispute settlement procedures among member countries and the World Trade Organization. *Id.*

114. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 1869 U.N.T.S. 299, 33 I.L.M 1197.

115. *Id.*

116. Molly Land, *Rebalancing TRIPS*, 33 MICH. J. INT'L L. 433, 439 (2012).

117. *Id.* at 434.

position – it is rarely sanctioned – tending instead to threaten and levy sanctions.[118] In this regard, the U.S. may have the most flexibility of any country.[119] After the *Myriad* and *D'Arcy* decisions, other countries may feel freer to change policy and exclude genes from the scope of patentability.[120]

VI. CONCLUDING THOUGHTS: *MYRIAD, D'ARCY*, AND THE GENE PATENT DEBATE

Without a doubt, the *Myriad*, and *D'Arcy* decisions have steered gene patent jurisprudence on a different course than the previous thirty years. In balancing the core principles underlying their respective patent law systems, the U.S. Supreme Court and Australian High Court have determined isolated DNA to be patent-ineligible. Although those in the biotech industry lambaste the *Myriad* and *D'Arcy* decisions, researchers, scientists, and doctors may now advance life-saving medicines and therapeutic treatments without the worry of patent litigation. *Myriad* and *D'Arcy* may be the impetus to change the ever-evolving patent regimes around the world, with Australia now joining the U.S. in excluding patents to isolated genetic material.

118. *See* Sarah R. Wasserman Rajec, *Evaluating Flexibility in International Patent Law*, 65 HASTINGS L.J. 154, 167 (2013) ("[T]he United States has been criticized for using coercive negotiating techniques to gain the consensus of developing countries. In particular, the Office of the United Stated Trade Representative threatened countries with trade retaliations under Special 301 Report if they chose to object to the negotiating positions of the United States on intellectual property rights in the TRIPS agreement.").

119. *Id.*

120. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2117 (2013); *D'Arcy v. Myriad Genetics Inc.* [2015] HCA 35 (Austl.).

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Drug Transparency Laws Will Not Drive Pharmaceutical Prices Down and Will Only Stifle Innovation

*Gilbert Carrillo**

I. INTRODUCTION

In the United States ("U.S."), prescription drug prices are largely unregulated.[1] Limited regulation plays a significant role in pharmaceutical companies setting their own prices for the use and purchase of prescription drugs.[2] Limited regulation has raised concern amongst patient advocates and researchers regarding the increase in costs and reduced access to medication.[3] Moreover, the precise amount of investment costs for the research and development ("R&D") of pharmaceutical drugs has been questioned by patient advocates and researchers.[4] In an effort to encourage transparency and drive down the price of pharmaceutical drugs, state legislatures have attempted to pass legislation that would require pharmaceutical manufacturers to disclose profits, operation costs, and production costs.[5] Although proposed legislation in each state varies, legislators collectively aim to bring transparency to a section of the healthcare industry that currently remains unclear.[6] While drug manufacturers should be more transparent with

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1. John. A. Vernon, *Drug Research and Price Controls*, REG., 22, 22 Winter 2002-2003, http://www.cato.org/pubs/regulation/regv25n4/v25n4-7.pdf.

2. Nadia Kounang, *Why Pharmaceuticals Are Cheaper Abroad*, CNN (September 28, 2015, 8:46 AM), http://www.cnn.com/2015/09/28/health/us-pays-more-for-drugs/.

3. Salomeh Keyhani et al., *US Pharmaceutical Innovation in an International Context*, 100(6) AM. J. PUB. HEALTH 1075, 1076 (2010).

4. *See generally* Jerry Avorn, *The $2.6 Billion Pill – Methodologic and Policy Considerations*, 372 NEW ENG. J. OF MED. 1877, 1877 (2015) for a discussion on the Tufts Center Report about drug development costs rising from $802 million in 2003 to $2.6 billion in 2014. The author believes that the Tufts Center Report fails to provide information regarding the research mechanism used which would allow analysts to assess the claims that drug development costs are as high as $2.6 billon. *Id.* Moreover, the article calls for an accurate listing of the true costs to produce drugs by manufacturers to help guide pharmaceutical reform. *Id.*

5. *Runaway Drug Prices*, N.Y. TIMES, (May 5, 2015) http://www.nytimes.com/2015/05/05/opinion/runaway-drug-prices.html.

6. *See* Chris Kardish, *In States' Fight for Price Transparency, Drugmakers Are Winning*,

regard to cost, legislation supporting transparency will not drive drug prices down and will only further stifle health care innovation.

This article will evaluate drug transparency legislation in three parts. First, this article will analyze issues and research pertaining to drug manufacturing costs. Second, the article will explore state legislation proposed in the U.S., specifically that of New York and Massachusetts. Finally, this article will analyze the question of whether passing drug transparency laws will make a difference in the rising costs of prescription drugs.

II. ISSUES AND RESEARCH ON DRUG MANUFACTURING COSTS

A. FDA Requirements to Produce Drugs

The primary regulator of pharmaceutical drugs in the U.S. is the Food and Drug Administration ("FDA") Center for Drug Evaluation and Research ("CDER"),[7] which is "charged with ensuring the safety and efficacy of the medicines available to Americans."[8] Drug companies seeking FDA approval to sell a new prescription drug must test the drugs in various ways including laboratory testing, animal testing, and testing on humans, called clinical trials.[9] After adequately testing the drug through the various required stages, the company must file a New Drug Application ("NDA"), which includes: the drug's test results, manufacturing information, and the company's proposed label.[10] If upon review, the drug's benefits outweigh the known risks and the manufacturer can produce a quality product, the drug will be approved and marketed in the U.S.[11]

Despite the very specific FDA requirements, these requirements provide very little knowledge regarding the true costs of bringing drugs to the market, and how drug manufacturers determine the selling prices of these drugs.[12] In

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HEALTH & HUMAN SERVS. (May 5, 2015), http://www.governing.com/topics/health-human-services/gov-drug-cost-transparency-sovaldi.html (analyzing state legislation requiring drug transparency and alluding to pharmaceutical lobbyists as the catalyst for why legislation has not passed); *see also* Andrew Pollack, *Drug Prices Soar, Prompting Calls for Justification*, N.Y. TIMES (July 23, 2015), http://www.nytimes.com/2015/07/23/business/drug-companies-pushed-from-far-and-wide-to-explain-high-prices.html ("As complaints about exorbitant drug prices, pharmaceutical companies are coming under pressure to disclose the development costs and profits of those medicines and the rationale for charging what they do.").

7. *Drugs: FDA Basics*, FDA, http://www.fda.gov/AboutFDA/Transparency/Basics/ucm192696.htm (last updated Sept. 9, 2015) [hereinafter *FDA Basics*].

8. Charles L. Hooper, *Pharmaceuticals: Economics and Regulation*, THE CONCISE ENCYCLOPEDIA OF ECON. (2008), http://www.econlib.org/library/Enc/PharmaceuticalEconomicsandRegulations.html.

9. *What is the Approval Process for a New Prescription Drug?*, FDA. http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194949.htm (last updated Sept. 9, 2015).

10. *Id.*

11. *Id.*

12. Scott Gavura, *Legislators Want "Pharmaceutical Cost Transparency": Are They*

other words, determining market entry does not determine market price.

B. DiMasi Tufts Center Study and Critique

In a 2014 study by Joseph DiMasi at the Tufts Center for the Study of Drug Development, it was calculated that it costs pharmaceutical companies $2.6 billion to develop a new drug.[13] This represents a significant increase from the $802 million estimated by the Tufts Center in 2003.[14] The *DiMasi* study analyzed the R&D costs of sixty-eight randomly selected new drugs from a survey of ten unnamed pharmaceutical firms.[15] The *DiMasi* study concluded that since the collective costs of failed drugs is higher than the costs of the successful drugs, it is the development process that may in fact be driving up the prices of prescription drugs instead of increased regulation.[16]

However, this study has been met with multiple criticisms. In one such critique published in the *New England Journal of Medicine*, Dr. Jerry Avorn of Harvard called for a more accurate determination of all the costs that go into the creation of a new drug as a much needed effort to inform and encourage open discussions about how to best pursue pharmaceutical development and to determine the most reasonable way of paying for truly innovative medications.[17] Dr. Avorn observed that there was limited transparency regarding the information used to obtain this $2.6 billion figure cited in the study, especially since the drug manufacturers themselves provided the samples for the *DiMasi* study.[18]

As expected, drug manufacturers tend to agree with the substantial investment costs reported in the *DiMasi* study and highlight that costs escalate to these enormous figures due to the FDA's safety and quality requirements.[19] Prior to approval, the FDA requires a series of animal testing,

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Asking the Wrong Question?, SCI.-BASED MED. (May 15, 2015), http://www.sciencebasedmedicine.org/legislators-want-pharmaceutical-cost-transparency-are-they-asking-the-wrong-question/.

13. *Cost to Develop and Win Marketing Approval for a New Drug Is $2.6 Billion*, TUFTS CTR. FOR STUDY DRUG DEV. (Nov. 18, 2014), http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study.

14. Avorn, *supra* note 4, at 1877.

15. The DiMasi study is based on a random selection of drugs given by unnamed pharmaceutical companies. Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 185 (2003). The goal of the study was to show how high drug production costs are. *Id.* The results of the study seemed to justify the high costs that pharmaceutical companies charge to use these drugs. *Id.*

16. *Id.* at 182-183.

17. Avorn, *supra* note 4, at 1879.

18. *See id.* at 1878-79 (noting that there was limited information regarding the methods used to arrive at the $2.6 billion figure, that the raw data was not available for analysis, and that the study failed to account for public subsidies into drug development).

19. Hooper, *supra* note 8 ("The main reason for the high cost is the aforementioned high level of proof required by the Food and Drug Administration. Before it will approve a new

followed by a series of tests clinical trials.[20] The process is slow and usually ranges from ten to fifteen years.[21] Many drug manufacturers claim that high drug costs are related to high R&D costs, the long trials of FDA testing, and the fact that many drugs fail during trial and investment costs must be absorbed by other, more successful drugs that make it to market.[22]

C. FDA's Time-Consuming Process Should Not Be Used to Prevent Transparency

The time-consuming process of adhering to FDA requirements along with the high cost of drug R&D should not excuse drug manufacturers from disclosing costs. Dr. Aaron Kesselheim of Harvard states that in the U.S., "[W]e don't have a central agency, governmental or NGO (non-governmental organization) that engages in comparative research that comes up with clear statements of drug efficacies."[23] Without transparency of drug costs, it is difficult to determine whether the drug manufacturers are truly justified in their price setting. As a result of conflicting reports and analysis, state legislatures should encourage greater transparency from drug manufacturers with regards to drug R&D costs.

III. STATE PROPOSED LEGISLATION

The apparent disjunction between profits, operating costs and cost of production in drug manufacturing coupled with drug manufacturers' ability to set prices has encouraged state legislatures to propose bills intended to require heightened transparency in the pharmaceutical field.[24] Several states, namely New York, California, Oregon, Massachusetts, North Carolina, and Pennsylvania, have attempted to enact legislation to manage prescription drug costs.[25] As Representative Tony DeLuca of Pennsylvania stated, "If the public gets to know how much profit these drug companies are making,. . .[drug manufacturers] are going to be hard pressed to continue keeping pharmaceutical prices so high."[26] While the bills vary on which costs should be disclosed, they all call for some form of cost transparency in the drug manufacturing industry. This article will specifically address the

drug, the FDA requires pharmaceutical companies to carefully test it in animals and then humans in the standard phases 0, I, II, and III process.").

20. *FDA Basics*, *supra* note 7.

21. Hooper, *supra* note 8 ("The path through the FDA's review process is slow and expensive. The ten to fifteen years required to get a drug through the testing and approval process leaves little remaining time on a twenty-year patent.").

22. Gavura, *supra* note 12.

23. Kounang, *supra* note 2.

24. Kardish, *supra* note 6; Pollack, *supra* note 6.

25. Kardish, *supra* note 6.

26. *Id.*

proposed legislation of New York and Massachusetts.

A. Analysis of New York's Proposed Legislation

The New York bill, the Pharmaceutical Cost Transparency Act of 2015, is the most recent bill proposed of the six aforementioned states. It provides a requirement that each manufacturer of a prescription drug file a public report if the drug is made available in New York and has a wholesale annual cost equal to or in excess of $10,000.[27] The public report would display the total cost of the production of the drug including, but not limited to, the total marketing and advertising costs for the promotion of the drug directly to consumers.[28] Additionally, the New York legislation will require drug manufacturers to itemize and document all pricing information, and the drug manufacturer must have their records fully audited by a third-party auditor prior to filing their public report with the state.[29]

One issue in particular with this legislation is that it falls short of accounting for failed drugs that never make it to market. Lori Reilly, Executive Vice President for Policy and Research at the Pharmaceutical Research and Manufacturers of America notes that it is misleading to analyze only the cost of developing a particular, successful drug because it ignores the money spent on drugs that fail during development.[30] Only about twelve percent of drugs tested in clinical trials reach the market, resulting in significant underreporting of total costs.[31] Pharmaceutical executives usually do not tie the price of any particular drug exclusively to its development cost, but drug manufacturer sales must recover drug manufacturers' investment in R&D if the companies are to stay operable.[32]

Another issue regarding the New York legislation is the cost of annual reporting on the most expensive drugs.[33] Drug manufacturers would need to implement a procedure and create a method of how best to compile the list of requirements mandated by the New York legislation.[34] This will no doubt

27. S. 5338, 2015 Leg., Reg. Sess. (N.Y. 2015) [hereinafter New York Legislation].
28. *Id.*
29. *Id.*
30. Pollack, *supra* note 6.
31. *Id.*
32. *Id.*
33. New York Legislation, *supra* note 27.
34. Under the proposed bill, drug manufacturers must produce an annual report of any drug that has an annual wholesale acquisition cost of $10,000 or higher. *Id.* This report must include the total production costs, including 1) R&D costs paid by the manufacturer and any entity that previously developed the drug; 2) the total costs of clinical trials; 3) the total costs for materials, manufacturing, and administration of the drug; 4) the total costs paid by any other entity for R&D for the drug; 5) the total costs of acquiring the drug, including patents; 6) the total marketing and advertising costs. *Id.* The annual report must also include "a cumulative annual history of average wholesale price and wholesale acquisition cost increases

create extra work for drug manufacturers, and the cost of complying with the bill could result in diversion of some of the financial resources used to produce drugs. Furthermore, although the legislation addresses what the state would like in the annual report, it does not list guidelines for how drug manufacturers can verify compliance.[35] For instance, the bill does not identify or create an agency within the state government to which the report should be addressed.[36] While the legislation calls for drug manufacturers to include total costs, it falls short of including any penalties for noncompliance.[37]

Aside from the financial resources required of drug manufacturers to comply with this legislation, the bill seems to expect manufacturers will pay for their own audit of the itemized report as a new cost of doing business.[38] Drug manufacturers must hire their own third party auditors, who may or may not be subject to approval by the state, which could lead to additional considerations and opportunities for drug cost increases without further guidance from the state. The aforementioned are just a few issues that the New York legislation fails to fully address, which need to be further developed in order for the bill to gain meaningful support.

B. Analysis of Massachusetts' Proposed Legislation

Massachusetts, although similar to New York, has an even more cumbersome bill that permits the review and consideration of all data reported to the "commission" and the "center." To determine whether the price of the prescription drug is significantly high, the commission and center will review the following: "(i) the prescription drug's medical benefits, (ii) the cost to develop and manufacture the prescription drug, and (iii) the prices charged by the manufacturer in other countries."[39] If the commission

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for the drug," the total profit attributable to sales of the drug, and the total amount the manufacturer obtained from financial assistance, such as patent prescription assistance programs. *Id.*

35. *See generally* Kardish, *supra* note 6 ("[T]he drug trade group PhRMA and bioscience firms argued the new requirements would be onerous and could discourage investment without providing any truly actionable information.").

36. *See* New York Legislation, *supra* note 27 ("The Department shall convene an advisory panel to develop the form required by this Section. The panel shall include, but need not be limited to, representatives from the pharmaceutical industry, health care service plans and insurers, pharmacy benefit managers, governmental agencies, consumer advocates, and physicians.").

37. The bill states that manufacturers "shall" report; however, the bill lacks any form of penalty provision. *Id.*

38. *See id.* ("All of the information. . .shall be itemized and documented by the manufacturer, and audited by a fully independent third-party auditor prior to filing.").

39. "Commission" and "center" are never fully identified aside from these references. S. 1048, 2015 Leg.,189th Gen. Ct., Reg. Sess. (Mass. 2015) [hereinafter Massachusetts Legislation].

determines that the price of a prescription drug is significantly high, the commission may set a maximum allowable price the manufacturer can charge for that prescription drug.[40]

Aside from a lack of clarity regarding the makeup of the "commission" and "center," the Massachusetts legislation raises another significant concern. In the event that the price cap is not up to drug manufacturers' satisfaction, manufacturers could refuse to sell new, innovative drugs in the Massachusetts market because their revenues would be at the mercy of the state.[41] Further, there are a variety of organizations trying to purchase drugs in the U.S., including individual insurance groups, hospitals, and insurance plans that buy for their individual customers.[42] Unregulated pricing results from plans and groups negotiating their own pharmaceutical prices.[43] If Massachusetts were to regulate pricing, drug manufacturers would likely sell to other states that do not have such regulation.[44] Similar to how fireworks are smuggled from one state to another because of certain regulatory laws, an illegal market may arise with prescription drugs not permitted to be sold in Massachusetts because of this proposed legislation.

In an effort by state legislatures to provide drug cost transparency, the New York and Massachusetts bills have revealed numerous issues that still need to be addressed before any of the legislative goals can be successful. However, despite the action to create laws, there is little evidence to prove that such laws, even when perfected, will reduce drug costs.

IV. DRUG COST TRANSPARENCY LAWS WILL STIFLE INNOVATION AND WILL NOT EFFECTIVELY DRIVE DOWN PRICES

Prescription drugs have become a part of our everyday culture. Spending on all prescription drugs, including antibiotics, accounts for one tenth of the nation's total health spending.[45] A recent report found that nearly half of all Americans take at least one prescription drug, and more than twenty percent of Americans had taken three or more prescriptions in the last thirty days.[46] With the amount of prescription drugs being consumed along with the cost of each drug, Americans should be informed about how high drug prices correlate with production costs.

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40. *Id.*
41. Kardish, *supra* note 6.
42. Kounang, *supra* note 2.
43. *Id.*
44. Kardish, *supra* note 6.
45. *Runaway Drug Prices*, *supra* note 5.
46. *Therapeutic Drug Use,* CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/nchs/fastats/drug-use-therapeutic.htm (last updated May 14, 2015).

A. Other Costs to Manufacturers Not Covered by Legislation

While proposed pharmaceutical legislation intends to elucidate the connection between the cost of production and the sticker price seen by individual patients,[47] the legislation fails to take into consideration other costs that drug manufacturers must incur. Other costs, such as fees associated with regulatory compliance and employee salaries, should also be considered.[48] The type of legislation proposed by the various states does not factor in these additional costs, but rather only focuses on costs related to a specific successful drug.[49] Even though the legislation will shed some light on the costs to produce these drugs, it may not provide any more insight to help understand real pharmaceutical R&D costs and pricing.[50]

B. Drug Manufacturers Will Have Difficulty Complying with Legislation

Additionally, lobbyists for drug manufacturers maintain that legislation requiring transparency would be costly to comply with and disclosing such information would only be misleading.[51] Len Nicols, a health care economist at George Mason University, said, "The past R&D cost is really kind of a red herring." [52] Nicols stated that current revenue funds current R&D; it does not pay for past R&D.[53] Thus, knowing how much revenue drug manufacturers receive for a particular drug has little to do with the drug's price, and knowing such R&D cost information will not necessarily decrease prices.[54]

C. Legislation Does Not Factor in the Value of Certain Drugs

Another argument against transparency legislation is that drug manufacturers price drugs based on value provided.[55] Moreover, these drug manufacturers are in direct competition with other rival manufacturers' drugs already on the market.[56] A director of a multiple sclerosis drug developer stated, "[Drug manufacturers] all look at each other and keep pace with each

47. *See* Gavura, *supra* note 12 ("There are also the ongoing costs of making a drug available—the costs of meeting regulatory requirements, and the overhead cost of running a business with tens of thousands of employees. The legislation ignores all of those costs as well, focusing only on that that can be directly linked to a chemical. If this legislation succeeds. . .it will be no more helpful in helping us understand pharmaceutical R&D costs and pricing.").
48. *Id.*
49. *Id.*
50. *Id.*
51. Pollack, *supra* note 6.
52. *Id.*
53. *Id.*
54. *Id.*
55. *Id.*
56. *Id.*

other."[57] Although transparency regarding drug production costs would be ideal, there is very little indication that even with that information, drug prices will decrease.

D. Legislation Could Adversely Impact Innovation

Although the above incentives provide measures of innovation, theorists have expressed concern that patent protections and unregulated pricing measures exploit consumers.[58] Yet, studies indicate that price controls, such as those suggested by the Massachusetts state legislature, would cut the return that pharmaceutical companies receive on the sale of their drugs and ultimately reduce the number of new drugs being brought to the new market, thus stifling innovation.[59] If legislatures were authorized to set a maximum allowable price that manufacturers can charge for prescription drugs, drug manufacturers would not be as motivated to produce new drugs.[60] Cheaper prices for drugs may help the wallets of consumers now, but ultimately could prevent drug manufacturers from producing new and better drugs.[61] Therefore, an immediate benefit for consumers could lead to a negative future impact on social welfare.[62] The negative effects may not be fully understood for decades given the lengthy process of creating new drugs.[63]

One study, conducted by Thomas Abbott and John Vernon with the National Bureau of Economic Research, takes into account the uncertainty around R&D costs, the success rates for drug developments, and the financial returns to those products that are successfully launched into the market.[64] Their basic finding is that cutting drug prices by forty to forty-five percent in the U.S., as seen in other countries, could lead to between fifty to sixty percent fewer R&D projects being taken into human trials, an essential stage of developing a new drug.[65] However, relatively modest price changes, such as five to ten percent, are estimated to have a relatively small impact on the

57. *Id.*

58. *Id.*

59. David R. Francis, *The Effect of Price Controls on Pharmaceutical Research*, NAT'L BUREAU OF ECON. RES., http://www.nber.org/digest/may05/w11114.html (analyzing the Abbott and Vernon study regarding the impact of future price controls on future drug development).

60. *Id.*

61. *Id.*

62. *Id.*

63. *Id*.

64. Thomas A. Abbott & John A. Vernon, *The Cost of US Pharmaceutical Price Reductions: A Financial Simulation Model of R&D Decision* 1 (Nat'l Bureau of Econ. Research, Working Paper No. 11114, Feb. 2005) http://www.nber.org/papers/w11114.pdf (analyzing how "future price controls in the U.S. will impact early-stage product development decisions in the pharmaceutical industry").

65. *Id.* at 23.

incentives for product development, perhaps as little as a five percent decrease.[66] Based on this research, it seems that transparency regarding development costs for a particular drug has very little to do with that drug's pricing.[67] Even if legislation requires drug manufacturers to disclose this information, it will likely not keep prices down and will only further stifle innovation.[68]

V. CONCLUSION

There are many obstacles to innovation in health care. In order to combat rising prescription drug prices, many have called for more transparency in the industry. Although drug manufacturers should be required to disclose their production costs, it does not appear that such transparency laws will drive drug prices down. In sum, legislation, such as the proposed Massachusetts and New York bills that allow the states to set a maximum price drug manufacturers can charge, will only further stifle health care innovation.

66. *Id.*
67. *Id.* at 24.
68. *Id.*

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Power to the People: How Medical Mobile Apps Are Increasing Patient Knowledge and Changing the Doctor-Patient Relationship

*Sarah Costa**

I. INTRODUCTION

In 2015, an estimated 1.91 billion mobile phones will be in use worldwide, creating easy access to the Internet and all of the information it has to offer.[1] Nearly two thirds of all Americans own smartphones and nineteen percent of those individuals rely on their smartphone for access to the Internet.[2] The way in which people access information is changing. More people turn to their cell phones for Internet access than ever before and those people are using the Internet for everything from online banking to submitting job applications.[3] In fact, sixty-two percent of smartphone users in the United States turn to their phone to access information about health conditions.[4]

With this increase in information accessibility and newfound dependence on smartphones, a new healthcare technology has emerged: medical mobile applications.[5] These applications range in function from fitness trackers that collect information about an individual's heart rate and the number of steps taken in a day to attachments that can be used to monitor blood sugar or track heart rhythms.[6] In a survey performed by the Economist Intelligence Unit, sixty-four percent of healthcare executives interviewed believed the introduction of medical mobile technology could dramatically improve health outcomes for patients, and sixty-three percent believed that increased access to health information would allow individuals to make better decisions

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1. *2 Billion Consumers Worldwide to Get Smart(phones) by 2016*, eMARKETER (Dec. 11, 2014), http://www.emarketer.com/Article/2-Billion-Consumers-Worldwide-Smartphones-by-2016/1011694.

2. Aaron Smith, *U.S. Smartphone Use in 2015*, PEW RESEARCH CTR. (Apr. 1, 2015), http://www.pewinternet.org/ 2015/04/01/us-smartphone-use-in-2015/.

3. *Id.*

4. *Id.*

5. Eric J. Topol, *The Future of Medicine Is in Your Smartphone*, WALL ST. J. (Jan. 9, 2015), http://www.wsj.com/articles/the-future-of-medicine-is-in-your-smartphone-1420828632.

6. *Id.*

about their health.[7]

Patients are more educated about health care than ever before, which has changed the relationship that patients have with their doctors.[8] Traditionally, the doctor-patient relationship was one-sided – patients relied heavily on the opinion of their doctors and waded through red tape to access documents such as lab reports and doctors' notes.[9] The introduction of medical mobile applications is changing that relationship.[10] Now patients have access to information that was previously only available to their doctor.[11] As a result, patients are gaining more control over their own medical care.[12] The growth in popularity of medical mobile applications will forever change the healthcare industry and affect every area from patient care to physician reimbursement.[13] Medical mobile applications are significantly changing the way patients seek care and the relationship patients have with doctors. Large-scale use of medical mobile applications can have a positive effect on the doctor-patient relationship. However, in order to do so the Food & Drug Administration's ("FDA") regulations must be expanded to cover a larger category of applications, the patient information stored on applications must be secure, and patients must take a more active role in their own health care.

II. MOBILE HEALTH APPLICATIONS

The use of mobile technology in medicine began in 2007 with the launch of the first iPhone.[14] From that point on, anyone could develop a mobile application to be sold in the Apple Application Store ("App Store").[15] Currently, there are about 1.5 million applications in the App Store and this number is continuously growing.[16] As technology progresses, these

7. ECONOMIST INTELLIGENCE UNIT, POWER TO THE PATIENT: HOW MOBILE TECHNOLOGY IS TRANSFORMING HEALTHCARE 4 (2015).

8. Topol, *supra* note 5.

9. *Id.*

10. *See id* (Easy to access mobile applications are giving patients the ability to perform their own test at home and send the information to their doctors for interpretation or advice. Patients no longer need to schedule an appointment to get the tests done and wait hours or days for the results, but rather can perform the test themselves and get results almost immediately.).

11. ECONOMIST INTELLIGENCE UNIT, *supra* note 7.

12. *Id.* at 12.

13. *Id.*

14. Press Release, Apple, Apple Reinvents the Phone with iPhone (Jan. 9, 2007), http://www.apple.com/pr/library/2007/01/09Apple-Reinvents-the-Phone-with-iPhone.html.

15. Press Release, Apple, iPhone to Support Third-Party Web 2.0 Applications (June 11, 2007), http://www.apple.com/pr/library/2007/06/11iPhone-to-Support-Third-Party-Web-2-0-Applications.html.

16. *Number of Apps Available in Leading App Stores as of July 2015*, STATISTA, http://www.statista.com/statistics/ 276623/number-of-apps-available-in-leading-app-stores/ (last visited Sept. 27, 2015).

applications have become increasingly sophisticated – allowing for smartphones to be transformed into tools as simple as a flashlight or as complex as a heart monitor.[17] Medical mobile applications take advantage of a smartphone's built-in features including touch screens, cameras, wireless connectivity, and software.[18] There are an estimated 26,000 healthcare applications available for download today, and only 7,400 are intended for doctor use.[19] Using the built-in features of smartphones to collect data in combination with medical mobile applications that process the data, a smart phone user can receive an individual diagnosis in minutes.[20] These applications cover many different areas of the medical field ranging from fitness and nutrition to dermatology applications that analyze moles for melanoma.[21]

Responding to the increase in medical mobile applications, the FDA has taken steps to regulate some applications for quality assurance.[22] In doing so, the FDA has issued two statements regarding the use and development of medical mobile applications.[23] In 2011, the FDA issued guidelines for those who wished to develop and use medical mobile applications.[24] In 2013, the FDA moved beyond guidelines and began to impose regulations on specific medical applications – namely, those the FDA deemed to be medical devices.[25] The FDA considers applications to be medical devices if the user utilizes the application as an accessory to an already regulated medical device or if the application transforms a smartphone into a regulated medical device.[26] The FDA defines a medical device as an instrument intended to be

17. Sangeeta Ghosh Dastidar, *iPhone, iPad App to Convert SmartPhone into Mobile Medical Monitor*, INT'L BUS. TIMES (Oct. 7, 2011, 7:09 AM), http://www.ibtimes.com/iphone-ipad-app-convert-smartphone-mobile-medical-monitor-321913.

18. Nathan Cortez, *The Mobile Health Revolution?*, 47 U.C. DAVIS L. REV. 1173, 1177 (2013).

19. David Lee Scher, *The Big Problem with Mobile Health Apps*, MEDSCAPE (Mar. 4, 2015), http://www.medscape.com/viewarticle/840335_print.

20. *Id.*

21. *See* Topol, *supra* note 5.

22. Valerie Bauer, *MHealth and the Transformation of Mobile Medical Applications*, PHX (Mar. 18, 2015), http://www.phx-online.com/ecudednews/mhealth-and-the-transformation-of-mobile-medical-applications/.

23. *Id.*

24. *Id.*

25. *Id. See also* FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH AND HUMAN SERV'S, MOBILE MEDICAL APPLICATIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 33-37 (Feb. 9, 2015), *available at* http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf (the FDA regulatory requirements imposed on mobile application manufacturers include the registration of establishments to let the FDA know what applications each establishment is manufacturing, the running of clinical trials, product labeling requirements, quality system regulation, and adverse event reporting).

26. Bauer, *supra* note 22; *see also Mobile Medicine Resources: FDA Approved Apps*,

used for diagnosis of disease or prevention of disease.[27] Medical mobile applications are thus separated into two different categories: 1) those considered medical devices requiring regulation by the FDA, and 2) those considered low risk applications not requiring FDA regulation.[28] For example, the application BlueStar monitors a patient's blood sugar and offers coaching to diabetic patients.[29] The FDA has stated that because the application transforms a smartphone into a device to test blood glucose levels, FDA approval is required for its use.[30] Conversely, the FDA considers the fitness application MyFitnessPal, which contains a database of foods and allows users to track the number of calories consumed, a low risk application that does not require regulation.[31] Although the FDA has enforced regulations to protect medical application users, the majority of applications available for download do not require FDA approval.[32] In today's world, any information a person could ever need is available at the push of a button.[33] Patients are beginning to demand quick and easy access to health care.[34] While patients want faster health care, concern over the effectiveness of medical mobile applications as well as the security of patient information cannot be overlooked.[35]

BERNARD BECKER MED. LIBR., http://beckerguides.wustl.edu/c.php?g=299564&p=2000997 (last visited Nov. 16, 2015) (providing examples of applications that have been approved by the FDA include: Alivecor, an application and portable device that allows the user to record ECG readings on a smart phone; MobiUS, an application and portable device that performs an ultrasound reading; and the Gauss Surgical Triton Fluid Management System that tracks blood loss during surgery on a mobile platform).

27. *What is a Medical Device?*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/Transparency/Basics/ucm211822.htm (last visited Nov. 30, 2015) (the FDA defines a medical device as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article" which is "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals.").

28. Stephen McInerney, *Can You Diagnose Me Now? A Proposal to Modify FDA's Regulation of Smartphone Mobile Health Applications with a Pre-Market Notification and Application Database System*, 70 FOOD & DRUG L.J. 161, 164 (2015).

29. Tim Stanton & Demir Bingol, *WellDoc Launches BlueStar, First FDA-Cleared, Mobile Prescription Therapy for Type 2 Diabetes with Insurance Reimbursement*, BUS. WIRE (June 13, 2013), http://www.businesswire.com/news/home/20130613005377/en/WellDoc-Launches-BlueStar-FDA-Cleared-Mobile-Prescription-Therapy.

30. *Id.*

31. McInerney, *supra* note 28, at 165.

32. Scher, *supra* note 19.

33. *See* Smith, *supra* note 2 (detailing the use of smart phones and how they are being used by Americans to access the internet).

34. Topol, *supra* note 5.

35. *See* Scher, *supra* note 19 (explaining how doctors are concerned with the efficacy and accuracy of medical mobile applications and the security of patient information with the use of medical mobile applications).

III. CHALLENGES MEDICAL MOBILE APPLICATIONS FACE IN CHANGING THE DOCTOR-PATIENT RELATIONSHIP

The doctor-patient relationship is a crucial component of patient care.[36] However, the relationship has historically been paternalistic – the doctor is responsible for making healthcare decisions for the patient while the patient holds little or no authority in the decision-making process.[37] While a doctor is more educated in the area of medicine, the introduction of medical mobile applications into mainstream medicine gives the patient more power and access to medical information.[38] This introduction of new technology is not without issues, which will serve as roadblocks to the potential effectiveness of medical mobile applications.[39] The challenges medical mobile applications pose for the doctor patient-relationship vary significantly.[40] Three challenges that threaten the development of medical mobile applications are: 1) regulatory issues concerning the accuracy of applications that diagnose medical conditions, 2) protection of patient information security and HIPAA,[41] and 3) the growing need for patient involvement.[42]

A. Regulatory Barriers to Medical Mobile Applications

As previously stated, the FDA regulates some medical mobile applications.[43] FDA oversight guarantees that applications with higher potential for risk are evaluated to bring safe and effective products to the market.[44] However, simply because an application is not regulated by the FDA does not mean that risk is non-existent.[45] For example, in a recent study

36. Susan Dorr Goold & Mack Lipkin, Jr., *The Doctor-Patient Relationship: Challenges, Opportunities, and Strategies*, J. GEN. INTERNAL MED. S26, S26 (1999).

37. Topol, *supra* note 5.

38. *Id.*

39. *See generally* Scher, *supra* note 19 (many doctors are concerned about security and potential HIPAA violations, as well as the safety of applications that may go unnoticed and unregulated by the FDA).

40. *Id.* (explaining that the areas in which doctors are concerned include security, accuracy of the application, and efficacy of the application).

41. *Id.* (explaining that if doctors are concerned about the security of patient information they will likely choose not to use medical mobile applications in their practice).

42. Beth Walsh, *Patient Engagement Efforts Drive Mobile Health*, CLINICAL INNOVATION + TECH. (Oct. 30, 2013), http://www.clinical-innovation.com/topics/mobile-telehealth/patient-engagement-efforts-drive-mobile-health (explaining that as mobile technology becomes more popular and affordable it is being used to engage patients in their health care).

43. Bauer, *supra* note 22.

44. *FDA's Role in Ensuring American Patients Have Access to Safe and Effective Medical Device Technology*, U.S. FOOD & DRUG ADMIN. (Mar. 31, 2015), http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm456969.htm.

45. *See generally* Stephen Spotswood, *Dermatology Mobile Technology Burgeons; VA Has New App on Drawing Board*, COMPENDIUM FED. MED. (2014), http://www.usmedicine.com/agencies/department-of-veterans-affairs/dermatology-mobile-technology-

researchers looked at a non-FDA regulated dermatology application that analyzes moles and found that the application misidentified as many as thirty percent of melanomas.[46] The study catalogued more than 200 different medical mobile applications specializing in dermatology that performed a variety of tasks such as monitoring psoriasis, connecting patients with support groups, and giving sunscreen advice.[47] However, the applications that concerned researchers the most were those that dealt with the identification of melanomas, primarily because of the catastrophic consequences related to misidentification of a cancerous mole.[48]

Doctors and patients alike must be careful about which medical mobile applications to depend on for health-related information.[49] Patients need to understand that applications such as those used to diagnose melanoma or general symptom trackers cannot replace professional physicians and are not regulated by the FDA.[50] Heavy reliance on medical mobile applications for diagnosis removes the possibility of discovering a secondary diagnosis – something a doctor may discover during a physical exam.[51] However, with the growing number of smartphone users in the world today, complete avoidance of medical mobile applications is unfeasible.[52] In order to better protect patients, the FDA must expand regulation of medical mobile applications beyond those deemed medical devices.[53] Achieving such protection from medical mobile applications will require doctors and patients to discuss the potential uses and drawbacks involved in utilizing medical applications.[54] This can help the doctor and patient reach a mutual decision on how to approach the patient's health. [55]

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burgeons-va-has-new-app-on-drawing-board/ (explaining that even applications that do not meet the FDA regulation standards can have a substantial risk to patients if used without doctor supervision).

46. *Id.*

47. *Id.*

48. *Id.* (explaining that misidentification of a cancerous melanoma could allow the cancer to spread to other parts of the body and decrease a patient's likelihood of survival or significantly complicate a patient's treatment).

49. McInerney, *supra* note 28, at 167.

50. *Id.*

51. *See id.* at 168 (symptom-checking applications are only programmed to present the most likely diagnosis and fail to take into consideration that more than one condition could be causing a patient's symptoms to occur).

52. *See id.* (stating that the majority of Americans own smartphones with the ability to access medical mobile applications).

53. *See* Spotswood, *supra* note 45 (explaining that applications not regulated by the FDA can pose a significant risk to patients).

54. *See Healthcare On-The-Go: Pros and Cons of Mobile Health Apps*, SUPPLEMENTAL HEALTH CARE (Aug. 27, 2013), http://www.supplementalhealthcare.com/blog/2013/healthcare-go-pros-and-cons-mobile-health-apps (explaining the pros and cons of medical mobile use applications).

55. *See generally* Topol, *supra* note 5.

B. Security and HIPAA Concerns

Many doctors are hesitant to use medical mobile applications because of concern for the security of their patients' personal information.[56] Now that many hospitals and doctors' offices have shifted to electronic medical records, the safety of patients' personal information has been a serious concern of doctors and patients alike.[57] Recently, hackers broke into patient records at the University of California, Los Angeles and stole patient names, medical information, social security numbers, Medicare numbers, birthdays, and addresses.[58] The increase in security breaches at large institutions such as hospitals and universities has heightened awareness about the safety of personal information.[59] Due to the increasing popularity of medical mobile applications, doctors and patients should be cautious about using an application that could be lacking security protection.[60]

In a survey performed by The Economist Intelligence Unit, forty-nine percent of individuals interviewed believed that consumer wariness and privacy concerns would be a barrier to the adoption of mobile health applications.[61] If doctors do not believe the applications to be safe, they will not use them in their practice, which could stop the mobile health movement before it truly begins.[62] The federal government has said that it will better define HIPAA standards to ensure patient privacy and safety; however, until safety can be assured the number of physicians who choose to use medical mobile applications will likely remain relatively low.[63] Until physicians can be sure that confidential patient information is safe they will continue to be reluctant to introduce medical mobile applications into their practice.[64] Without physicians willing to actively pursue the use of medical mobile applications, they will never reach the numbers necessary to disrupt the doctor-patient relationship on a large scale.[65] If the use of medical mobile applications is to become a driving force in the healthcare market, security

56. Scher, *supra* note 19.

57. Jose Pagliery, *UCLA Health Hacked, 4.5 Million Victims*, CNN MONEY (July 17, 2015), http://money.cnn.com/2015/07/17/technology/ucla-health-hack/.

58. *Id.*

59. *See id.* (explaining that large institutions are popular targets for hackers).

60. Scher, *supra* note 19.

61. ECONOMIST INTELLIGENCE UNIT, *supra* note 7, at 4.

62. Scher, *supra* note 19.

63. *See id.* Forty six percent of health care professionals say that they will introduce medical mobile applications into their practice in the next five years, however, only sixteen percent of health care professionals already use mobile medical applications in their work with patients. Rajiv Leventhal, *Survey: Doctors and Patients See Benefits in Mobile Apps*, HEALTHCARE INFORMATICS (Mar. 24, 2015), http://www.healthcare-informatics.com/print/news-item/survey-doctors-and-patients-see-benefits-mobile-apps.

64. Scher, *supra* note 19.

65. ECONOMIST INTELLIGENCE UNIT, *supra* note 7, at 4.

must be a priority for companies developing medical mobile technology.[66]

IV. THE SHIFT IN POWER TO THE PATIENT

The final and perhaps most important challenge to ensuring that medical mobile applications have a positive effect on the doctor-patient relationship is increasing patient autonomy.[67] Medical mobile technology makes information that was once only seen by physicians readily available to patients.[68] Patients will soon be able to conduct tests in the privacy of their own homes using attachments or images on their cell phone.[69] Patients with chronic conditions will be able to remotely monitor their conditions, making patients better equipped to discuss their condition with their doctor and in turn make health decisions as a team.[70]

With the direction healthcare monitoring is headed, patients will soon be able to analyze their health in real time, and mobile applications will soon take the place of routine visits to the doctor.[71] However, visits to a primary care physician are not the only service in the medical field that will likely decrease.[72] With increased ability for patients to perform lab tests at home, patients will have the opportunity to directly receive the results of their tests before sending them to their doctor.[73]

The increase in mobile technology gives healthcare providers the ability to expand care to individuals in areas where hospitals and doctors are sparse.[74] In a study performed by the U.S. National Institutes of Health and Qualcomm in Arizona, fifty individuals suffering from congestive heart failure were given home monitors to allow the individuals to self-monitor and have direct contact with a doctor if a medical issue arose.[75] The results of the

66. *See* David Lee Scher, *Critical Considerations in Designing Medical Mobile Apps*, QMED http://www.qmed.com/mpmn/article/critical-considerations-designing-mobile-medical-apps (last visited Nov. 30, 2015) (explaining that companies and individuals developing applications must consider security issues when developing their product and not just as an afterthought).

67. ECONOMIST INTELLIGENCE UNIT, *supra* note 7, at 12.

68. Topol, *supra* note 5.

69. ECONOMIST INTELLIGENCE UNIT, *supra* note 7, at 13.

70. Eugenio Santoro et al., *Social Media and Mobile Applications in Chronic Disease Prevention and Management*, 6 FRONTIERS IN PSYCHOL. 1, 1, (2015), *available at* http://journal.frontiersin.org/article/10.3389/fpsyg.2015.00567/full.

71. Sundar Subramanian et al., *Personalized Technology Will Upend the Doctor-Patient Relationship*, HARV. BUS. REV. (June 19, 2015), https://hbr.org/2015/06/personalized-technology-will-upend-the-doctor-patient-relationship (arguing that if patients will have the ability to perform routine procedures outside of the office and on their smart phones they will no longer feel the need for regular doctor visits).

72. ECONOMIST INTELLIGENCE UNIT, *supra* note 7, at 12.

73. *Id.*

74. *Id.* at 6.

75. *Id.*

study were shocking: the average number of days a patient spent in the hospital plummeted from fourteen days per month to five days per month, saving patients more than $90,000 per person.[76] The monitors gave patients the ability to address health problems before they became more serious and taught patients which symptoms were not signs of more threatening conditions requiring hospitalization.[77] The change to a more remote doctor-patient relationship has educated patients, causing them to better understand their medical conditions.

While the doctor-patient relationship will experience drastic changes in the years to come, it will not disappear. The focus of care will likely shift from reactive care, which treats diseases after symptoms begin to occur, to proactive care, which attempts to prevent diseases before they occur.[78] The relationship will be more remote, resulting in yearly visits as opposed to regular appointments to treat colds and illnesses.[79] Medical mobile applications, as well as doctors, must focus on encouraging patient involvement in order to be successful.[80] However, this shift will only occur if patients are willing to accept a more active role in their own health care.[81] A study performed by The Healthcare Information and Management Systems Society found that patients who were more involved in their own health care showed better outcomes in the long run.[82] By creating patient engagement, medical mobile applications and doctors can work to help patients help themselves.[83]

V. CONCLUSION

With increased availability of technology, more people will have access to previously unattainable medical information.[84] Medical mobile applications offer both patients and doctors a chance to enhance the doctor-patient relationship through transparency and communication.[85] Unfortunately, without increased security and regulation this may not be possible. Until applications can guarantee that patient information is secure and that mobile

76. *Id.*

77. *Id.*

78. *Id.* at 12.

79. *Id.*

80. Vera Gruessner, *Mobile Health Impacts Patient Engagement, Accountable Care*, MHEALTH INTELLIGENCE (July 28, 2015), http://mhealthintelligence.com/news/mobile-health-impacts-patient-engagement-accountable-care.

81. *Id.* (patients are the driving force behind the mobile medical application movement).

82. *Id.*

83. *See id.* (by encouraging patient involvement doctors and medical mobile applications will encourage a healthier community and cause patients to be healthier).

84. Topol, *supra* note 5.

85. *Id.* at 5.

applications will be accurate, use of mobile applications will remain low among doctors and the doctor-patient relationship will largely go unchanged.

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Tough Love: Why Patients Should Change Physician Expectations

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I. INTRODUCTION

Less than twenty years ago, research showed healthcare providers that a key factor concerning long-term viability in the healthcare industry is customer satisfaction.[1] Customer satisfaction in the healthcare industry focuses on meeting or exceeding patient expectations.[2] At that time, researchers believed patient satisfaction was a desired outcome of patient care.[3] Information collected about patient satisfaction was viewed as indispensable to the assessment of quality management of a healthcare system.[4]

Today, more recent research calls into question the need for customer service in the healthcare industry.[5] In fact, some research shows a correlation between high customer satisfaction and more frequent hospital visits, higher healthcare costs, and shockingly high mortality rates.[6] This article will argue

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1. *See* Syed Saad Andaleeb, *Determinants of Customer Satisfaction with Hospitals: A Managerial Model*, 11 INT'L J. OF HEALTH CARE QUALITY ASSURANCE 1, 1 (1998) ("Many providers, with help from the research community, are beginning to realize that providing customer satisfaction is a key element of strategy and a crucial determinant of long-term viability and success.").

2. *See* Joel M. Kupfer & Edward U. Bond, *Patient Satisfaction and Patient-Centered Care*, 308 JAMA 139, 139 (2012) ("Patient satisfaction [. . .] is a different concept, which has its roots in consumer marketing, and is a measure of how services or products of a company meet or exceed the anticipated expectations of the customer.").

3. *See* Andaleeb, *supra* note 1, at 1 (quoting various researchers who all agreed customer satisfaction is an imperative aspect to patient satisfaction).

4. *See id.* ("[I]nformation about patient satisfaction should be as indispensible to assessments of quality as to the design and management of health care systems.").

5. *See* Linda Brookes & Joshua J. Fenton, *Patient Satisfaction and Quality of Care: Are They Linked?*, MEDSCAPE MULTISPECIALTY (June 11, 2014), http://www.medscape.com/viewarticle/826280 (research showing increased admittance to hospitals, healthcare expenditures, and death rates).

6. *See id.* ("[A March 2012 study using] data from more than 50,000 adult patients indicat[ed] that the most satisfied patients (highest patient satisfaction quartile relative to the lowest quartile) were 12% more likely to be admitted to the hospital and had both total healthcare expenditures and prescription drug expenditures that were 9% higher. Most perplexing to many readers at the time, these patients were also 26% more likely to die.").

that customer satisfaction should not be a focal point in physician care due to the potentially negative health effects patients may experience, as well as the unnecessary costs that accompany methods used to increase customer satisfaction.[7] This article will specifically evaluate customer satisfaction in light of the recent enactment of the Affordable Care Act (ACA), which encourages a practice ultimately hurting the health of patients to push for patient satisfaction.[8] In evaluating these issues, this article will focus on the development of patient satisfaction, why patient satisfaction contradicts the practice of healthcare, how the ACA has implemented patient satisfaction as a new provision in the healthcare industry, the negative effects this provision has on the healthcare industry, and the extra costs associated with the new ACA provision.

II. THE START OF THE CUSTOMER SATISFACTION PHENOMENON

The American Marketing Association defines customer satisfaction as "a measure of how products and services supplied by a company meet or surpass customer expectation."[9] It further defines customer satisfaction by "the number of customers, or percentage of total customers, whose reported experience with a firm, its products, or its services exceeds specified satisfaction goals."[10] Customer satisfaction is a cornerstone of a successful business because it gives a business the information it needs to manage, improve, and increase revenue.[11] Some key reasons businesses find customer satisfaction so important include differentiating one's business from market competitors, lowering costs, eliminating negative publicity, and increasing customer loyalty.[12] This customer satisfaction phenomenon started in the

7. *See generally* Joshua J. Fenton et al., *The Cost of Satisfaction*, 172 ARCHIVES OF INTERNAL MED. 405, 409-10 ("Without additional measures to ensure that care is evidence based and patient centered, an overemphasis on patient satisfaction could have unintended adverse effects on health care utilization, expenditures, and outcomes.").

8. Michael L. Millenson & Juliana Macri, *Will the Affordable Care Act Move Patient-Centeredness to Center Stage*, URBAN INST. 1 (Mar. 2012) ("Nearly a decade after the Institute of Medicine (IOM) designated ―'patient-centeredness' as one of six goals for a 21st century health care system, the Patient Protection and Affordable Care Act (ACA) has mandated the use of measures of the quality of care, public reporting, and performance payments that reflect this ambitious aim.").

9. *Dictionary*, AM. MKTG. ASS'N, https://www.ama.org/resources/Pages/Dictionary.aspx?dLetter=C (last visited Sept. 19, 2015) (defining customer satisfaction).

10. *Id.*

11. Ross Beard, *Why Customer Satisfaction Is Important (6 Reasons)*, CLIENT HEARTBEAT BLOG (Jan. 20, 2014), http://blog.clientheartbeat.com/why-customer-satisfaction-is-important/; Tim Pokalsky, *The Importance of Customer Satisfaction and Loyalty Research*, SSRS RESEARCH REFINED 1, http://ssrs.com/wp-content/uploads/2014/10/SSRS_Loyalty_Satisfaction_WP_Sept_2014.pdf (last visited Nov. 13, 2015).

12. *See* Ross Beard, supra note 11 (listing the top six reasons why customer satisfaction is so important, which include: "[i]t's a leading indicator of consumer repurchase intentions

1980's when product differentiation started to become increasingly difficult.[13] Management was forced to turn to new strategies to maintain business viability.[14]

The research community led healthcare providers to believe the customer satisfaction phenomenon was a transferrable strategy that would yield positive health outcomes.[15] Congress first became involved in the 1980s when it requested a report that would include an overview of patient feedback.[16] However, this report played no role in assessing physician care at the time.[17] In the 1990s, focus shifted to "managed competition"[18] due to a reform proposal by Clinton's administration.[19] Fear then arose regarding Medicare health plans and the government created a survey in response.[20] This survey compared different Medicare plan sponsors.[21] By 2006, this survey morphed into the survey now used by the ACA to collect data on patient satisfaction in hospitals receiving Medicare funding.[22]

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and loyalty; [i]t's a point of differentiation; [i]t reduces customer churn; [i]t increases customer lifetime value; [i]t reduces negative word of mouth; [i]t's cheaper to retain customers than acquire new ones.").

13. *See* Dayr Leticia et al., *Customer Satisfaction: the Historical Perspective*, 41 J. OF MGMT. HIST. 195, 195 (2003) (explaining that in the 1980s and early 1990s companies developed closer ties to their customers and therefore were able "to pick up more differentiated signals from the market and thus respond to different segments of demand"); *see also* Ray Poynter, *The Rise of Customer Satisfaction Research*, VISION CRITICAL BLOG (Nov. 6, 2013), https://www.visioncritical.com/rise-customer-satisfaction-research/ ("The 1980s saw several changes in how businesses operated. The ability of brands and services to have clear product differences started to diminish.").

14. *See id.* ("As companies became larger and increasingly multinational, they turned to management consultants to create complete/integrated strategies; these strategies often included boosting customer satisfaction.").

15. *See* Brookes & Fenton, *supra* note 5 ("Since the 1980s, interest in the measurement of patients' satisfaction with their healthcare experience has increased following reports that high patient satisfaction is associated with better health outcomes."); *see also* Andaleeb, *supra* note 1 (explaining the research community helped providers realize a key strategy for viability and success was customer satisfaction).

16. Millenson & Macri, *supra* note 8, at 2.

17. *See id.* ("At the time there was neither agreement on the role to be played by patient feedback nor consensus on measurement instruments.").

18. Alain C. Enthoven, *The History and Principles of Managed Competition*, 12 HEALTH AFFAIRS 24, 29 (1993) ("Managed competition is a purchasing strategy to obtain maximum value for money for employers and consumers").

19. Millenson & Macri, *supra* note 8, at 2 ("By the early 1990s, when health plans assumed a more prominent health system role under the Clinton administration's 'managed competition' reform proposal, the measurement focus shifted there.").

20. *See id.* ("Because of fears that health plans serving Medicare beneficiaries might cut corners to control costs, the government funded development of a survey of health plan members about access, provider communication, and other measures of quality.").

21. *See id.* ("Consumer Assessment of Health Plans Study (CAHPS) [. . .] was a standardized and validated questionnaire that could be used to compare results among different plan sponsors and over time.").

22. *Id.*

III. WHY THE HEALTHCARE INDUSTRY CONTRADICTS THE MARKETING STRATEGY

With regards to marketing strategy, there are two major differences between medicine and other traditional services.[23] First, patients cannot efficiently evaluate the quality of care they receive.[24] Lack of knowledge of medical care standards and expectations can lead to patients overemphasizing the elements they understand while undervaluing those they do not.[25] The three major concerns with patient satisfaction measuring assessments are that: (1) patients do not have proper medical knowledge through which to relay credible feedback; (2) patients will potentially relay feedback that is not associated with the physicians' quality of care; and (3) patients are likely to provide feedback based on their own desires and expectations going into an appointment with their physician.[26] Second, unlike the typical marketing setup, healthcare users are typically not the direct payer for their health services, breaking the link of cost consideration that consumers typically think through in making a purchase.[27] With the separation of consumer (the patient) and payer (insurance), neither party is able to make sound, holistic conclusions on the trade-off involved like a customer is able to do in a normal business setting.[28] Taking these two points into consideration, it is clear patient satisfaction surveys do not appropriately measure physician performance.

One study led by Dr. Joshua Fenton found correlations between patient satisfaction and increased inpatient utilization, expenditures on both healthcare and prescription drugs, and mortality rates.[29] The researchers explained patients commonly bring personal expectations to medical consultations and make specific requests of physicians.[30] Patient satisfaction correlates with the physician's ability and willingness to fulfill the patient's expectations.[31] The expectations and demands of a patient do not always

23. Kupfer & Bond, *supra* note 2, at 140.

24. *Id.*

25. *Id.*

26. Matthew P. Manary et al., *The Patient Experience and Health Outcomes*, 368 NEW ENG. J. MED. 201, 201-02 (2013).

27. *See* Kupfer & Bond, *supra* note 2, at 140 ("[R]ecipients and payers are frequently not the same entities. This is different from the marketing perspective in which evaluations of satisfaction are linked with considerations of cost that are immediately and directly felt by the customer.").

28. *Id.*

29. Fenton et al., *supra* note 7 at 407.

30. *Id.*

31. *Id.*; *see also* Aleksandra Zgierska, et al., *Patient Satisfaction, Prescription Drug Abuse, and Potential Unintended Consequences*, 307 JAMA 1377, 1377 (2012) ("[P]atient expectations shape the health encounter. Many patients expect to receive an intervention that only a clinician can provide, a prescription for a medication. Patients may not be interested in

meet the medical necessity of a situation, and medical professionals should feel comfortable denying a patient's demands and risking lower satisfaction in order to maintain an effective practice.[32]

IV. IMPLEMENTATION BY THE AFFORDABLE CARE ACT

In October 2012, the ACA implemented a new provision requiring hospitals to report data from patient satisfaction surveys,[33] developed by The Centers for Medicare & Medicaid Services (CMS) and the Agency for Healthcare Research and Quality.[34] The survey is a compilation of thirty-two questions including demographic information, and twenty-one questions of patient perspectives on care as well as patient rating items encompassing nine key topics.[35] The key topics are communication with doctors, communication with nurses, responsiveness of hospital staff, pain management, communication about medicines, discharge information, cleanliness of the hospital environment, quietness of the hospital environment, and transition of care.[36] The Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) is the standard survey responsible for measuring patient satisfaction, which hospitals are encouraged to administer to produce comparable data across institutions.[37] CMS and the National Committee on Quality Assurance both require participating hospitals to publicly report data collected from these patient satisfaction surveys.[38]

Patient satisfaction survey responses determine thirty percent of a hospital's total federally-mandated score.[39] A hospital's "adherence to

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alternatives [. . .] and may be dissatisfied if their requests are not met. Research suggests this is a common pattern and confirms that fulfillment of patient expectations usually results in a more satisfied patient.").

32. *See* Kupfer & Bond, *supra* note 2, at 140 ("At times, the medical evidence does not support the demands of the patient, and it is the professional duty of the physician to deny these requests even though patient satisfaction may decline.").

33. *See* Alexandra Robbins, *The Problem with Satisfied Patients*, THE ATLANTIC (Apr. 17, 2015), http://www.theatlantic.com/health/archive/2015/04/the-problem-with-satisfied-patients/390684/ (stating that hospitals will only receive funding if they have high patient-satisfaction scores).

34. Joanne Kenen, *The ACA and Patient Satisfaction: Does It Improve Care?*, ASS'N OF HEALTH CARE JOURNALISTS (May 6, 2015), http://healthjournalism.org/blog/2015/05/the-aca-and-patient-satisfaction-does-it-improve-care/.

35. Centers for Medicare & Medicaid Services, CAHPS Hospital Survey, http://www.hcahpsonline.org/home.aspx (last visited Nov. 15, 2015).

36. *Id.*

37. *See id.* ("The intent of the HCAHPS initiative is to provide a standardized survey instrument and data collection methodology for measuring patients' perspectives on hospital care.").

38. Fenton et al., *supra* note 7, at 405.

39. Nina F. Geiger, *On Tying Medicare Reimbursement to Patient Satisfaction Surveys*, 112 THE AM. J. OF NURSING 11, 11 (2012).

clinical performance guidelines" determines the remaining seventy percent.[40] Medicare funding will increase or decrease depending on a facility's overall score compared to other hospitals across the country.[41] An estimated $500,000 to $850,000 annually is at risk for each hospital bound by the ACA provision.[42] This translates to almost $1 billion annually in hospital funding across the country.[43] This is a drastic amount of funding weighing on subjective surveys completed by patients.

When the ACA implemented this new provision for hospitals receiving Medicare funding, the government withheld approximately $850 million worth of Medicare reimbursements from hospitals for the year.[44] Specifically, this new provision required hospitals to take this pay cut up front as an incentive for hospitals to earn back the funding withheld.[45] This amount is anticipated to double by 2017.[46] Hospitals have an opportunity to make this money back, but only if they are able to report high customer satisfaction scores and have met the basic care standards set out by the ACA.[47]

In 2015, nearly 500,000 physicians working in large groups are starting to see their pay linked to responses from these patient satisfaction surveys.[48] This will be true for all physicians who take Medicare patients by 2017.[49] A system that ties funding to patient satisfaction teaches physicians to focus on patient approval in order to maintain the government funding they rely on.[50]

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40. *Id.*

41. *See* Robbins, *supra* note 33 ("Each year, only hospitals with high patient satisfaction scores and a measure of certain basic care standards will earn that money back, and the top performers will receive bonus money from the pool.").

42. Holly Korda, *Patient Satisfaction: Quality, Cost and the New Rules of Engagement*, CTR. FOR ADVANCING HEALTH (Nov. 6, 2012), http://www.cfah.org/blog/2012/patient-satisfaction-quality-cost-and-the-new-rules-of-engagement.

43. *See Patient Satisfaction and the Affordable Care Act*, KEYBRIDGE (Aug. 1, 2013), http://www.keybridgemed.com/revenue-cycle-minute/patient-satisfaction-and-the-affordable-care-act/ ("Over the next year, nearly $1 billion in hospital payments will be based in part on patient satisfaction.").

44. Robbins, *supra* note 33.

45. *See id.* (stating "only hospitals with high patient-satisfaction scores and a measure of certain basic care standards will earn [the] money back," implying it is taken up front).

46. *Id.*

47. *See id.* ("[T]he Affordable Care Act implemented a policy withholding 1 percent of total Medicare reimbursements—approximately $850 million—from hospitals [. . .]. Each year, only hospitals with high patient-satisfaction scores and a measure of certain basic care standards will earn that money back [. . .].").

48. *See id.* ("Large physician groups—those with 100 or more doctors, nurses, social workers or other health professionals—would gain or lose as much as 1 percent of their pay beginning in 2015.").

49. *See id.* ("[A]ll doctors who take Medicare patients will be part of the [ACA] program by 2017.").

50. *See* Kai Falkenberg, *Why Rating Your Doctor Is Bad for Your Health*, FORBES (Jan. 2, 2013, 9:06 AM), http://www.forbes.com/sites/kaifalkenberg/2013/01/02/why-rating-your-

With an increased usage of patient satisfaction surveys currently on hospitals and next on physicians in the healthcare industry, it is clear the ACA is moving healthcare quality assessment in the wrong direction.

V. THE NEGATIVE EFFECTS IMPOSED BY ACA

The ACA's provision that relies on customer satisfaction in determining funding disbursements has a negative effect on the overall quality of care physicians give their patients.[51] Dr. Fenton's study questioned the reliability of the current method of measuring patient satisfaction in the health care industry.[52] As previously mentioned, the researchers discovered a correlation between higher patient satisfaction and hospital admissions, increased healthcare and prescription drug costs, and mortality rates.[53] Furthermore, *USA Today* analyzed data provided by the U.S. Department of Health and Human Services Hospital Compare Website and found that high patient-rating scores for hospitals correlated with higher death rates.[54] These disturbing findings indicate that patient satisfaction is not a reliable indicator of quality healthcare.

While increased mortality rate is a significant issue to be concerned with, there are numerous other problems of which to take note.[55] For example, physicians admit they have changed their course of practice due to these new provisions under the ACA.[56] One disturbing example of this change is

doctor-is-bad-for-your-health/ ("Practicing physicians have learned—from reimbursement programs [. . .] that they will be rewarded for excess and penalized if they risk not doing enough.").

51. *See Patient Satisfaction Linked to Higher Health-Care Expenses and Mortality*, UC HEALTH SYS. (Feb. 13, 2012), http://www.ucdmc.ucdavis.edu/publish/news/newsroom/6223 ("A team of UC Davis researchers found that people who are the most satisfied with their doctors are more likely to be hospitalized, accumulate more health-care and drug expenditures, and have higher death rates than patients who are less satisfied with their care.") [hereinafter *Patient Satisfaction Linked Expenses and Mortality*].

52. *Fenton* et al., *supra* note 7, at 405.

53. *Id.*

54. *See* Geiger, *supra* note 39, at 11 (analyzing data collected by nearly 5,000 U.S. hospitals).

55. *See* Fenton et al., *supra* note 7, at 407 ("In a nationally representative sample, we found that higher patient satisfaction was associated with [. . .] higher inpatient utilization, greater total health care expenditures, and higher expenditures on prescription drugs.").

56. *See* William Sonnenberg, *Patient Satisfaction Is Overrated*, KEYSTONE PHYSICIAN, March 6, 2014, *reprinted in*, MEDSCAPE, http://www.medscape.com/viewarticle/821288 ("[A]t the Scientific Assembly of the American Academy of Family Physicians (AAFP) in San Diego, [while] giving a lecture to a large audience of Academy members, [. . .a] physician in the audience told the crowd that he was able to increase his satisfaction score by 7% simply by prescribing an antibiotic to all patients who call with a complaint of cough, sore throat, or sinus headache. One doctor reported to the media that he had to give Dilaudid® for minor pain because his Press Ganey score was low the previous month."); *see also* Zgierska, et al., *supra* note 31, at 1377 (explaining that physicians, seeking optimal survey scores, "may paradoxically promote prescribing of opioids or other addictive medications").

doctors who prescribe stronger drugs than a patient needs just to increase patient satisfaction scores.[57] While CMS has found improved scores from the HCAHPS surveys, they claim quality of care and patient-experiences are headed in opposite directions.[58] More specifically, CMS has failed to take action in relation to the HCAHPS survey to prevent overtreatment, a result which not only drives up costs, but also can ultimately hurt a patient's health.[59] Physicians are well-educated individuals who have quickly discovered the simple formula for the situation the ACA has presented them with: "More tests and stronger drugs equal more satisfied patients, and more satisfied patients equal more pay."[60] Hospitals are given the freedom to make the necessary adjustments to improve patient satisfaction and quality of care.[61] Consequently, at least one hospital has gone to such extreme measures to improve patient satisfaction scores that it now provides prescription medication to all discharged patients.[62] Dr. H. Gilbert Welch, author of *Overdiagnosed*, says that, "Almost any unnecessary or discretionary test has a good chance of detecting an abnormality. . .often leading to the detection of abnormalities that are not destined to ever bother us."[63] Overtreatment can adversely affect the patient and has been found to lead to higher mortality rates.[64]

While the adverse effects of overtreatment is a primary concern of meeting patient expectations, the opposite holds true as well.[65] It is likely that

57. *Id.*

58. *See* Rich Daly, *A Satisfactory Measure? Studies Show Focus on Keeping Patients Happy Can Have Unintended Costs*, MOD. HEALTHCARE (Jan. 5, 2015), http:// www.modernhealthcare.com/article/20130105/MAGAZINE/ 301059942 ("The [CMS] agency found HCAHPS scores have improved since they were linked to hospital reimbursement. But officials there say that some providers are seeing quality and patient-experience indicators moving in opposite directions.").

59. *See id.* ("[A] CMS official admits there are no specific provisions in HCAHPS that are designed to prevent overtreatment that drives up costs and ultimately can hurt the patient's health.").

60. Falkenberg, *supra* note 5050.

61. *See* Daly, *supra* note 58 ("[I]t is left up to hospitals to determine how best to improve patients' experience, just as they determine how to improve quality of care.").

62. *See* Sonnenberg, *supra* note 56 ("One emergency room with poor survey scores started offering hydrocodone 'goody bags' to discharged patients in order to improve their ratings."); *see also* Falkenberg, *supra* note 50 ("One emergency room with poor survey scores started offering Vicodin 'goody bags' to discharged patients in order to improve their ratings.").

63. Falkenberg, *supra* note 50.

64. For example, the family of an elderly woman the doctors deemed ready for discharge insisted on her staying at the hospital, and her elongated stay resulted in exposing her to hospital-borne infections and increased hospital bills. *See id.* ("The UC Davis authors posit that the most satisfied patients have a higher mortality rate because they receive more discretionary services- interventions that carry a risk of adverse effects.").

65. In an expert interview with Dr. Fenton, a leading researcher of a patient satisfaction study pointed out, "We also don't want physicians to avoid taking care of patients [. . .] who

consumers do not want physicians to start avoiding patients who are more likely to give lower satisfaction ratings.[66] There is additional concern that physicians might modify their advice to cater to patient wants rather than solely their needs for the purpose of high ratings.[67] This type of tactic ultimately hurts the quality of care a patient receives from his or her physician when the physician is focused on scores rather than a patient's health.

Physicians are also now facing the dilemma of having conversations with patients about changing bad habits that are negatively affecting their health and risking bad patient satisfaction scores because of these topics.[68] A prime example of this would be when a physician is treating a patient who is overweight.[69] Weight loss is often the healthiest intervention for these patients; however it is possible these patients would not react well to their physician telling them to change their lifestyle.[70] Consequently, these patients could be more susceptible to filling out negative patient satisfaction surveys.[71] With the threat of bad reviews resulting in decreased funds to hospitals and physicians individually, doctors are inclined to tell patients what they want to hear rather than what they need to hear.[72]

Nurses are experiencing a similar situation in their efforts to serve patients as well.[73] For example, one question on the HCAHPS survey asks about the immediacy of a nurse's response to a patient pressing the call button.[74] This question may measure whether a nurse met the patient's expectations, but the question does not consider whether these calls were for medically necessary

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are more likely to report dissatisfaction." Brookes & Fenton, *supra* note 5.

66. Dr. Fenton, a leading researcher of a patient satisfaction study, stated in an interview that doctors may avoid "Medicaid patients and those with mental health issues," to avoid low patient satisfaction scores. *Id.*

67. *See id.* ("Tying a very large percentage of a primary care physician's income to patient satisfaction would be problematic, because it could skew the physician's priorities and lead some physicians to neglect some of their essential duties as primary care clinicians.").

68. *See* Sonnenberg, *supra* note 57 ("[D]octors face the reality that uncomfortable discussions on behavioral topics—say, smoking or obesity—come with the risk of a pay cut.").

69. *Id.*

70. *See* John M. Jakicic, et al., *Appropriate Intervention Strategies for Weight Loss and Prevention of Weight Regain for Adults*, 33 MED. SCI. SPORTS EXERCISE 2145, 2145 (2001) (discussing the issue of obesity as "a significant health problem in the United States," and giving "recommendations for safe and effective weight loss and prevention of weight regain [. . .] after weight loss.").

71. Brookes & Fenton, *supra* note 5.

72. *See* Robbins, *supra* note 33 ("By attempting to satisfy patients, healthcare providers unintentionally might not be looking out for their [patient's] best interests. [. . .] [E]valuating hospital care in terms of its ability to offer positive experiences could easily put pressure on the system to do things it can't, at the expense of what it should.").

73. *See id.* (giving examples of questions on the HCAHPS survey geared towards the care given to the patient by the nurse).

74. *See id.* (giving an example question stating, "During this hospital stay, after you pressed the call button, how often did you get help as soon as you wanted it?").

situations.[75] When patients were given comment sections on these surveys, patients responded with all sorts of complaints ranging from, " 'My roommate was dying all night and his breathing was very noisy' to 'The hospital doesn't have Splenda.' "[76] These are complaints that do not relate to quality of care given by nurses; rather they are superfluous complaints made by agitated patients.

Generally speaking, patients have unrealistic expectations for the care they receive from medical personnel.[77] With the new provisions under the ACA, physicians are changing their course of practice to avoid funding cuts, and consequently, patients are missing out on the quality care they would otherwise receive.[78]

VI. INCREASED COSTS DUE TO THE AFFORDABLE CARE ACT

Hospitals and patients are both experiencing increased costs from the expectations imposed by the ACA.[79] Research shows a direct correlation between the most satisfied patients and higher healthcare costs.[80] In 2011, $226 billion was spent on overtreatment measures such as unnecessary procedures and prescriptions.[81] Overtreatment is both a waste of time for doctors, who must dedicate extra time treating patients for issues that do not need medical attention, and for patients who are spending more time with their doctor than necessary, consequently costing the patient more money.

Administering these mandatory patient satisfaction surveys also costs extra to healthcare providers.[82] Hospitals dedicate a significant amount of time, money, and effort towards conducting these patient satisfaction surveys and specifically tracking scores across departments as well as individual

75. *See id.* ("This question is misleading because it doesn't specify whether the help was medically necessary.").

76. *Id.*

77. *See id.* (pointing to an experience from "[a]n Oregon critical-care nurse [who] had to argue with a patient who believed he was being mistreated because he didn't get enough pastrami on his sandwich (he had recently had quadruple-bypass surgery).").

78. *See* Zgierska, et al., *supra* note 31 at 1378 ("[P]hysicians who do not comply with patient requests may be the recipients of poor ratings on patient satisfaction scores, possibly resulting in emotional financial, and professional penalties. These issues may be inadvertent but powerful disincentives for physicians to provide medically correct care and may contribute to the erosion of trust needed in a healthy patient-physician relationship.").

79. *See* Falkenberg, *supra* note 50 (explaining that patients and hospitals are both facing enormous price tags for overtreatment).

80. *See Patient Satisfaction Linked Expenses and Mortality*, *supra* note 51 ("[P]atients who were most satisfied had greater chances of being admitted to the hospital and had about nine percent higher total health-care costs as well as nine percent higher prescription drug expenditures.").

81. Falkenberg, *supra* note 50.

82. *See* Falkenberg, *supra* note 50 (explaining that the Cleveland Clinic spends $500,000 a year on government-dictated surveys).

physicians.[83] The money going towards administering these mandatory patient satisfaction surveys is money that could otherwise be spent on more important aspects of health care, such as medical research.

With the pressure hospitals and physicians are facing through the ACA provisions, one must wonder how far these healthcare providers will go to ensure positive patient satisfaction surveys. Hospitals are dedicating money to frivolous amenities such as flat screen televisions, live music, valet parking, and custom-order room-service meals.[84] Some are taking it a step further with loyalty programs that provide VIP lounges for their patients.[85] Patients should not expect unnecessary amenities such as these when going to a hospital for healthcare treatment. Hospitals exist to tend to patients' healthcare needs, not to patients' superfluous wants.

Healthcare providers are also putting money towards training for patient satisfaction.[86] With a majority of the HCAHPS survey questions involving nurses, some hospitals are requiring their nurses to attend non-medical related training, wasting nurses' time when they could be attending to the medical needs of patients.[87] It also wastes healthcare providers' money sending nurses to these training courses.[88] Some hospitals even provide nurses with scripts to use with patients and hire actors to help the nurses rehearse their lines.[89] Furthermore, in 2013 "nearly 2,000 administrators spent $1,100 or more each to attend Press Ganey's glittery client conference."[90] Press Ganey, the leading provider of customer satisfaction surveys for hospitals, [91] hosts these conferences to ensure hospitals are filling the obligations set out by the ACA provisions.[92] The excessive amounts of money spent by healthcare providers to ensure patient satisfaction with every aspect of their time spent with the provider is outrageous, however unavoidable with the new provisions of the ACA.

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83. Kupfer & Bond, *supra* note 2, at 139-40.

84. Robbins, *supra* note 33.

85. *Id.*

86. *See* Kenen, *supra* note 34 (explaining that hospitals "are training nurses to focus on "customer service" not patient care").

87. Robbins, *supra* note 33.

88. *See id.* ("An entire industry has sprouted, encouraging hospitals to waste precious dollars on expensive consultants claiming to provide scripts or other resources that boost satisfaction scores.").

89. *See id.* ("Some administrators are ordering nurses to use particular phrases and to gush effusively to patients about both their hospital and their fellow nurses, and then evaluating them on how well they comply. [. . .] Some institutions have even hired actors to rehearse the scripts with nurses.").

90. Falkenberg, *supra* note 50.

91. Sonnenberg, *supra* note 57.

92. Falkenberg, *supra* note 50.

VII. CONCLUSION

The ACA needs to put an end to the push for high patient satisfaction measurements. Focusing on customer satisfaction adversely affects the reason consumers seek physicians to care for them. Although consumers today require satisfaction with products and services they use and pay for, patients need to understand that healthcare providers are not here to merely make them content. Instead, healthcare providers are here to ensure total population health, which is an unachievable end when physicians are forced to ensure the satisfaction of their patients over their health.