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ANNALS OF HEALTH LAW
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

Editor's Note

The *Annals of Health Law and Life Sciences* is proud to present the twenty-fourth issue of our online, student-written publication, *Advance Directive*. This Issue's articles focus on how the United States health care system approaches and treats individuals with chronic diseases. Chronic diseases are defined broadly by the Centers for Disease Control and Prevention to include conditions that last one year or longer, require ongoing medical attention, and/or limit daily activities. Six in ten Americans currently live with at least one chronic disease while four in ten Americans have more than one chronic condition. Heart disease, cancer, and diabetes are the top three chronic diseases that lead to death and disability in the United States.

The *Spring 2020 Advance Directive* Issue will dive into a broad spectrum of topics within the current conversation taking place in the United States surrounding the diagnosis and treatment of chronic diseases. Many Americans with chronic conditions struggle to access care due to economic, environmental, and other social barriers in place. According to the National Center for Chronic Disease Prevention and Health Promotion, the healthcare system in the United States spends $3.5 trillion per year on chronic disease treatment. This Issue addresses how providing patients with the tools to manage their chronic conditions and develop stronger physician-patient relationships may mitigate the cost of chronic conditions in the United States.

This Issue also explores how environmental factors like poor air quality, inconsistent housing, food deserts, and neighborhood violence exacerbate chronic conditions. Populations that face with environmental barriers often belong to a lower socioeconomic class and live in densely populated areas with little access to preventive care. Government programs like Medicaid are meant to expand access to healthcare among these populations, yet states have attempted to place barriers such as work requirements on access to Medicaid benefits. This Issue contemplates how these barriers can impact Americans suffering from chronic diseases.

Furthermore, this Issue analyzes how federal and state law affects the healthcare available for Americans suffering with chronic diseases. First, the Issue discusses the impact of fitness trackers on chronic conditions. Fitness trackers are a form of technology that are widely available and relatively easy to use. They present an opportunity to track and share information about chronic symptoms to a patient's physician. However, the information collected, stored, and shared by fitness trackers is not well-regulated. Second, the Issue investigates how federal and state regulation of telehealth can lead to better communication among physicians and patients and more effective treatment of chronic diseases can lead to better management of chronic conditions.

We would like to thank Alesandra Hlaing, our Technical Production Editor. Without her knowledge and commitment, this Issue would not have been possible. We would also like to give a special thanks to Isabella Masini, our *Annals* Editor-in-Chief, for her leadership and support. We would also like to thank and acknowledge our *Annals* Executive Board Members: Christina Perez-Tineo, Nicolette Taber, and Raquel Boton, as well as the *Annals* Senior Editors: Haley Comella, Liz Heredia, Rachel Kemel, and Jan Dervish for providing invaluable editorial assistance with this Issue. The members of *Annals* deserve recognition for their hard work, dedication and well-thought articles. Lastly, we must thank the Beazley Institute for Health Law and Policy and our faculty advisors, Professor Larry Singer and Kristin Finn for their guidance and support.

We hope you enjoy this Issue of *Advance Directive*.

Sincerely,

Hannah Lehmann
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Rethinking Asthma Treatment for African American Children: A Change in Reimbursement

Harte Brick

INTRODUCTION

In the United States, asthma is the leading chronic illness among children.[1] The Centers for Disease Control and Prevention (CDC) estimates that one in twelve children have asthma.[2] Within the pediatric population, the highest prevalent rate is among five to fourteen year-olds with 9.7% of children affected by asthma.[3] Children with this chronic lung disease experience repeated episodes of chest tightness, coughing, wheezing, and breathlessness as a result of the inflamed and narrowed airways in their lungs.[4] Asthma is triggered when one is exposed to environmental pollutants, such as dust mites, cockroaches, high levels of ozone, and tobacco smoke.[5] As a result of uncontrolled triggers, asthma is the leading cause for children missing school.[6] In fact, a recent study, published in the Journal of Asthma, estimates that asthma accounts for an additional seven million missed school days in any given year.[7]

For African American children and their families, asthma creates an even greater health disparity.[8] According to the most recent data from the CDC, 12.6% of African American children under eighteen years old have asthma compared to 7.7% of white children.[9] Racial differences in asthma frequency,

1. Ctrs. for Disease Ctrl. & Prev. (CDC), *Asthma*, HEALTHY SCHOOLS, www.cdc.gov/healthyschools/asthma, (last visited Mar.. 15, 2020).

2. Hatice S. Zahran et al., *Vital Signs: Asthma in Children—United States, 2001-2016*, 67 MORBIDITY MORTALITY WKLY. REP. 149, 152 (2018).

3. CDC, *Most Recent National Asthma Data*, ASTHMA, www.cdc.gov/asthma/most_recent_national_asthma_data.htm, (last visited Mar. 18, 2020).

4. Zahran et al., *supra* note 2, at 149.

5. CDC, *Asthma*, HEALTHY SCHOOLS, *supra* note 1; Theresa Guilbert et al., *Racial Disparities in Asthma Related Health Outcomes in Children with Severe/Difficult to Treat Asthma*, 7 J. ALLERGY CLINICAL IMMUNOLOGY PRAC. 568, 575 (2019).

6. Asthma and Allergy Foundation of America, *Asthma Facts and Figures*, ASTHMA, www.aafa.org/asthma-facts/, (last visited Mar. 18, 2020).

7. Patrick Sullivan et al., *School Absence and Productivity Outcomes Associated With Childhood Asthma in the USA*, 55 J. OF ASTHMA 161, 161 (2018).

8. Annette Hines, *Asthma: A Health Disparity Among African American Children the Impact and Implications for Pediatric Nurses*, 26 J. OF PEDIATRIC NURSING 25, 25 (2011).

9. CDC, *Most Recent National Asthma Data*, *supra* note 3.

illness, and death, are associated with poverty, indoor allergens, poor health care, lack of patient education, and poor urban air quality.[10] Asthma is the third cause of hospitalization among children younger than fifteen years old;[11] additionally, asthmatic African American children under four years old account for the highest emergency room (ER) department and urgent care center visits.[12]

Although avoiding triggers and taking prescribed medications can control asthma, the necessary resources and precautions in many African American communities are not easily feasible or possible to obtain.[13] For example, much of the health disparity pertaining to asthma between African American and white children can be explained by differences in socioeconomic status;[14] yet, current asthma treatment only looks at symptom relief and does not account for poverty and neighborhood associated barriers.[15]

Indeed, Medicaid coverage must be expanded to provide for African American community-based asthma programs for families with asthmatic children. This paper proposes that the proper way to treat asthma, particularly in African American children, is to provide families of asthmatic children with reimbursement for the social determinants of health. Social determinants of health encompasses various aspects of a person's life such as their neighborhood, socio-economic status, systematic racism, education level, access to nutritious food, etc., all of which directly impact health and quality of life.[16] First, this paper will address social determinants of health as they relate to disparities in the chronic condition of asthma. Next, this paper will argue that addressing social determinants of health instead of treating asthma through conventional medicine will save healthcare costs. Finally, this paper will recommend a change in public policy in that Medicaid should be obligated to provide direct reimbursement for addressing social determinants of health as a foundational treatment protocol for pediatric asthmatic children.

SOCIAL DETERMINANTS OF HEALTH AND THE CHRONIC CONDITION OF

10. Asthma and Allergy Foundation of America, *supra* note 6.

11. *Id*.

12. *Id*.

13. *See id.* (noting the burdens African American communities face pertaining to asthma).

14. Elizabeth C. Matsui et al., *Closing the Door on Social Determinates of Health and Asthma Disparities: Not so Fast*, 7 J. ALLERGY CLINICAL IMMUNOLOGY PRAC. 2101, 2101 (2019).

15. *Id.*

16. *Social Determinates of Health*, HEALTHY PEOPLE, www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health, (last visited Mar. 18, 2020).

ASTHMA

Pediatric care in the United States is transforming beyond traditional medicine into a population health model.[17] The CDC defines population health as "an interdisciplinary, customizable approach that allows health departments to connect practice to policy for change to happen locally."[18] Under current healthcare reform, a population health model recognizes the need to treat beyond the clinical care setting and to address social determinates of health when treating patients.[19] It is estimated that social determinants of health "account for 60% of the risk of premature death due to chronic diseases and other health conditions," such as asthma.[20] Therefore, healthcare, particularly pediatric healthcare, should no longer consist solely of the doctor-patient relationship; rather, academia, local governments, and public health officials should partner together to achieve positive health outcomes.[21]

Asthma disproportionately affects children from urban and low socioeconomic groups and seemingly the majority of these children are African American.[22] Although this section will only address the environmental and socioeconomic characteristics in African American communities, other factors such as genetics, institutional racism, and barriers to access, like lack of insurance and cultural mistrust, affect the prevalence of pediatric asthma as well.[23]

Environmental factors are most influential when examining asthma as a health disparity in African American children.[24] Environmental factors such as poor air quality resulting in outdoor air pollutants begin to explain the

17. ROBERT SEIFERT & HILARY DEIGNAN, CTR. HEALTH L. ECONS. U. OF MASS. MED. SCH. TRANSFORMING PEDIATRICS TO SUPPORT POPULATION HEALTH, 5 (2019).

18. CDC, WHAT IS POPULATION HEALTH, www.cdc.gov/pophealthtraining/whatis.html, (last visited Mar. 18, 2020).

19. Loel S. Solomon & Michael H. Kanter, *Health Care Steps up to Social Determinants of Health: Current Context*, 22 PERMANENTE J. 18, 18 (2018).

20. Jessica Mantel, *Tackling the Social Determinates of Health: A Central Role for Providers*, 33 GA. ST. U. L. REV. 217, 221 (2017).

21. *See* ASTHO Staff, *Exploring the Role of Physicians in Addressing the Social Determinants of Health,* ASTHO EXPERTS BLOG (May 24, 2018, 2:51 PM), www.astho.org/StatePublicHealth/Exploring-the-Role-of-Physicians-in-Addressing-SDoH/05-24-18/ (discussing the need for providers to address social determinates of health as healthcare moves to a value-based reimbursement system).

22. *See* Hines, *supra* note 8, at 27-28 ("Asthma is overrepresented in children from urban and low socioeconomic groups, and African American children are more likely to be in these groups").

23. *See id.* at 27, 28 (noting "Asthma does have a significant genetic component. According to the Asthma and Allergy Foundation of America, if one parent has asthma, the child has a 30% chance of having asthma. The chance of asthma increases dramatically to 70% if both parents have asthma.").

24. *Id.* at 28.

onset and exacerbation of pediatric asthma.[25] Approximately forty-five percent of African American children live in low socioeconomic neighborhoods.[26] Neighborhoods with concentrated poverty contain greater pollution.[27] Despite efforts to reduce air pollution, African Americans still experience twice the health risk from air pollution compared to white children, exposing the alarming reality that low-income minority communities are still pollution centered "hot spots."[28] Consequently, air pollution has a detrimental effect on pediatric asthma outcomes.[29] For example, researchers affiliated with the American Psychology Association found that youth with persistent asthma from low-income urban United States areas suffer from increases in air pollutant concentrations and, therefore, experience lower pulmonary functioning, more missed school days, and increased symptoms.[30]

In addition to outdoor pollutants, children living in substandard housing are likely to suffer from indoor pollutants such as second-hand smoke and cockroaches which trigger asthmatic attacks.[31] There is a high prevalence of asthma in children living in public housing because they are more likely to face higher concentrations of cockroach, mice, and pet allergens.[32] In fact, intervention studies focusing on improving health outcomes for children with asthma prove successful when the presence of indoor allergens is reduced.[33] Similarly, studies show that because children living in low socioeconomic homes are more often subjected to second-hand smoke, they are at a higher risk of developing asthma and poor lung functioning that results in wheezing.[34]

Finally, environmental stress and violence is also a factor in the severity of pediatric asthma.[35] Community violence, which impacts many African

25. *Id.*

26. Algernon Austin, *African Americans are Still Concentrated in Neighborhoods with High Poverty and Still Lack Full Access to Decent Housing*, ECON. POL'Y INST. (July 22, 2013), https://www.epi.org/publication/african-americans-concentrated-neighborhoods/.

27. Hanna M. C. Schreier & Edith Chen, *Socioeconomic Status and the Health of Youth: A Multilevel, Multidomain Approach to Conceptualizing Pathways*, 139 PSYCHOL. BULL. 606, 609 (2013).

28. Misti Crane, *Low-Income, Black Neighborhoods Still Hit Hard by Air Pollution*, OHIO STATE NEWS (Aug. 10, 2019), https://news.osu.edu/low-income-black-neighborhoods-still-hit-hard-by-air-pollution/.

29. Schreier & Chen, *supra* note 27, at 609.

30. *Id.* at 611.

31. *Id.* at 621, 624.

32. Kelli Nicole DePriest, Investigating the Relationship Among Neighborhood Factors and Asthma Control in African American Children 22 (Feb. 2019) (unpublished Ph.D. dissertation, John Hopkins University) (on file with John Hopkins Sheridan Libraries).

33. Schreier & Chen, *supra* note 27, at 621.

34. *Id.* at 624.

35. Hines, *supra* note 8, at 28.

American children, is shown to cause and exacerbate asthma symptoms.[36] A recent study of African American mothers found that "prenatal exposure to community violence was associated with nearly twofold increased odds of current wheeze at age 2 years, even after accounting for outdoor pollutants, cockroach allergen levels, and other potential confounders."[37] The study also found a significant association of childhood asthma in boys with chronic maternal interpersonal trauma at six years of age.[38] Similarly, another Chicago-based study of 2,071 children concluded that "medium and high levels of community violence were associated with 1.6 times increased odds of report of physician diagnosed-asthma, even after accounting for potential confounders at the individual neighborhood level."[39] Therefore, it is clear that environmental factors are strongly corelated with asthma incidence rates in African American children.[40]

ADDRESSING THE SOCIAL DETERMINANTS OF HEALTH RELATED TO ASTHMA WILL SAVE HEALTHCARE COSTS

Pediatric asthma care, particularly for African American children, is a burden on the U.S. healthcare system; it is the third leading cause of hospitalization among children under the age of fifteen.[41] In 2013, total pediatric asthma care costs were $5.92 billion, with the average annual cost per child ranging from $3,076 to $13,612.[42] A significant portion of these costs result from ER visits.[43] Medicaid and The Children's Health Insurance Program (CHIP) cover approximately fifty-seven percent of African American children.[44] In 2010, Medicaid, as the primary payor of pediatric asthma ER visits, paid $272 million dollars on pediatric ER care as a result of an estimated 628,759 pediatric asthma related ER visits.[45]

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36. *Id.*

37. Jeremy Landeo-Gutierrez et al., *Exposure to Violence, Psychosocial Stress, and Asthma,* AM. J. RESPIRATORY CRITICAL CARE MED. (forthcoming).

38. *Id*.

39. *Id*.

40. *Id.*

41. William S. Pearson et al., *State-Based Medicaid Costs for Pediatric Asthma Emergency Department Visits*, 11 CDC, June 26, 2014, at 1; *see also* Office of Minority Health, ASTHMA & AFRICAN AMERICANS, https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=15 (noting hospital admission rate for asthma, children 2-17: Black 275.7, White: 4.5).

42. Richard Perry et al., *The Economic Burden of Pediatric Asthma in the United States*, 37 PHARMACOECONOMICS 155, 155 (2019).

43. Pearson et al., *supra* note 41, at 2; Perry et al., *supra* note 42, at 155.

44. Dawn Godbolt, *Medicaid Provides Health Coverage for 28% of Black Adults and 57% of Black Children*, BLACKMANSSTREET (July 6, 2017), https://blackmansstreet.today/health/medicaid-provides-health-coverage-28-percent-black-adults-57-percent-black-children/.

45. Pearson et al., *supra* note 41, at 2, 3.

The notion that African American children end up in the ER far more often than white children suggests that asthma is often more severe or under-treated in lower socioeconomic communities.[46] ER physicians note that their pediatric asthmatic patients oftentimes do not have access to a primary care physician, nor can they afford to pay for the daily medication needed to prevent an asthma attack from occurring and ultimately are unable to avoid routine trips to the ER.[47] In fact, one study found that on average less than half of African American children with asthma took their prescribed asthma medication.[48] Therefore, parents who have children with uncontrolled asthmatic symptoms oftentimes solely rely on extremely expensive ER visits/hospitalization to control their child's chronic condition.[49]

Implementing community-based initiatives has proven successful in addressing the considerable costs pertaining to pediatric asthma care.[50] The Boston Children's Hospital Community Asthma Initiative (CAI) is successfully partnering with public health, community, and housing authorities to address health disparities related to asthma with the goal of ultimately reducing asthma morbidity.[51] Within this program, case managers and nurses provide asthma action plans and coordinate care in order to proactively address a child's asthmatic condition before a trip to the ER is needed.[52] Furthermore, families are given access to high-efficiency particulate air (HEPA) filter vacuum cleaners, bedding encasements, legal services, and assistance accessing benefits such as food stamps.[53] This initiative has resulted in significantly lower hospitalization, and substantial cost savings.[54]

Similarly, The Children's Hospital of Philadelphia (CHOP) Community

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46. Sarah Fentem, *Black Children in St. Louis Far More Likely To Visit the ER for Asthma Than Whites*, ST. LOUIS PUBLIC RADIO (Jan. 14, 2019), https://news.stlpublicradio.org/post/black-children-st-louis-far-more-likely-visit-er-asthma-whites#stream/0.

47. *Id.*

48. Jennifer Rohan et al., *Adherence to Pediatric Asthma Treatment in Economically Disadvantaged African-American Children and Adolescents: An Application of Growth Curve Analysis*, 35 J. PEDIATRIC PSYCHOL. 394, 401 (2009).

49. *Id.*

50. *See* Elizabeth R. Woods et al., *Community Asthma Initiative to Improve Health Outcomes and Reduce Disparities Among Children with Asthma,* 65 MORBIDITY & MORTALITY WKLY. REP. 11, 13 (2016) ("CAI has significantly reduced asthma morbidity among black and Hispanic children in Boston. Data from parent/guardian reports indicate a decrease in number of children with any (one or more) asthma-related hospitalizations and emergency department visits, and hospital administrative data indicate a decrease in mean number of asthma-related hospitalizations.").

51. *Id.*

52. *Id.*

53. *Id.*

54. *Id.*

Asthma Prevention Program (CAPP) provides community-based interventions and in-home services.[55] CAPP is successful in part due to free education classes for parents and children, as well as individual training, in-home self-management education, and home and bedroom trigger removal processes.[56] Moreover, this program helps to coordinate a child's care between school nurses, social services, and medical personnel.[57] To date, more than 3,000 caregivers and children have participated in CAPP, and multiple community sites have been established.[58] As a result of this program, relevant data related to the implementation of home visits shows a decrease in ED visits and hospitalizations and overall cost savings.[59] Further, data related to the primary care program shows improved medication use and severity classification amongst child participants.[60]

MANDATORY REIMBURSEMENT AIMED AT PREVENTING PEDIATRIC ASTHMA DISPARITIES

Medicaid is designed to pay healthcare providers for traditional care delivery.[61] While in-home intervention and community-based programs have proven effective in treating African American children with asthma, a lack of comprehensive coverage for this nontraditional treatment creates a barrier to improvement.[62] Generally speaking, there are limited ways for states to provide reimbursement for non-traditional care.[63] For instance, as of January 2019, only twenty-two states were using CHIP Health Services Initiatives (HSIs) to improve the health of children living in eligible low socioeconomic households through non-clinical prevention services.[64] Arguably, only eight

55. HUD OFFICE OF LEAD HAZARD CONTROL AND HEALTHY HOMES, GUIDE TO SUSTAINING EFFECTIVE ASTHMA HOME INTERVENTION PROGRAM, 28 (2018).

56. *Id.*

57. *Id.*

58. *The Children's Hospital of Philadelphia- Community Asthma Prevention Program,* AMERICAN HOSPITAL ASSOCIATION, www.aha.org/case-studies/2012-04-26-childrens-hospital-philadelphia-community-asthma-prevention-program, (last visited Mar. 29, 2020).

59. *Id.*

60. *Id.*

61. CONGRESSIONAL RESEARCH SERVICE, MEDICAID: AN OVERVIEW, 13 (2019).

62. *See* Raphael et al., *More Than Wheezing: Incorporating Social Determinants into Public Policy to Improve Asthma Outcomes in Children,* 81 PEDIATRIC RESEARCH 2, 2 (2017) (noting "efforts are emerging to integrate social determinates into healthcare," but a comprehensive nationwide Medicaid program does not exist).

63. *See* CHILDHOOD ASTHMA LEADERSHIP COALITION, PATHWAYS TO MEDICAID REIMBURSEMENT FOR PEDIATRIC ASTHMA SERVICES, 1 (2016) [hereinafter PATHWAYS] (stating "Medicaid offers several strategies for expanding effective community-based asthma programs for low-income and medically underserved populations.").

64. CHILDHOOD ASTHMA LEADERSHIP COALITION, HEALTH SERVICES INITIATIVES: USING A CHIP STATE PLAN OPTION TO ADDRESS ASTHMA AMONG CHILDREN IN LOW INCOME HOUSEHOLDS, 1 (2019) [hereinafter HEALTH SERVICES INITIATIVES].

of the twenty-two states have an HSI that remotely impacts asthma disparities through school- based health services programs.[65]

Maryland, however, is the first and only state to implement a CHIP HSI directly targeting home-based asthma services for children in low-income households.[66] Under Maryland's program, each county health department provides services and supplies in children's homes and seeks reimbursement through the submission of at-cost invoices to the State.[67] This program has successfully provided home-based asthma care to a "finite number of children with especially high needs."[68] While this is a step in the right direction, this HSI does not change the underlying scope of Medicaid coverage benefits; nor does it enable community-based asthma workers to be direct Medicaid providers.[69] For real change to take hold, community-based workers must be treated like all other providers with corresponding billing and coding privileges.[70] Therefore, all fifty states should offer direct reimbursement for non-clinical services aimed at asthma prevention.[71] These programs must target African American children living in urban low-income neighborhoods, as they are most at risk of asthma triggers and hospitalization.[72]

Previously, Medicaid did not pay for services that were generally available to the public free of charge.[73] Accordingly, schools could not receive payment for asthma care delivered to students.[74] For instance, if the school nurse gave a child a nebulizer treatment, the school could not receive Medicaid reimbursement, where as a physician doing the same thing in his or her office would receive payment from Medicaid.[75] In late 2014, Centers

65. *Id.* at 3 (indicating Maryland has an HSI purpose of "reduc[ing] the impact of . . . asthma on children in low income households" and Florida, Idaho, Massachusetts, Missouri, Nevada, New Jersey, New York, and West Virginia have HSI purposes of funding "school-based health services" and noting the remaining fourteen states have developed an HSI to improve the health of children in low-income households through other non-related asthma initiatives such as, providing vision exams and glasses to uninsured children in Delaware schools); *See also* CDC, CONTROLLING ASTHMA IN SCHOOLS, https://www.cdc.gov/asthma/controlling_asthma_factsheet.html, (last visited Mar. 18, 2020), (school-based asthma programs can provide education that teaches children how to monitor their symptoms and manage their medications to prevent asthma attacks).

66. Health Services Initiatives*, supra* note 63 at 4.

67. *Id.* at 5.

68. *Id.*

69. *Id.*

70. *Id.*

71. *Id*. at 4, 7.

72. *See* Office of Minority Health, *supra* note 41 (noting the alarming statistics concerning asthma in African American communities).

73. PATHWAYS, *supra* note 63, at 2.

74. *Id.*

75. *Id.*

for Medicare and Medicaid (CMS) changed its policy to allow states to pay for Medicaid covered services in school settings.[76] Yet many states have failed to adopt the necessary state specific legislation allowing the schools to receive this benefit.[77]

CONCLUSION

Addressing the social determinants of health saves money and reduces disparities in healthcare services across socio-economic boundaries. In order for states to receive Medicaid funds, federal guidelines must be developed requiring states to develop community-based asthma interventions that utilize non-traditional providers in non-clinical settings. Providing reimbursement for community-based programs will improve the lives of African American children and save hundreds of thousands of dollars in scarce healthcare resources.[78] This kind of initiative necessitates significant changes in regulation as well as start-up funding for local communities.[79] State Medicaid programs may want to pursue social impact financing with private investors to share the burden of these initial pediatric asthma focused initiatives.[80] In this type of model, private investors pay the upfront costs, including the direct reimbursement to care givers; they have the opportunity to share in any savings resulting to the healthcare system from this program.[81] Only through this type of creative approach, coupled with mandatory legislative changes, will asthma health disparities decrease in African American children.[82]

76. *Id.*

77. *Id.*

78. *See* Raphael et al., *supra* note 62, at 3. ("With increasing awareness of SDH as a powerful mechanism in health and health care and new opportunities afforded through the Affordable Care Act, the potential to translate the evidence on asthma outcomes among children into public policy is unprecedented.").

79. Steven Farmer et al., *A Case Study in Payment Reform to Support Optimal Pediatric Asthma Care*, CTR. FOR HEALTH POL'Y AT BROOKINGS, 4 (2015) (noting community asthma initiatives are rarely covered through fee-for-service payment models).

80. PATHWAYS, *supra* note 63, at 7.

81. *Id.*

82. *Id.*

Federal Regulation of Telemedicine: Weighing Benefits to Patients with Chronic Illnesses Against Constitutional Questions

Mallory Burney

INTRODUCTION

Telemedicine is defined as the use of electronic information and telecommunication technologies to support and promote long-distance clinical health care, patient and professional health-related education, public health, and health administration.[1] The benefits of telemedicine are especially apparent to patients navigating chronic illnesses in an already overburdened American healthcare system.[2] Chronic illnesses are broadly classified as those lasting one or more years that require "ongoing medical attention or limit activities of daily living."[3] According to the Centers for Disease Control and Prevention (CDC), these illnesses include various cancers, heart disease, Alzheimer's Disease, diabetes, chronic kidney disease, and chronic lung diseases, among many others.[4] It is estimated that forty-five percent of the American public suffer from one or more chronic illnesses.[5] In addition to an incalculable toll on public health, chronic illnesses cost American taxpayers $3.5 trillion annually, constituting one of the largest expenses in the American healthcare system.[6] Despite these staggering statistics, many people with chronic illnesses experience barriers to healthcare that impede

1. *Telehealth Programs*, HEALTH RES. & SERVS. ADMIN., www.hrsa.gov/rural-health/telehealth (last visited Feb. 14, 2020).

2. Rashid L. Bashshur et al., *The Empirical Foundations of Telemedicine Interventions for Chronic Disease Management*, 20 TELEMEDICINE J. AND E-HEALTH 769, 795 (2014) (discussing improved health outcomes for those being telemonitored).

3. *About Chronic Diseases*, CTRS. FOR DISEASE CONTROL & PREVENTION, www.cdc.gov/chronicdisease/about/index.htm (last edited Oct. 23, 2019).

4. *Id*.

5. Jay Holder Bennett, *Telehealth for Chronic Illnesses*, AMERICAN WELL BLOG (June 12, 2018), www.americanwell.com/telehealth-for-chronic-illnesses/.

6. *About Chronic Diseases*, *supra* note 3.

effective treatment.[7] These include cost-related barriers,[8] lack of access to services, mobility issues,[9] and lack of support and advocacy.[10] Telehealth can improve affordable access to quality care by removing many of these burdens and has been widely viewed as "a game-changer for health care service delivery."[11] According to the Coalition to Transform Advanced Care, when "fully embraced and executed, telehealth can expand and enhance the delivery of health care services to geographically disadvantaged or underserved populations" including those with chronic illnesses.[12]

However, despite its potential benefits to patients with chronic illnesses, a burdensome state-by-state system for physician licensing threatens to stifle the integration of telemedicine into the American healthcare system.[13] Although federal regulation of physician licensing requirements to practice telemedicine would provide much needed uniformity, there is also the potential for constitutional friction between the states' police power under the Tenth Amendment and Congress' powers under the Commerce Clause, the Necessary and Proper Clause, and the Taxing and Spending Clause.[14]

Because the benefits of telemedicine are so pronounced in populations affected by chronic illness, further federal regulation is needed in this area to more uniformly outline practitioners' licensing requirements and ultimately ensure patient safety. The remainder of this article will address the pressing need for widespread adaptation of telemedicine and how the patchwork state-by-state licensing scheme hinders adoption of telemedicine. Finally, this article will address why federal regulation is a permissible use of the Federal Government's powers under the Commerce Clause and Necessary and Proper Clause, despite several states' claim that this impedes their police powers.

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7. Andrea S. Christopher et al., *Access to Care and Chronic Disease Outcomes Among Medicaid-Insured Persons Versus the Uninsured*, 106 AJPH POLICY, 63, 67 (2016) (discussing how insurance is a barrier to healthcare); BRIAN W. WARD, BARRIERS TO HEALTHCARE FOR ADULTS WITH MULTIPLE CHRONIC CONDITIONS: UNITED STATES 2012-2015 5 (NCHS Data Brief, No. 275, 2017) (discussing how age and the number of diagnosed chronic conditions effect the non-cost related reasons for not seeking treatment).

8. Ward, *supra* note 7, at 5.

9. University of Jyväskylä - Jyväskylän yliopisto, *Chronic Diseases Restrict the Mobility of Older People—Often Unconsciously,* SCIENCEDAILY (April 11, 2019), www.sciencedaily.com/releases/2019/04/190411101740.htm.

10. COLLEEN SCHNEIDER, CHRONIC DISEASE: ACCESS TO HEALTH CARE AND BARRIERS TO SELF-MANAGEMENT 6 (Cmty. Health Advisory Councils, 2010).

11. CTAC-AHIP COLLABORATION, LEVERAGING TELEHEALTH TO SUPPORT AGING AMERICANS 2 (2018).

12. *Id*.

13. Carl F. Ameringer, *State-Based Licensure of Telemedicine: The Need for Uniformity But Not A National Scheme*, 14 J. HEALTH CARE L. & POL'Y 55, 57 (2011).

14. Bill Marino et al., *A Case for Federal Regulation of Telemedicine in the Wake of the Affordable Care Act*, 16 COLUM. SCI. & TECH. L. REV. 274, 296–306 (2015).

ACCESS TO TELEHEALTH IS NEEDED TO PROVIDE CARE TO PATIENTS WITH CHRONIC ILLNESSES

Telehealth has the potential to vastly improve quality of life for those suffering from chronic illnesses.[15] Many chronic illnesses require treatment by specialists that are unlikely to be readily available to the fifty-seven million Americans living in rural communities.[16] Gaining access to these specialists may require hours of travel, posing challenges to patients dealing with illnesses affecting mobility, such as Parkinson's Disease.[17] Patients living in rural communities are more likely to die prematurely of chronic conditions such as stroke, heart disease, cancer, unintentional injury, and respiratory illnesses.[18] Accessing in-person care also necessitates time off work, resources to arrange travel, and planning child or elder care.[19] Remote monitoring of these patients will reduce unnecessary travel and cost of care, and prevent the worsening condition that often accompanies a lack of access to specialized care.[20] Additionally, many treatment plans for chronic conditions require lifestyle changes that should be monitored on a day-to-day basis that would be impossible through traditional appointments.[21] Moreover, using electronic monitoring technology and instant communication, doctors are able to triage new symptoms in real-time and can immediately recommend emergency care when needed.[22] Because patients with chronic conditions currently account for eighty-one percent of hospital admissions, this would be an exceptionally useful tool in reducing unnecessary admissions while ensuring that patients do not ignore new symptoms.[23]

In addition to the need for increased access to healthcare for patients, implementing telehealth as a response to chronic illnesses also has considerable financial benefits.[24] Currently, heart disease and stroke alone

15. *4 Benefits of Telemedicine in Chronic Disease Management*, INTOUCH HEALTH, https://intouchhealth.com/4-benefits-of-telemedicine-in-chronic-disease-management/ (last visited Feb. 14, 2020).

16. *Id*.

17. *Id*.

18. *Telehealth in Rural Communities*, CTRS. FOR DISEASE CONTROL & PREVENTION, www.cdc.gov/chronicdisease/resources/publications/factsheets/telehealth-in-rural-communities.htm (last updated May 31, 2019).

19. *4 Benefits of Telemedicine in Chronic Disease Management*, *supra* note 15.

20. *Id*.

21. *Id*.

22. *Id*.

23. *Id*.

24. Maryam Alvandi, *Telemedicine and its Role in Revolutionizing Healthcare Delivery*, AM. J. OF ACCOUNTABLE CARE e1, e1 (2017) ("Telemedicine connects the convenience, low cost, and ready accessibility of health-related information and communication using the Internet and associated technologies.").

cost the U.S. economy $199 billion annually.[25] It is estimated that the annual total cost of cancer care is over $174 billion. [26] Many of these conditions are avoidable with adequate preventative care and could potentially save taxpayers millions.[27] Additionally, estimates put the number of people over age 65 at twenty percent of the population by 2030, creating concern of disrupting the ratio of tax-payers to those receiving benefits such as Medicaid, Medicare, and SSI.[28]

In addition to the financial benefits of telemedicine, public health crises such as the emergence of the novel coronavirus, or SARS-CoV-2, necessitate an alternative approach to in-person doctor visits.[29] Appointments that were once routinely conducted now pose a significant risk to public health.[30] This is especially true for patients with chronic illnesses, who require ongoing care and may be immunocompromised, leading to an increased risk of death if they are exposed to the virus.[31] Doctors and healthcare systems are now more incentivized than ever to shift appointments on-line in an attempt to protect themselves and the public from being exposed to symptomatic patients.[32] In the week of March 15, 2020, Teladoc Health, America's largest provider, says its video appointments surged 50 percent.[33] The push to implement telemedicine has already resulted in Medicare announcing that it would expand telehealth coverage in light of the pandemic.[34] Additionally, since the arrival of the pandemic, the United States Department of Health and Human Services has eased physician licensing requirements on telemedicine.[35] These

25. *About Chronic Diseases*, *supra* note 3.

26. *Id.*

27. *Preventable Diseases Costing U.S. Billions, Report Finds*, PND (Nov. 20, 2019), https://philanthropynewsdigest.org/news/preventable-diseases-costing-u.s.-billions-report-finds ("Behaviors, such as smoking and obesity, are limiting our nation's ability to make progress and costing billions in unnecessary, preventable healthcare costs.").

28. Alvandi, *supra* note 24, at 2.

29. Benjamin Mueller, *Telemedicine Arrives in the U.K.: '10 Years of Change in One Week'*, NEW YORK TIMES (Apr. 4, 2020), https://www.nytimes.com/2020/04/04/world/europe/telemedicine-uk-coronavirus.html.

30. *Id*.

31. Allison Wallis, *What It's Like to Be Immunocompromised During the COVID-19 Outbreak*, HEALTHLINE (March 31, 2020), https://www.healthline.com/health-news/what-its-like-to-be-immunocompromised-during-the-covid-19-outbreak.

32. Mueller, *supra* note 29.

33. Geoffrey A. Fowler & Laurie McGinley, *The Webcam Will See You Now: Doctors Urge Patients to Replace In-person Visits With Apps*, THE WASHINGTON POST (March 19, 2020), https://www.washingtonpost.com/technology /2020/03/19 /telehealth-apps-coronavirus/.

34. *Id.*

35. U.S. Dep't of Health and Human Servs., *Waiver or Modification of Requirements Under Section 1135 of The Social Security Act* (March 13, 2020), https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx.

changes include temporarily waiving the restriction on practicing telemedicine in states in which the practitioner is not licensed, and highlights the pressing need for widespread and permanent reform.[36] As more and more people engage in virtual or phone appointments, many experts believe that the shift toward telemedicine will not disappear once social distancing restrictions are lifted.[37]

Even before the emergence of the novel coronavirus, the demand for telehealth had not gone unnoticed.[38] In November 2019, the Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT) Health Act of 2019 was unveiled.[39] The bill would empower the Secretary of the Department of Health and Human Services (HHS) to waive telehealth restrictions, remove geographic restrictions for mental health and emergency care services, and require the Centers for Medicare and Medicaid Services (CMS) to add telehealth services to better consider how telehealth can improve access to care.[40] Despite this progress, serious obstacles to the adoption of telemedicine, largely due to restrictive state laws placed on practitioners wishing to engage in telemedicine still exist.[41]

LEGAL FRAMEWORK

Arguably the largest barrier to wide-spread adoption of telemedicine is the state-by-state regulation of licensing requirements, each of which have unique policies for licensing telemedicine practitioners.[42] This fragmented system has been referred to as "duplicative, expensive, and burdensome," "[an] economic trade barrier restricting the free flow of medical services," and even "the greatest challenge to the interstate practice of telemedicine."[43] Licensing refers to "the process of securing the authority to practice medicine in the state."[44] The vast majority of states require that doctors receive licensure in the state where the patient is receiving care, in addition to requiring every site delivering telemedicine to verify the doctor's license,

36. *Id*.
37. Mueller, *supra* note 29.
38. Kevin B. O'Reilly, *Federal Law Cripples Telehealth in Medicare, New Bill Changes That*, AM. MED. ASS'N (Nov. 5, 2019), www.ama-assn.org/practice-management/digital/federal-law-cripples-telehealth-medicare-new-bill-changes.
39. *Id.*
40. *Id*.
41. Ameringer, *supra* note 13, at 59.
42. U.S. DEP'T OF HEALTH & HUMAN SERVS. & HEALTH RES. & SERVS. ADMIN., HEALTH LICENSING BOARD REPORT TO CONGRESS 6 (2011).
43. Marino, *supra* note 14, at 278–79.
44. *Licensing and Credentialing of Telehealth Programs*, RURAL HEALTH INFO. HUB, www.ruralhealthinfo.org/toolkits/telehealth/4/licensing-and-credentialing (last visited Feb. 14, 2020).

provide training, education, and other information.[45] Some states have taken steps to ensure that physician licenses better reflect the realities of telemedicine, such as setting up Uniform Applications for Licensure and participating in interstate compacts.[46] However, the availability of these solutions varies by state, and does not tackle the lack of uniformity facing doctors wishing to practice telemedicine across state lines.[47]

Doctors wishing to offer medical advice remotely must obtain and maintain a license in whichever state the patient is located, costing doctors $300 million annually.[48] This challenging landscape for practitioners has raised concerns that the public will be denied the benefits of telemedicine, with the Federal Communications Commission (FCC) warning that "[i]f states fail to develop reasonable [telemedicine] licensing policies over the next eighteen months, Congress should consider intervening to ensure that Medicare and Medicaid beneficiaries are not denied the benefits of [telemedicine]"[49] Additionally, there have been at least two bills presented before Congress since 2013 imploring reform to the state-by-state licensing system.[50] One of these bills, the Telehealth Promotion Act of 2012 (H.R. 6719), sponsored by Rep. Mike Thompson (D-CA), focused on increasing federal support and spending on telehealth.[51] The bill would ensure that individuals are reimbursed such that "no [medical] benefit covered shall be excluded solely because it is furnished via a telecommunications system,"[52] and has been referred to the subcommittee on Health for review.[53] The Telemedicine Act of 2013 (H.R. 3077) seeks to overcome the state-by-state licensing requirements by allowing a physician licensed in one state to practice telehealth in a different state, and has also been referred to the Subcommittee on Health for review.[54]

Despite this apparent movement toward a federal regulatory scheme, there has been debate as to whether federal regulation of medical licenses is an

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45. *Id*.
46. *Id*.
47. *Id*.
48. Christine Vestal, *Expanding Telemedicine Beyond State Borders*, USA TODAY (March 7, 2014, 9:44 AM), www.usatoday.com/story/news/nation/2014/03/07/stateline-telemedicine-expansion/6159775/.
49. FED. COMMC'N COMM'N, CONNECTING AMERICA: THE NATIONAL BROADBAND PLAN 206.
50. Erin McCann, *Proposed Bill Would Expand Telehealth Services, Bolster Federal Payouts*, HEALTHCARE IT NEWS (Jan. 3, 2013), www.healthcareitnews.com/news/proposed-bill-would-expand-telehealth (discussing the Telemedicine for Medicare Act (H.R. 3077) and the Telehealth Promotion Act (H.R. 6719), both introduced in the House in 2013).
51. *Id.*
52. *Id.*
53. Telehealth Promotion Act of 2012, H.R. 6719, 112th Cong. (2012).
54. TELE-MED Act of 2013, H.R. 3077, 113th Cong. (2013).

impermissible encroachment on the states' police powers under the Tenth Amendment.[55] The remainder of this article will explore how a federal regulatory scheme is constitutional under the Commerce Clause through the Necessary and Proper Clause, especially in light of the severity of the economic and humanitarian crises caused by chronic illness in the United States.

THE CONSTITUTIONAL DEBATE

Despite the advantages of federal reform to the current state-by-state patchwork of telemedicine licensing requirements, there has been debate that such reform would violate states' police powers to determine their own requirements.[56] In making this argument, states may turn to the language used in *Florida v. HHS*, which states that "the health care industry. . . falls within the sphere of traditional state regulation"[57] and that "a state's role in safeguarding the health of its citizens is a quintessential component of its sovereign powers."[58]

However, this argument against federal regulation of licensing overlooks more recent decisions that have offered expansive interpretations of the federal government's power under the Necessary and Proper Clause, the Commerce Clause, and spending powers.[59] Since the New Deal, "assertions of federal power" have been largely "unassailable."[60] This is particularly true under the Commerce Clause, which empowers Congress to regulate anything that substantially effects interstate commerce, is a channel of interstate commerce, or is an instrumentality of interstate commerce.[61]

FEDERAL REGULATION IS PERMISSIBLE UNDER THE COMMERCE CLAUSE AND NECESSARY AND PROPER CLAUSE:

Congress has the constitutional power to regulate commerce among states if such regulation passes the "Substantial Effect" test established in the seminal 1995 Supreme Court decision in *United States v. Lopez*.[62] Under this test, federal legislation is permissible if it falls under one of the following types of activities:

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55. Marino, *supra* note 14, at 296-306.
56. *Id.*
57. *Florida v. Dep't of Health and Human Servs.*, 648 F.3d 1235, 13o5 (11th Cir. 2011).
58. *Id.*
59. Marino, *supra* note 14, at 299.
60. Linda Greenhouse, *The Revolution Next Time*?, N.Y. TIMES (Dec. 16, 2010, 8:00 PM), http://opinionator.blogs.nytimes.com/2010/12/16/the-revolution-next-time/.
61. Marino, *supra* note 14, at 304.
62. United States v. Lopez, 514 U.S. 549, 549 (1995).

(1) Regulation of use of channels of interstate commerce;
(2) Regulation and protection of instrumentalities of interstate commerce; or
(3) Regulation of activities having substantial effect on commerce.[63]

Arguably, federal regulation of the licensing requirements for telemedicine falls into all three of the categories under *Lopez*.[64] Regulation directly involves interstate and foreign commerce "by allowing or denying a telemedicine provider to conduct business across borders."[65] Furthermore, restrictions placed on adoption of telemedicine has a substantial impact on the overall price of healthcare.[66] Imposing national standards would reduce the administrative costs associated with practicing across state lines, and impact the price of delivering healthcare by removing incentives to avoid the telemedicine market.[67] The fact that the practice of health care has been held to be interstate trade for the purposes of antitrust laws strengthens this argument.[68] Telemedicine regulation clearly fits under the definition of "substantial effect" under *Lopez*, which includes intrastate production of a commodity that in the aggregate impacts interstate economic activity.[69]

Although the Commerce Clause has been interpreted expansively, if Congress lacks the power to regulate telehealth under the Commerce Clause, the Necessary and Proper Clause extends Congress's reach.[70] Under Article I, Section 8 of the Constitution, Congress has the power "to make all Laws which shall be necessary and proper for carrying into Execution the foregoing Powers, and all other Powers vested by this Constitution in the Government of the United States, or any Department or Officer thereof."[71] *Gonzales v. Raich* explains that the Necessary and Proper Clause allows the Commerce Clause to reach activities "substantially affecting interstate commerce" but that "are not themselves a part of interstate commerce if doing so is necessary to make interstate commerce effective."[72] The language of this decision is in line with recent expansion of federal regulatory power, and because of the aforementioned reasons clearly encompasses regulation of telemedicine.[73]

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63. *Id*. at 558–59.
64. Amar Gupta & Deth Sao, *The Constitutionality of Current Legal Barriers to Telemedicine in the United States: Analysis and Future Directions of Its Relationship to National and International Health Care Reform*, 21 HEALTH MATRIX: THE J. OF L.-MED., 385, 427 (2012).
65. *Id.* at 429.
66. *Id.*
67. *Id*. at 433.
68. *See*, e.g., Arizona v. Maricopa County Medical Soc'y., 457 U.S. 332 (1982).
69. *Lopez* at 561.
70. Marino, *supra* note 14, at 304.
71. U.S. CONST. art. I, § 8, cl. 18.
72. Gonzales v. Raich, 545 U.S. 1, 19 (2005).
73. Marino, *supra* note 14, at 304.

FEDERAL REGULATION IS PERMISSIBLE UNDER CONGRESSES SPENDING POWERS

Furthermore, Congress' Taxing and Spending power could support a federal spending program implementing telemedicine licensure if such a program "provides for the general welfare of the citizens of this country."[74] As discussed previously, the benefits of telemedicine to U.S. citizens include increasing access to healthcare and addressing the hemorrhaging effects of chronic illnesses on healthcare system.[75] Congress displayed its willingness to regulate the health industry under the Taxation and Spending Clause in *National Federation of Independent Businesses v. Sebelius*, in which the Supreme Court held that it was within Congress' taxation power to mandate individuals to purchase health insurance or pay a penalty.[76] Writing separately, Justice Ginsburg stated that "as evidenced by Medicare, Medicaid, [the Employee Retirement Income Security Act of 1974], and [the Health Insurance Portability and Accountability Act of 1996], the Federal Government plays a lead role in the health-care sector, both as a direct payer and as a regulator."[77]

Congress's involvement in the regulation of healthcare is also highlighted in *Liberty University, Inc. v. Geithner*, in which the Court stated "through ERISA, [and] enactments like Health Insurance Portability and Accountability Act of 1996 . . . the federal government has come to occupy much of the field of the regulation of health benefits, and many state and local attempts to regulate health insurance have been held preempted" so it cannot "be said that health insurance or health services have always been the province of the states."[78] It therefore follows that "a state has no constitutional basis to claim exclusive authority over health regulation."[79] Because implementing a uniform licensing scheme would provide for the general welfare of the citizens of this country by increasing access to care and reducing cost, Congress has the power to implement a spending program under the Spending Powers.

CONCLUSION

Although states may argue that the Tenth Amendment reserves regulation of physician licensing requirements under the states' police powers, recent cases, including the adoption of the Affordable Care Act, suggest an

74. *Id*. at 304–05.
75. *Id*.
76. Nat'l Fed'n of Indep. Bus. v. Sebelius, 567 U.S. 519, 563 (2012).
77. *Id.* at 622 (Ginsburg, J., concurring in part, concurring in judgment in part, and dissenting in part).
78. Liberty Univ., Inc. v. Geithner, 671 F.3d 391, 438 (4th Cir. 2011).
79. Gupta & Sao, *supra* note 64, at 413.

expansive view on the federal government's power under the Commerce Clause, the Necessary and Proper Clause, and the power to tax.[80] Further, federal regulation of licensing requirements to practice telehealth would improve an overly complicated and burdensome patchwork system that is impeding access to affordable and quality care.[81] This is especially true for patients suffering from chronic illnesses. Patients with chronic illnesses effecting mobility may have difficulties commuting to necessary doctors' appointments.[82] Further, chronic illnesses often necessitate specializations that are unlikely to be accessible to patients in rural areas.[83] Finally, increasing access to telemedicine would alleviate one of the largest expenses in the American healthcare system by reducing unnecessary utilization of emergency departments, and increasing access to preventative resources.[84] Because there are no constitutional impediments on federal regulation of licensing requirements, and because of the benefits that come along with telemedicine, Congress should create uniform requirements for doctors wishing to practice telemedicine.

80. Marino, *supra* note 14, at 296–306.
81. *Id*. at 296.
82. *4 Benefits of Telemedicine*, *supra* note 15.
83. *Id*.
84. *Id*.

Cultivating the Therapeutic Alliance Through Reimbursement Regulation

Daniel Duffy

I. INTRODUCTION

Chronic diseases represent more than seventy-eight percent of U.S. health costs[1] and are projected to cost "$4.2 trillion in treatments, costs, and lost economic output" annually.[2] Debate exists regarding whether mental illness is included as part of the definition of chronic disease or a separate category of diagnoses.[3] Notwithstanding categorization confusion, seminal studies on the mind body connection have found patients could improve their chronic conditions by learning "to slow down and chill out."[4] Further research has confirmed that mental health interventions can improve chronic conditions, and theoretically, its socio-economic consequences.[5]

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1. Gerard Anderson & Jane Horvath, *The growing burden of chronic disease in America*, 119 PUB. HEALTH REP. 263, 264 (2004).

2. ROSS DEVOL & ARMEN BEDROUSSIAN, MILIKEN INST., AN UNHEALTHY AMERICA: THE ECONOMIC BURDEN OF CHRONIC DISEASE 11 (2007).

3. *See generally* Stephanie Bernell & Steven Howard, *Use your Words Carefully: What is a chronic disease?* 1- 4 FRONTIERS IN PUB. HEALTH 1, 1–2 (2016) (discussing there is wide variation in the definition of chronic disease and provides several examples); *Compare Chronic Conditions*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/CC_Main (last visited Apr. 17, 2020) (Centers for Medicare and Medicaid Services' definition of chronic disease includes mental illness diagnoses, such as alcohol/substance abuse, depression, schizophrenia, and other psychotic disorders), *with About Chronic Diseases*, CTRS. FOR DISEASE CONTROL & PREVENTION, www.cdc.gov/chronicdisease/about/index.htm (last visited Apr. 17, 2020) (Centers for Disease Control and Prevention (CDC) limits chronic illnesses and diseases to "classic" chronic conditions: heart disease, cancer, chronic lung disease, stroke, Alzheimer's disease, diabetes, and chronic kidney disease), *and* NAT'L CTR. FOR CHRONIC DISEASE PREVENTION & HEALTH PROMOTION, CTRS. FOR DISEASE CONTROL & PREVENTION, *Mental Health and Chronic Disease*, 1 (2012), www.cdc.gov/workplacehealthpromotion/tools-resources/pdfs/issue-brief-no-2-mental-health-and-chronic-disease.pdf (CDC further distinguishes mental health disorders as "medical conditions that disrupt a person's thinking, feeling, mood, ability to relate to others and daily functioning").

4. Elaine Woo, *Meyer Freidman: Doctor Identified 'Type A' Behavior,* L.A. TIMES (May 6, 2001 12:00AM), www.latimes.com/archives/la-xpm-2001-may-06-me-60173-story.html (Cardiologist's initial observation of coronary patients causing the upholstery on the waiting room chairs to wear down in an unusual manner led to a body of research confirming the relationship between anxious behaviors and heart disease).

5. Daniel P. Chapman, et al., *The vital link between chronic disease and depressive*

Unfortunately, while mental health rates indicate a huge demand for mental health treatment,[6] efficacious treatment is threatened by private equity (PE) firms acquiring of mental health service providers[7] and recently proposed price transparency rules.[8]

The efficacy of psychotherapy is highly reactive to seemingly unrelated healthcare matters. Strategic regulatory measures need to be implemented to ensure and incentivize and ensure the therapeutic alliance, and thus, the efficacy of psychotherapy. First this paper will illustrate the need for mental health treatment and discuss how the therapeutic alliance is essential to efficacious mental health treatment. Then this paper will provide examples the therapeutic alliance, and thus, mental health treatment, is highly responsive to regulation, or lack thereof. The first example this paper will discuss how practitioners are incentivized to sell their practices to PE firms, who in turn implement strategies that damage the therapeutic alliance. Strategic regulatory reimbursement procedures will be offered as a solution to ensure the therapeutic alliance, and thus efficacious mental health treatment. The second example this paper will discuss is how proposed price transparency rules will damage the therapeutic alliance by revealing to the patient how third-party payors determine the amount of care provided. Further, this proposed rule provides an additional illustration of how the cost of regulatory compliance incentivizes providers to sell their practices. Conclusions will point out that PE Firms' strategies and the proposed transparency rule are only recent changes threats to the efficacy of psychotherapy and protections need to be in place to mitigate against the highly reactive nature of the therapeutic alliance. Further, the proposed strategies to respond to PE firms, only addresses substance abuse treatment, and other coverage decisions need to be developed to incentivize evidence-based treatment for other disorders.

II. DEMAND FOR EFFICACIOUS PSYCHOTHERAPY

Overall 19.1% of American adults reported experiencing a mental illness, while 4.6% of American adults reported having a serious mental illness 2018.[9] Further, one in six minors, ages six to seventeen, experience a

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disorders, 2 PUB. HEALTH RES., PRACTICE, & POL'Y 1, 2–5 (2005); *see also*, PROMOTING CHRONIC DISEASE MANAGEMENT: A GUIDE FOR BEHAVIORAL HEALTH CARE TEAMS, WASH. COUNCIL FOR BEHAVIORAL HEALTH, 1 (2018), https://depts.washington.edu/fammed/wp-content/uploads/2018/05/Promoting-Chronic-Disease-Management_180508.pdf.

6. *See* discussion *infra* Section II.

7. *See* discussion *infra* Section III.B.

8. *See* discussion *infra* Section IV.

9. SUBSTANCE ABUSE & MENTAL HEALTH SERVICES ADMINISTRATION, DEP'T. OF HEALTH & HUMAN SERV., KEY SUBSTANCE USE AND MENTAL HEALTH INDICATORS IN THE UNITED STATES: RESULTS FROM THE 2018 NATIONAL SURVEY ON DRUG USE AND HEALTH 43-

mental health disorder each year.[10] The opioid epidemic further illustrates the prevalence of mental illness, as genetic predisposition and environmental factors lead to high comorbidity rates between drug abuse and another mental illnesses.[11] Currently there are over 130 people dying each day from opioid overdose.[12] Further, four to six people who first misuse prescription opioids transition to other illicit drugs such as heroin.[13] It is estimated that 21.2 million Americans need substance abuse treatment each year, while 3.7 million Americans actually received treatment each year.[14]

While 3.7 million Americans receiving treatment should be celebrated, regulatory processes need to ensure efficacious treatment is being provided. Within the field of clinical psychology, there is broad consensus that there are common factors to psychotherapy that are responsible for patient's success regardless of the concerning problem or the therapist's theoretical orientation.[15] Amongst the common factors, "therapeutic alliance" is given considerable weight, so much so, that it is considered the active ingredient that causes the client to adhere to therapy.[16] The "therapeutic alliance" is characterized as tasks, bonds, and goals.[17] "Tasks" refers to the substance of therapy.[18] Each party (client and therapist) must perceive the substance as relevant and effective, and understand each parties' role or responsibility in

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44 (2019) (defining "any mental illness" as "any mental illness, behavioral, or emotional disorder in the past year that met DSM-IV criteria," excluding developmental and substance abuse disorders; and defining "serious mental illness" as "any diagnosable mental , behavioral, or emotional disorder, other than a developmental or substance abuse disorder that substantially interfered with or limited one or major life activities.").

10. *Mental Health By The Numbers*, NAMI (2019) (retrieved data from Daniel G. Whitney & Mark D. Peterson, *US National and State Level Prevalence of Mental Health Disorders and Disparities of Mental Health Care Use in Children,* 4 JAMA PEDIATRICS 173, 389-391 (2019)).

11. Nora D. Volkow & Maureen Boyle, *Neuroscience of Addiction: Relevance to Prevention and Treatment*, 175 AM. J. PSYCHIATRY 729, 731 (2018).

12. NATIONAL INSTITUTE ON DRUG ABUSE, DEP'T OF HUMAN HEALTH & SERV., *Opioid overdose Crisis*, (2019), www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis#one (computed from CDC and NCHS National Vital Statistics System data) (last visited Mar. 17, 2020).

13. *Id*.

14. SUBSTANCE ABUSE & MENTAL HEALTH SERVICES ADMINISTRATION, DEP'T. OF HEALTH & HUMAN SERV., *supra* note 9, at 50-51.

15. Martin E.P. Seligman, *The Effectiveness of Psychotherapy: The Consumer Reports Study*, 50 AM. PSYCHOLOGIST, 965, 969 (1995).

16. Adam O. Horvath & Lester Luborsky, *The role of the therapeutic alliance in psychotherapy*, 61 J. CONSULTING & CLINICAL PSYCH, 561, at 563 (1993); Michael J. Lambert & Dean E. Barely, *Research Summary on the Therapeutic Relationship and Psychotherapy Outcome*, 38 PSYCHOTHERAPY THEORY RES. & PRACTICE, 357, 358 (2001).

17. Horvath & Luborsky, *supra* note 16; Lambert & Barely, *supra* note 16, at 359.

18. Horvath & Luborsky, *supra* note 16.

the therapeutic process.[19] "Bonds" refers to the attachment between the parties that must be founded in mutual trust, acceptance, and confidence.[20] "Goals" are the therapeutic objectives and should be mutually shared by the parties.[21] Determinative to the client's understanding of the goals is the therapist's ability to communicate the link between the task and the goal.[22] This alliance allows the client to deal with the initial discomforts of therapy, as well as the next phase of therapy where the therapist may challenge the client's maladaptive behavior.[23]

III. PE FIRMS AND BEHAVIORAL HEALTH

In recent years, the merger and acquisition activity for behavioral health service providers has been described as "white hot."[24] The impetus behind this trend has been a series of federal statutes that increased the likelihood of third-party reimbursement for mental health services.[25] Specifically, "the U.S. Mental Health Parity Act of 2008, which requires mental illness to be reimbursed on par with physical illness, the U.S. Affordable Care act of 2012, which abolished lifetime and 30-day limits on inpatient behavioral health care, and the U.S. 21st Century Cures Act of 2016, which further clarified parity."[26] At the same time, physicians are motivated to sell their practices due to realities in health care management, such as competing for insurance contracts and inability to invest in necessary billing and technology.[27]

PE firms are cited as the most frequent purchaser in this market.[28] PE

19. *Id*.

20. *Id*.; Lambert & Barely, *supra* note 16, at 359.

21. Horvath & Luborsky, *supra* note 16; Lambert & Barely, *supra* note 16, at 359.

22. Horvath & Luborsky, *supra* note 16, at 564.

23. *Id*. at 564-67.

24. Debora Balshem, *Behavioral Health Continues to Attract Private Equity Investors*, FORBES (July 6, 2017, 8:15 AM), www.forbes.com/sites/mergermarket/2017/07/06/behavioral-health-continues-to-attract-private-equity-investors/#66a254716210.

25. Benjamin Brown, et al., *Private Equity Investment in Behavioral Health Treatment Centers*, 77 JAMA PSYCHIATRY 229, 229 (2020); *Behavioral Health Care M&A Activity Slowed in Q4:2019, According to Acquisition Data From Helathcaremanda.com*, MARKET INSIDER (Jan. 19, 2020 8:00AM), https://markets.businessinsider.com /news/stocks /behavioral-health-care-m-a-activity-slowed-in-q4-2019-according-to-acquisition-data-from-healthcaremanda-com-1028827560.

26. Brown, et al., *supra* note 25.

27. *Id*.; Mark Gilreath, et al., *Physician Practice Management and Private Equity: Market Forces Drive Change*, 17 CLINICAL GASTROENTEROLOGY & HEPATOLOGY 1924, 1925 (2019).

28. Tom Valentino*, TCIV Spotlight: Behavioral Health M&A Activity Slows in Q3*, Psychiatry & Behavioral Health Learning Network (2019), www.psychcongress.com/article/tciv-spotlight-behavioral-health-ma-activity-slows-q3; MERTZ-TAGGERT*,* BEHAVIORAL HEALTH M&A REPORT: Q2 2019 at 1 (2019),

firms generally function by purchasing a company, adding value to that company through some sort of action, and then selling their ownership in that company at a higher price than they originally paid.[29] Previously, PE firms have used several strategies to increase the value of medical service providers including price increases, reducing costs (often through layoffs), consolidating or internalizing previously outsourced processes like billing, and doing all of this while increase patient volume.[30] PE firms are attracted to the healthcare industry because of inefficiencies, the relative ease in controlling a geographic market, and the consistent revenue generated by providing treatment for chronic conditions.[31] Conversely, many physicians are motivated to sell their practices out of concerns of competing for insurance contracts and inability to invest in necessary billing and technology.[32]

While activity in this market slowed in 2019, it comes after several years of PE firms acquiring treatment centers with the goal of turning a fragmented industry into regional and national behavioral health platforms.[33] PE firms have been interested in behavioral health entities who provide a continuum of care, meaning treatment from inpatient to outpatient therapy.[34] In particular, PE firms have been building networks for substance abuse treatment and services for people with autism spectrum disorder (ASD).[35]

A. PE Firms' Effect on Quality of Care

PE firms' previous health care acquisition trends indicate a pattern of sacrificing quality of care for profit.[36] For example, dermatologists at PE

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mertztaggart.com/ behavioral-health-q2-ma-report/.

29. Suhas Gondi & Zirui Song, Opinion, *Potential Implications of Private Equity Investments in Health Care Delivery*, 321 JAMA 1047, 1047 (2017).

30. *Id*.

31. *Id*. at 1047.

32. *Id*.; Gilreath, et al., *supra* note 27.

33. Brown, et al., *supra* note 25; *Behavioral Health Care M&A Activity Slowed in Q4:2019, According to Acquisition Data From Helathcaremanda.com*, MARKET INSIDER (Jan. 19, 2020 8:00AM), https://markets.businessinsider.com/ news/stocks /behavioral-health-care-m-a-activity-slowed-in-q4-2019-according-to-acquisition-data-from-healthcaremanda-com-1028827560.

34. Balshem, *supra* note 24.

35. Valentino, *supra* note 28; MERTZ-TAGGERT, *supra* note 28.

36. Jack S. Resneck *Dermatology Practice Consolidation Fueled by Private Equity Investment Potential Consequences for the Specialty and Patients*, 1 JAMA DERMATOL. 154, 13-14 (2018) (reporting that dermatologists in PE firm owned practices lose autonomy to investors who value profits over what is best for the patient); Letter from Sen. Elizabeth Warren, Rep. Mark Pocan, and Sen. Sherrod Brown, U.S. Members of Congress, to Kewsong Lee, CEO and Glen A. Youngkin Co-CEO of the Carlyle Group, 1 (Nov. 12, 2015), www.warren.senate.gov /imo/media/doc/2019-11-

firm-owned practices reported increased pressure to see more patients, sell products, and make outside referrals to affiliated specialists.[37] Further, these dermatologists also reported more instances of up charging and increased reliance on physician assistants in unsupervised settings.[38]

Additionally, the history of PE firm ownership of skilled nursing facilities (SNFs) has demonstrated an inability to impose legal or regulatory ramifications on these firms.[39] In 2007, a New York Times investigation revealed that PE firms' acquisition of SNFs, and subsequent staff cuts, led to decreases in quality of care and increases in wrongful death suits.[40] PE firms were able to successfully minimize the financial and regulatory impact from these wrongful death suits by dividing ownership of their facilities and, thus insulating the SNFs from each other.[41] Congress responded to outrage over PE firms' practices with accountability and transparency provisions in the Affordable Care Act, but failed to implement these measures.[42] Recent research and investigative reporting have verified that PE firm owned nursing homes, relative to non-PE owned nursing homes, continue to fail safety inspections, increase safety risks, and expose patients to inexcusable living conditions.[43] In response to this re-discovery, Congress members have requested that firms owning nursing homes disclose their investment portfolios.[44] Additionally, Senator Elizabeth Warren introduced legislation that would limit PE firms' ability to transfer money across their insulated facilities and would prevent these jointly-

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15%20Letters%20to%20PE%20Firms%20re%20Nursing%20Homes.pdf (". . .large for-profit nursing home chains, which research has shown often provide worse care than not-for-profit facilities.").

37. Resneck, *supra* note 36, at 14.

38. *Id*.

39. *Who Owns Nursing Facilities and Why?* CTR. FOR MEDICARE ADVOCACY, www.medicareadvocacy.org/who-owns-nursing-facilities-and-why/ (last visited Apr. 17, 2020).

40. Charles Duhigg, *At Many Homes, More Profit and Less Nursing*, N.Y. TIMES (Sept. 23, 2007), www.nytimes. com/ 2007/09/23/business/23nursing.html.

41. *Id*.

42. CTR. FOR MEDICARE ADVOCACY, *supra* note 39.

43. *See* Letter to Kewsong Lee, CEO and Glen A. Youngkin, *supra* note 32, at 1-2, (citing Peter Whoriskey & Dan Keating, *Overdoses, Bedsores, Broken Bones: What Happened When A Private-Equity Firm Sought to Care for Society's Most Vulnerable*, WASH. POST. (Nov. 25, 2018), www.washingtonpost.com/business/economy/opioid-overdoses-bedsores-and-broken-bones-what-happened-when-a-private-equity-firm-sought-profits-in-cari/; Jennifer Gollan, *Elderly Often Face Neglect in California Care Homes that Exploit Workers*, REVEAL NEWS (Sep. 18, 2019) https://www.revealnews.org/article/elderly-often-face-neglect-in-california-care-homes-that-exploit-workers/).

44. *Id*.; Maggie Flynn, *Citing Quality Concerns, Senators Demand Answers from Major Private Equity Owners of Nursing Homes*, SKILLED NURSING NEWS (2019), https://skillednursingnews.com/2019/11/citing-quality-concerns-senators-demand-answers-from-major-private-equity-owners-of-nursing-homes/.

owned facilities from being insulated from each other's legal judgments.[45]

B. Will History Repeat Itself with PE Firms' Acquisitions of Mental Health Services?

Autism service and substance abuse treatment providers have been the two of the largest targets for PE firms.[46] Autism service providers are considered "the hottest commodity in the sector."[47] Services for children with autism spectrum disorder (ASD) consists of early treatment with evidenced-based interventions is important while they are in elementary school.[48] Services for adults (eighteen or older) with ASD center on living independently and obtaining a supportive residence throughout their adulthood, rather than clinical symptoms.[49] There are a relative small number of autism service providers that exist, many of whom are caring for individuals with ASD out of their own homes.[50] PE firms' ability to build national and regional platforms from these fragmented providers is speculated to be their motivation.[51] Additionally, PE firms are attracted to autism service providers because of their highly variable operating profit margins.[52]

PE firms are also acquiring substance abuse centers due the continuum of treatment options available and the chronic nature of the disease.[53] For instance, "40–60% of patients treated for alcohol or other drug dependence return to active substance use within a year following treatment discharge."[54] The continuum of treatment options at substance abuse centers include a range from high-end inpatient residential to outpatient treatment for substance abuse,[55] as well as, treatment for the underlying mental illness that often accompanies substance abuse.[56]

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45. Flynn, *supra* note 44.

46. *See* sources cited in *supra* note 35.

47. MARKET INSIDER, *supra* note 33.

48. *My Child has Autism Spectrum Disorder: What Does the Future Hold?* RAISING CHILDREN (Last updated or reviewed Dec. 18, 2018), https://raisingchildren.net.au/autism/learning-about-asd/about-asd/asd-the-future.

49. Marina Sarris*, A Place of Their Own: Residential Services for Soon-to-Be Adults with Autism*, INTERACTIVE AUTISM NETWORK (Mar. 19, 2013), https://iancommunity.org/print/13488.

50. Valentino, *supra* note 28; Brown, *supra* note 33.

51. Valentino, *supra* note 28; Brown, *supra* note 33.

52. Balshem, *supra* note 24. (noting that EBITA margins vary across autism service providers from 5-25%).

53. MERTZ-TAGGERT, *supra* note 33; Market Insider, *supra* note 28.

54. A. Thomas McLellan, et al., *Drug Dependence, A Chronic Medical Illness: Implications for Treatment, Insurance, and Outcomes Evaluation*, 284 JAMA 1689, 1689 (2000).

55. Balshem, *supra* note 24.

56. MERTZ-TAGGERT, *supra* note 28.

Previously, PE firms have employed strategies that decrease the quality of care provided at their facilities. While recent measures proposed by Congress in response to PE firms' management of SNFs could be applied to behavioral health, such measures are retro-active. Proactive measures need to be taken that assure patient's success by assuring the delivery of evidence-based care. For substance abuse treatment, Motivational Interviewing (MI) is widely understood evidence based care.[57] MI is a therapeutic technique that encourages the patient to consciously measure their ambivalence towards seeking treatment and decide whether they want to seek treatment.[58] This intervention can be challenging to administer as the therapist needs to find the balance between the often-opposing counseling strategies of empathy and directiveness.[59] By striking this balance, the therapist is able aid patients in measuring their ambivalence towards recovery and make a decision on whether to progress with therapy.[60] Essential to this treatment intervention and common to all psychotherapeutic interventions, the therapeutic alliance must be established in order to for the client to adhere and commit to tasks of the intervention.[61] For MI, the therapeutic alliance allows the patient feel understood, yet directed in making a decision regarding treatment.[62]

The future use of MI at PE-owned centers is doubtful as the central aspect of the therapeutic intervention is to let the patient decide when they are ready for treatment.[63] This directly contradicts PE firms' motivation of increasing patient volume.[64] Further, even if this technique is provided at PE-owned substance abuse centers, the effectiveness of this intervention could be PE firms' strategy of relying on less qualified professionals to provide care.[65] This is concerning because research has shown that MI's effectiveness is risked by providers who have not been adequately trained.[66]

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57. Proactive measures for services people with ASD will not be explored in this paper as such services for adults are focused on independent living and not clinical in nature (see, Sarris *supra* note 49); SUBSTANCE ABUSE & MENTAL HEALTH SERVICES ADMIN., *Enhancing Motivation For Change in Substance Abuse Treatment*, TREATMENT IMPROVEMENT PROTOCOL SERIES 35, page *xv* (1999).

58. SUBSTANCE ABUSE & MENTAL HEALTH SERVICES ADMIN, *supra* note 57, at 40 (discussing how therapist facilitates the clients' exploration into their own ambivalence).

59. *Id*.

60. *Id*. at 39 (discussing how the therapist's role helps the client prepare to change).

61. *Id*. at 11-12; *see supra* note 16 and accompanying text.

62. SUBSTANCE ABUSE & MENTAL HEALTH SERVICES ADMIN, *supra* note 57, at 11-12.

63. *Id*. at 39 (Text implicitly showing that clients with low readiness for change, chose not to participate in therapy but may chose therapy in a later time).

64. Gondi & Song, *supra* note 29.

65. Resneck. *supra* note 36.

66. SUBSTANCE ABUSE & MENTAL HEALTH SERVICES ADMIN, *supra* note 57, at 54 (Of the eleven studies reviewed, nine supported the effectiveness of MI, while two studies did not support. However the providers in these two studies delivered may not have adequately

C. Ensuring the Therapeutic Alliance with Reimbursement Regulation

Reviewing the scope and use of coverage decision is one way to proactively ensure effective interventions at PE firm owned treatment centers. The Centers for Medicare and Medicaid Services (CMS) only compensates for healthcare that is deemed "medically necessary," which is determined through national coverage determinations (NCDs).[67] While NCDs only have regulatory authority over providers who treat CMS beneficiaries, coverage decisions still have practical ramifications on all providers due to "Medicare Spillover."[68] "Medicare Spillover" describes private insurers' tendency and motivation to adopted CMSs' policies because of administrative simplification for providers who work with public and private insurers and, assuming the purpose of NCDs are to improve health outcomes and care, promote best clinical practices.[69]

Hopefully, if substance abuse patients are covered for MI interventions, then PE-owned facilities would be motivated to provide that intervention. Fortunately, there is an NCD regarding alcohol abuse that has a generic behavioral intervention that is synonymous with MI intervention (CMS does not identify specific interventions by name).[70] Unfortunately this NCD has several limitations that prevents its application to substance abuse centers. First, this NCD is limited to alcohol.[71] There is no reason for MI to be limited to treatment for alcoholism, when it is also effective for other substances and problematic behaviors,[72] and there is the demand for evidence-based interventions for other substances can be seen in the opioid

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been trained in MI as they delivered advice in an authoritarian manner, which is a departure from the spirit of the intervention.).

67. EVICORE HEALTHCARE, MEDICARE: HIERARCHY FOR APPLYING COVERAGE DECISIONS FOR LABORATORY TESTING, at 1 (MOL.AD. 101.A v2.0 2019), www.evicore.com/-/media/files/evicore/clinical-guidelines/solution/lab-management/healthplan/medicare-hierarchy-for-applying-coverage-decisions-for-laboratory-testingwellcare-rmhp-hamp-hne-conn.pdf; Coverage decisions at the state-level, CMS contracts with multi-state, regional Medicare Administrative Contractors to make local coverage determinations (LCDs) (Marta Podemska-Mikluch, *FDA-CMS Parallel Review: A Failed Attempt at Spurring Innovation* 7–8 (Mercatus Ctr.: George Mason U., Working Paper 2016), www.mercatus.org/system/files/podemska-mikluch-fda-cms-parallel-review-v1.pdf.).

68. David B. Muhlestein, et al., *The Spillover Effect of a Change in Medicare Reimbursements on Provider Behavior in Non-Medicare Population for Bariatric Surgery*, 8 WORLD MED. & HEALTH POL'Y 74, 88-89 (2016).

69. *Id*.

70. NCD 210.8, Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse (2011) (does not specifically endorse MI as "CMS does not identify specific alcohol misuse screening tools. Rather, the decision to use a specific tool is at the discretion of the clinician in the primary care setting.").

71. *Id*.

72. SUBSTANCE ABUSE & MENTAL HEALTH SERVICES ADMIN, *supra* note 57, at 30-33.

epidemic.[73]

Second, this NCD limits coverage to primary care doctors, other medical doctors, physician assistants, nurse practitioners, and clinical nurse specialists.[74] While it appears that CMS is limiting this intervention to qualified professionals, physicians who received MI training is the exception, rather than the rule.[75] Additionally, U.S. Bureau of Labor Statistics' 2019 employment data shows that counselors and social workers, in comparison to psychiatrists, overwhelmingly represent the substance abuse workforce.[76] Further, even if a counselor or social worker has not received MI specific training, the professional has received training in the underlying efficacious factors, as these factors are common across psychotherapeutic orientations.[77] If MI is evidence-based treatment for substance abuse, then it only makes sense to allow and promote the professions who provide the majority of treatment to bill for the intervention and are trained to do so.

Third, this NCD further limits providing the MI intervention at a primary care facility.[78] The NCD expressly states that primary care settings do not include "[e]mergency departments, inpatient hospital settings, ambulatory surgical centers, independent diagnostic testing facilities, skilled nursing facilities, inpatient rehabilitation facilities and hospices. . .".[79] In order to ensure quality of care, the limitation of primary care locations needs to be removed, so PE-owned firms can be certain that they will be compensated for this intervention.

Fourth, not only should this NCD be extended to non-primary care facilities, this NCD should be integrated into NCDs for admissions into

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73. *See* National Institute on Drug Abuse *supra* note 12.

74. NCD 210.8, *supra* note 70.

75. *See e.g.*, Katrina A. D'Urzo, et al., *Evaluating the Implementation and Impact of Motivational Interviewing Workshop on Medical Student Knowledge and Social Cognitions Towards Counseling Patients on Lifestyle Behaviors*, 32 TEACHING & LEARNING MED. 218, 219 (2020).

76. Occupational Employment Statistics, NAICS 6222000- Psychiatric and Substance Abuse Hospitals, U.S. Bureau of Labor Statistics (May 2019), www.bls.gov/oes/current/naics4_622200.htm (reporting employment data at this facility consists of 3,310 psychiatrists-largest group of medical doctors employed at this facility, 14,360 substance abuse, behavioral disorder and mental health counselors, and 10,160 mental health and substance abuse social workers); Occupational Employment Statistics, NAICS 623200- Residential Intellectual and Developmental Disability, Mental Health, and Substance Abuse Facilities, U.S. Bureau of Labor Statistics (May 2019), www.bls.gov/oes/current/naics4_623200.htm (reporting that a total of 580 psychiatrists-largest group of medical doctors employed at this facility, 34,310 substance abuse, behavioral disorder, and mental health counselors, and mental health and substance abuse social workers 12,470).

77. Seligman*, supra* note 15.

78. NCD 210.8, *supra* note 70.

79. *Id*.

substance abuse treatment centers. Currently, a MI intervention is absent from the NCDs that set the requirements for coverage for treatment at inpatient and outpatient facilities.[80] The addition of MI interventions into the coverage criteria would require therapists to "select appropriate treatment goals and methods *based on* the patient's interest in and willingness to change the behavior."[81] Requiring the therapist to elicit the patient's willingness to change is critical in understanding the patient's likelihood of adherence to treatment, as the patient's motivation has been identified as the critical predictor for successful completion and adherence to substance abuse treatment.[82] The risk associated with this inclusion is that patients choose not to proceed with therapy.

IV. PROPOSED TRANSPARENCY RULES THREATEN THERAPEUTIC ALLIANCE

In Fall 2019 the Departments of the Treasury, Labor, and Health and Human Services, (collectively, the Departments) proposed a rule that will require insurers to disclose the maximum amount they would pay for a covered item or service furnished by an out-of-network provider.[83] Specifically, the insurer will be required to inform beneficiaries the amount of any remainder of any service that is not fully reimbursed by the insurer.[84] The Departments argue that this rule will provide transparency in coverage expenses and will promote beneficiaries' ability to shop for items and services.[85] This rule change will have a considerable effect on mental health treatment as behavioral clinicians have the lowest network participation rates of all specialties, and have a disproportionate amount of out-of-network patients.[86] A solution for this rule change is not offered, as it

80. *See* NCD 130.1, Inpatient Hospital Stays for Treatment of Alcoholism (no requirement that the patient be ready to quit alcohol in order for the service to be covered by CMS); *and* NCD 130.2, Outpatient Hospital Services for Treatment of Alcoholism, *and* NCD 130.5, Treatment of Alcoholism and Drug Abuse in a Freestanding Clinic.

81. *See* NCD 210.0 *supra* note 70 (stating the provider and client must agree to select the appropriate treatment goals); *see also* SUBSTANCE ABUSE & MENTAL HEALTH SERVICES ADMIN., *supra* note 57.

82. Carlo DiClemente, *Motivation for Change and Alcoholism Treatment*, 23 ALCOHOL RES. & HEALTH 86, 87 (1999).

83. Transparency in Coverage, 84 Fed. Reg. 65464, 73 (proposed November 27, 2019) (to be codified 26 C.F.R. pt. 54, 29 C.F.R. pt. 2590, 45 C.F.R. pts.147 and 158) [hereinafter Transparency in Coverage, 84 Fed. Reg.].

84. Transparency in Coverage, 84 Fed. Reg. at 65474.

85. Transparency in Coverage, 84 Fed. Reg. at 65464.

86. Wendy Yi Xu, et al., *Cost-Sharing Disparities for Out-of-Network Care for Adults with Behavioral Health Conditions*, 2 JAMA NETWORK OPEN 1, 9 (2019); *See also* NAMI, OUT-OF-NETWORK, OUT-OF-POCKET, OUT-OF-OPTIONS: THE UNFULFILLED PROMISE OF PARITY 2 (2016) (reporting that private and public insurance beneficiaries "had more difficulty locating in-network providers and facilities for mental health care compared to general or specialty medical care.")

should not go into effect because its potential benefit is unlikely, while its harms are certain and considerable.[87]

There are numerous criticisms associated with this rule. First, the practice the rule calls for is known as "balanced billing," and, as of 2019, was illegal in twenty-eight states.[88] Second, this rule will increase the administrative burden on providers in sharing information with insurers.[89] CMS estimates the cost of compliance with this new rule to range from $231.8 million to $298.4 million per year, however the U.S. Chamber of Commerce notes that this estimate does not consider the initial providers will face in understanding their compliance obligations.[90] Further, this estimate is impractical as psychologists do not even feel comfortable discussing how many sessions therapy will last until the third session.[91] Researchers explained that the delay of this information is due to learning how the individual client's presenting problem, how that client responds to therapy, and how it may take weeks after the first session before the payer confirms payment.[92] Ultimately, if providers find a way around this delay, the cost of compliance to this rule will only further drive providers to sell their practices.[93]

Third, this rule will lead to decreases in the effectiveness of psychotherapy. The intended effect of this rule is to provide beneficiaries with estimates that aids them in shopping for items and services.[94] From these estimates beneficiaries will be aware of their out-of-pocket costs after the insurer's contribution.[95] This will have a negative effect on the success of therapy as previous research has shown that patients "whose choice of

87. *See* Comments, U.S. Chamber of Commerce, Comments to CMS on Transparency in Coverage Regulation (Jan. 29, 2020), www.uschamber.com/comment/comments-cms-transparency-coverage-regulation (arguing that the benefit of informing consumers will not be achieved as consumers will not know what billing codes are appropriate).

88. Transparency in Coverage, 84 Fed. Reg. at 65474; Jack Hoadley, et al., *States Are Taking New Steps to Protect Consumers from Balance Billing, But Federal Action Is Necessary to Fill Gaps*, COMMONWEALTH FUND (July 21, 2019), www.commonwealthfund.org/blog/2019/states-are-taking-new-steps-protect-consumers-balance-billing-federal-action-necessary (Balanced billing often occurs when patients "are treated by an out-of-network provider, either in an emergency or when they elect care form a network provider in a network facility but are treated by an out-of-network provider.").

89. Letter from American Hospital Association to Ms. Verma, Administrator for Centers for Medicare & Medicaid Services, regarding Transparency in Coverage, page 2 (Jan. 28, 2020) www.aha.org/system/files/media/file/ 2020/ 01/aha-comment-on-transparency-in-coverage-proposed-rule-1-29-2020.pdf.

90. *See* e.g. U.S. Chamber of Commerce, *supra* note 87.

91. Andrew M. Pomerantz, *Increasingly Informed Consent: Discussing Distinct Aspects of Psychotherapy at Different Points in* Time, 15 ETHICS & BEHAVIOR 351, 355 —56 (2005).

92. *Id*. at 56.

93. Gondi & Song, *supra* note 29.

94. Transparency in Coverage, 84 Fed. Reg. at 65464.

95. Transparency in Coverage, 84 Fed. Reg. at 65474.

therapist or duration of care was limited by their insurance coverage did worse."[96] Additionally, the negative effects of insurance determining the appropriate amount of care can be further exacerbated if providers' reveal to their opinions of third-party payors to the client.[97] Specifically, the client's understanding of the provider's opinion of third-party payors was found to negatively impact the therapeutic alliance and other common factors.[98]

V. CONCLUSION

On their face, PE firms' strategies and the proposed financial transparency rules do not appear to have negative ramifications on the effectiveness of mental health care. For example, PE firms are only purchasing service providers to build national and regional networks,[99] while the proposed price transparency rules aim to inform healthcare consumers.[100] Unfortunately, both of these realities have an unintended or subliminal negative effect on the therapeutic alliance, and thus, the efficacy of psychotherapy. Together, these realties suggest that the therapeutic alliance is highly reactive and can be cultivated under the appropriate level of regulatory oversight. For instance, the complete lack of regulatory oversight will fail to incentivize evidence-based treatment models. Conversely, regulations like the proposed price transparency rule changes can damage the therapeutic alliance and further incentivize practitioners to sell their firms.

PE firms and the proposed rule changes are only two examples of the therapeutic alliances' highly reactive nature. Regulators, legislatures, and health care providers need to be mindful of this reactive nature and take steps mitigate the effects of other threats to the efficacy of psychotherapy. The proposed MI NCDs must be implemented to ensure the efficacy of psychotherapy against PE firms, however they only incentivize evidence-based interventions for substance abuse. Similarly strategic NCDs need to be developed and implemented to ensure evidence phased treatment for all mental health disorders. Failure to develop and implement such coverage decisions will leave the effectiveness of psychotherapy exposed and,

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96. Seligman, *supra* note 15.

97. Andrew M. Pomerantz, *What if Prospective Clients Knew How Much Managed Care Impacts Psychologists' Practice and Ethics? An Exploratory Study*, 10 ETHICS & BEHAVIOR 159, 165 (2000); *see also* Richard M. Jung, et al., *The Impact of Specific Psychotherapist Beliefs Regarding Managed Care on Prospective Psychotherapy Clients*, 31 J. CONTEMPORARY PSYCHOTHERAPY 151, 155-57 (Table 1) (2001).

98. Pomerantz, *supra* note, 97.

99. Brown, et al., *supra* note 25; MARKET INSIDER, *supra* note 33.

100. Transparency in Coverage, 84 Fed. Reg. at 65464.

conceivably, increase terrible impact of chronic conditions on our nation's health.[101]

101. Chapman, et al., *supra* note 5, (arguing the link between chronic disease and mental health); *see* e.g., ROSS & BEDROUSSIAN, *supra* note 2, (reporting the socio-economic impact of chronic disease).

Everlywell or Everlybad? The Pitfalls of Direct-to-Consumer Food Sensitivity Testing

Catherine Feorene

INTRODUCTION

Food allergies are costly, potentially life threatening health conditions that have a significant impact on patients' lives.[1] Fortunately, physicians are able to order blood tests to accurately diagnose food allergies.[2] Individuals also have access to direct-to-consumer tests, which allegedly can be used to test susceptibility to intolerances.[3] Recent data suggests that around 10.8% of Americans suffer from some food allergy or intolerance, whereas nearly nineteen percent believe they have some food allergy or intolerance.[4] That equates to thirty-two million actually suffering from food allergies, versus fifty-seven million believing they do.[5] The public should be aware of how food allergies affect an individual, how at home testing kits work, and the pitfalls of direct-to-consumer testing.[6]

Celiac disease ("Celiac") is an autoimmune disorder that affects the small intestine.[7] When an individual with celiac eats gluten, their body attacks the villi of the small intestine leading them to flatten.[8] This results in malabsorption and serious digestive issues, along with other secondary symptoms.[9] Celiac affects around three million Americans, or one percent

1. Ruchi S. Gupta, et al., *Prevalence and Severity of Food Allergies Among US Adults*, JAMA NETWORK (Jan. 4, 2019).

2. *Testing for Food Allergies*, WEBMD, https://www.webmd.com/allergies/food-allergy-test (Last accessed Apr. 16, 2020).

3. *Learn How Your Body Responds to 96 Different Foods*, EVERLYWELL, https://www.everlywell.com/products/food-sensitivity/ (Last accessed Apr. 16, 2020) [hereinafter EVERLYWELL].

4. Gupta, *supra* note 1.

5. *Facts and Statistics*, FOOD ALLERGY RESEARCH & EDUCATION, https://www.foodallergy.org/resources/facts-and-statistics (Last accessed Apr. 16, 2020).

6. *Food Sensitivity Tests: The Pitfalls of Home Testing Kits*, NATIONWIDE CHILDREN'S (Jul. 19, 2018) https://www.nationwidechildrens.org/family-resources-education/700childrens/2018/07/at-home-allergy-tests; *infra* note 19–25.

7. *What is Celiac Disease?,* CELIAC DISEASE FOUND., https://celiac.org/about-celiac-disease/what-is-celiac-disease/ (Last accessed Apr. 16, 2020).

8. *Id.*

9. *Id.*

of the population.[10] Gluten sensitivity, a less severe form of Celiac, affects around eighteen million individuals, or six percent of the population.[11] Despite the fact that only roughly seven percent of the population needing to follow a gluten-free diet, thirty percent of shoppers choose gluten-free options.[12] Many Americans believe they are gluten sensitive and should avoid foods made with gluten, despite no medical necessity justifying a limited diet.[13] A gluten-free diet is not necessarily beneficial for individuals that do not suffer from some sort of gluten intolerance.[14] Whole grains are a vital part of any diet, and thus leaves individuals unnecessarily following a gluten-free diet lacking certain nutrients.[15] Further, many gluten-free counterparts to traditional whole grains are lower in nutrients and higher in sugars, sodium, and fat.[16] This is because gluten protein substitutes are often less healthy, or companies will add sugars and fats to make the product more palatable to consumers.[17] For example, a gluten free bagel compared to its traditional counterpart contains seven more grams of fat.[18]

Despite these issues and increased attention to the matter, it takes the average person around four years for a celiac diagnosis, increasing the risk of developing other serious disorders.[19] For individuals that suffer from these allergies, it is very important for accurate and timely diagnosis.[20] Some companies, such as EverlyWell and TestMyAllergy, have jumped at this rising concern and created theoretically easier and cheaper options than the tests a physician orders.[21] However, due to a lack of regulation and

10. THE UNIVERSITY OF CHICAGO MEDICINE, CELIAC DISEASE CENTER, FACT SHEET, CELIAC DISEASE FACTS AND FIGURES [hereinafter CELIAC FACT SHEET].

11. Julie Upton, *Think You're Sensitive to Gluten? Think Again*, U.S.NEWS (Jun. 11, 2015) https://health.usnews.com/health-news/blogs/eat-run/2015/06/11/think-youre-sensitive-to-gluten-think-again.

12. *Id.*

13. *Id.*

14. *Id.*

15. Mayo Clinic Staff, *Whole Grains: Hearty Options for a Healthy Diet*, MAYOCLINIC, https://www.mayoclinic.org/healthy-lifestyle/nutrition-and-healthy-eating/in-depth/whole-grains/art-20047826 (Last accessed Apr. 16, 2020).

16. Upton, *supra* note 11.

17. *Six Truths About a Gluten Free Diet*, CONSUMER REPORTS (Nov. 2014), https://www.consumerreports.org/cro/magazine/2015/01/will-a-gluten-free-diet-really-make-you-healthier/index.htm (explaining that a gluten-free bagel as compared to its traditional counterpart contains seven more grams of fat).

18. *Id.*

19. CELIAC FACT SHEET, *supra* note 10.

20. *Id* (explaining that when celiac disease is left undiagnosed it can lead to the development of other serious autoimmune disorders and in rare cases cancer).

21. Jill Weisenbeger, *The Best Food Sensitivity Test 2019*, INNERBODY (Oct. 21, 2019) https://www.innerbody.com/home-health-tests/food-sensitivity-tests; EVERLYWELL *supra* note 3; *Home-to-Lab Tests Made Easy*, TESTMYALLERGY, https://www.testmyallergy.com (accessed Mar. 23, 2020).

sound scientific testing there is concern around these types of tests.[22] The tests physicians order test different markers and blood levels; however, these companies still argue their tests can be used to check sensitivities for certain foods.[23] Physicians have long recognized the pitfalls of the at home tests and raise concerns that these tests are only causing nutritional deficiencies and consumer confusion in susceptible individuals.[24] The public should be aware of how food allergies affect an individual, how at home testing kits work, and the pitfalls of direct-to-consumer testing.[25]

HISTORY

Food allergies have not always been closely regulated, nor have they been a significant part of the United States medical profession.[26] Comparatively, today an increasing number of people have become aware of their food allergies or intolerances, and as a result, are more concerned with testing, monitoring and eating "clean."[27] Prior to 2013, there was no federal regulatory standard for the food industry to use in labeling products as gluten-free.[28] This left consumers with gluten related food allergies unsure of which foods were gluten-free, a risk that could negatively affect their health.[29] In 2013, the Food and Drug Administration ("FDA") implemented a rule specifying what foods may be labeled as gluten-free.[30] However, manufacturers are not required to have this type of labeling if their food does not contain gluten at any point during the manufacturing process.[31] The primary requirement to bear this label is that the food must

22. *The Myth of IGG Food Panel Testing*, AAAAI, https://www.aaaai.org/conditions-and-treatments/library/allergy-library/IgG-food-test (accessed Feb. 17, 2020) (explaining that the studies used to support this type of test is out of date, in non-reputable journals and do not use the correct the IgG).

23. *Food Allergy Testing*, AM. COLL. OF ALLERGY, ASTHMA & IMMUNOLOGY (Mar. 18, 2019) https://acaai.org/allergies/types/food-allergies/testing.

24. Allison Bond, *A 'Shark Tank' – Funded Test for Food Sensitivity is Medically Dubious, Experts Say*, STAT (Jan. 23, 2018) https://www.statnews.com/2018/01/23/everlywell-food-sensitivity-test/ ("Yet physician groups have for years advised against using immunoglobin G tests to evaluate for so-called food sensitivities or intolerances. And allergy experts told STAT that the test is useless at best and could even cause harm if it leads customers to unnecessarily cut nutritious foods from their diet.").

25. *Id.*

26. Hugh A. Sampson, *Food Allergy, Past, Present & Future*, 65 ALLERGOLOGY INT'L 363–69 (2016).

27. *Id.*

28. *Gluten and Food Labeling*, FDA (Jul. 16, 2018) https://www.fda.gov/food/nutrition-education-resources-materials/gluten-and-food-labeling.

29. *Id.*

30. 21 CFR §101.91; FDA, *Food Labeling; Gluten-Free Labeling of Foods*, 78 FED. REGISTER 47154 (Aug. 5, 2013)

31. *Gluten and Food Labeling, supra* note 28 (This includes both coming in contact

contain less than twenty parts per million (ppm) of the gluten protein.[32] This is how the FDA tests whether a food is gluten-free and whether it may bear the label.[33] Other countries, such as Canada, use this same regulation, since most Celiac, allergic or gluten-sensitive individuals can tolerate this level of gluten.[34] Manufacturers were given until 2014 to comply, and now any label not in compliance is subject to action by the FDA.[35]

Food allergies have been around for centuries,[36] but following this change in FDA regulation, allergy diagnoses and intolerances have increased dramatically.[37] Correspondingly, there has been greater community concern regarding diagnosis and elimination diets.[38] As the number of people who are properly diagnosed with allergies and intolerances has risen, so too has the number of people who falsely believe they have a food allergy.[39]

TESTING METHODS

Increasingly, people are concerned with whether they, or a member of their family, have a food intolerance.[40] Prior to the recent direct-to-consumer tests, only doctors could test for these allergies and intolerances.[41] In the past five years, especially in the US, individuals have exhibited an increased desire to discover their own intolerances.[42] Besides seeking physician assistance , there are two primary ways individuals are testing for their own intolerances. The first is at home blood tests which test Ig-gA.[43] These tests have proven to be inaccurate and ineffective, so much so that some studies have shown that these tests merely register what foods an individual has eaten the day they took the test.[44] The second method of

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with gluten on the machines, and processes that are able to eliminate the protein through manufacturing.).

32. *Id.*
33. *Id.*
34. *Id.*
35. *Id.*
36. *Id.*
37. Sampson, *supra* note 26.
38. Bryan Walsh, *Food Sensitivities and Intolerances: How and Why to do an Elimination Diet,* PRECISION NUTRITION https://www.precisionnutrition.com/elimination-diet (accessed Feb. 20, 2020).
39. Gupta, *supra* note 1.
40. Alexandra Santos, *Why the World is Becoming More Allergic to Food,* BBC NEWS (Sept. 13, 2019) https://www.bbc.com/news/health-46302780.
41. Victoria Groce, *How Food Allergies are Diagnosed,* VERYWELLHEALTH (Sept. 10, 2019) https://www.verywellhealth.com/five-tools-for-diagnosing-food-intolerances-1324070.
42. Sampson, *supra* note 26.
43. EVERLYWELL *supra* note 3.
44. Barbara Gordon, *Are Food Sensitivity Tests Accurate?*, EAT RIGHT (Aug. 20, 2019)

testing is at-home genetic tests.[45] These tests, while not able to diagnose an allergy in an individual, will show propensity towards a certain allergy.[46] Armed with this information, individuals can follow up with a doctor for further testing and diagnosis.[47]

Given the high level of misdiagnosis due to the inaccuracy of these at-home methods, more issues than solutions are being created. Thus, the US has many people down playing the severity of food allergies, leaving harmful effects for those that actually suffer.[48] If a manufacturer, restaurant, or private cook starts to downplay the severities of a food allergy because of the large number of individuals falsely claiming to be allergic to a food, those that actually suffer from a food allergy can have serious health issues.[49] This could include: anaphylactic shock, severe gastro-intestinal distress and potential trips to the ER.[50] The seriousness of downplaying reactions should not be ignored, as individuals should feel confident in the food industries claims of safety.[51]

There is currently a lack of federal regulation for these direct-to-consumer tests.[52] No Federal Drug Administration ("FDA"), Federal Trade Commission ("FTC"), Clinic Laboratory Improvement Amendments ("CLIA") or state regulation exist to protect individuals looking for a proper food allergy or sensitivity diagnosis from direct-to-consumer testing.[53] None of these organizations are statutorily required to get involved in this realm, arguably though, the FTC should get involved when there are false claims being made regarding individual's health.[54] Especially since, as established before, these tests lead to nutritional deficiencies and consumer

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https://www.eatright.org/health/allergies-and-intolerances/food-intolerances-and-sensitivities/are-food-sensitivity-tests-accurate.

45. *See generally* Jin Li et al., *Are Generic Tests Informative in Predicting Food Allergy*?, 16 CURRENT OPINION ALLERGY CLINICAL IMMUNOLOGY 257 (2016).

46. *Id.*

47. *Id.*

48. Heidi Hatch, *Family Shares Tragic Story of Child Lost as Food Allergies Skyrocket*, KUTV (Nov. 9, 2017) https://kutv.com/news/local/severe-allergic-reactions-to-food-skyrocket-researchers-dont-know-why.

49. *Id.*

50. *Id.*

51. *Id.*

52. *Direct-to-Consumer Tests,* FDA (Dec. 20, 2019), https://www.fda.gov/medical-devices/vitro-diagnostics/direct-consumer-tests; Lesley McClurg, *Do DIY Medical Tests Promise More Than They can Deliver?*, NPR (May 28, 2018), https://www.npr.org/sections/health-shots/2018/05/28/614125270/do-diy-medical-tests-promise-more-than-they-can-deliver.

53. McClurg *supra* note 52; Joanna Fantozzi, *The Miracle Food Intolerance Test You've Been Seeing all Over Instagram is Unreliable, According to Many Doctors*, INSIDER (July 12, 2017), https://www.insider.com/pinnertest-food-test-science-2017-7.

54. I*nfra* notes 104–06 and corresponding text.

confusion.[55] The FTC could restrict some of these false claims or otherwise mandate that manufacturers of these products clarify that there is no scientific proof behind their products.

Direct-to-consumer food sensitivity tests arrive in a box to the consumer's house, where the consumer pricks their finger and sends back their blood sample.[56] The companies then test for up to ninety-six common food sensitivities.[57] These companies test for an immune protein that is activated upon eating certain foods, immunoglobin G (igG).[58] Most of these companies market that taking the test and following an elimination diet can help alleviate various symptoms from diarrhea to eczema.[59] However, physicians and allergy experts are warning individuals not to use these tests.[60] Most experts cite them as completely useless, and in some cases, harmful.[61] These companies maintain that these tests are useful and aid in helping individuals' health,[62] but physicians raise concerns that people who test positive for sensitivities may cause them to unnecessarily cut perfectly healthy, nutritious food from their diets.[63]

Food sensitivity is a wide term used to affect a variety of symptoms. However, none of these symptoms involve an immune response.[64] Food allergies however, do have an immune response, followed by more serious symptoms.[65] Not to downplay the seriousness of food sensitivities, merely to highlight that there is no immunoglobin reaction to test for via a blood prick. Immunoglobin G comes from the body's normal response to exposure to foods.[66] Thus, these tests do not indicate a sensitivity, they merely point out what foods a person ate before drawing their blood.[67]

The European Academy of Allergy and Clinical Immunology, the American Academy of Allergy, Asthma & Immunology, and the Canadian

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55. Bond, *supra* note 24.

56. EVERLYWELL, *supra* note 3.

57. *Id.*

58. Steven O. Stapel et al., *Testing for IgG4 Against Foods is Not Recommended as a Diagnostic Tool: EAACI Task Force Report*, 63 ALLERGY 793 (Jun. 28, 2008).

59. EVERLYWELL, *supra* note 3.

60. Bond, *supra* note 24.

61. *Id* (explaining that experts from allergists to physicians recognize the inaccuracy of these tests and explain them as useless).

62. EVERLYWELL, *supra* note 3.

63. Bond, *supra* note 24.

64. *Food Allergy and Intolerance*, BETTERHEALTH CHANNEL, https://www.betterhealth.vic.gov.au/health/conditionsandtreatments/food-allergy-and-intolerance, (accessed Mar. 13, 2020).

65. *Id.*

66. Jacek Gocki & Zbigniew Bartuzi, *Role of Immunoglobin G Antibodies in Diagnosis of Food Allergy*, 33 ADVANCES IN DERMATOLOGY AND ALLERGOLOGY 253–56 (Aug. 16, 2016).

67. AAAAI, *supra* note 22; Bond, *supra* note 24.

Society of Allergy and Clinical Immunology, have all released statements noting the issues surrounding the use of these tests.[68] The only doctor-approved at-home test to establish a food sensitivity is to follow an elimination diet, i.e. eliminating foods and slowly adding them back in to see what bothers you.[69] Given the restrictive nature of these diets, it is easy to see why individuals are so drawn to the idea of a quick fix – these direct-to-consumer blood tests.[70] Yet, working with a physician is the only proven, safe way to establish the proper diagnoses of a food sensitivity.[71]

With food allergies there are blood tests a doctor can perform in order to test for certain antibodies.[72] Specifically with celiac, the body produces certain antibodies since it views gluten as a threat.[73] There are multiple tests a doctor may order to test for celiac, however they usually will start with a tTg-IgA test as this is the most sensitive and accurate test.[74]

Additionally, there are genetic tests that may indicate the odds of developing Celiac, or other certain food allergies.[75] However, having the gene only increases the risk of developing the disorder by two percent.[76] First-degree family members of those living with Celiac should be regularly screened due to increased likelihoods of also developing the disease.[77]

The only way to accurately be diagnosed with a food sensitivity or allergy, is to go to a physician and get official testing ordered.[78] However, this is costly,[79] which is why many individuals turn to the inaccurate, yet comparatively inexpensive, direct-to-consumer food sensitivity kits.[80]

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68. AAAI Support of the EEACI Position Paper on IgG4, Position Statement, AAAI, May 2010.

69. McClurg, *supra* note 52.

70. *Id.*

71. *Id.*

72. WEBMD, *supra* note 2.

73. *Testing*, CELIAC DISEASE FOUNDATION, https://celiac.org/about-celiac-disease/screening-and-diagnosis/screening/ (visited Mar. 13, 2020).

74. *Id*; AAAAI, *Don't Perform Unproven Diagnostic Tests, Such as Immunoglobulin G (IgG) Testing or an Indiscriminate Battery of Immunoglobulin E (IgE) tests, in the Evaluation of Allergy*, CHOOSING WISELY (Apr. 4, 2012) http://www.choosingwisely.org/clinician-lists/american-academy-allergy-asthma-immunology-diagnostic-tests-for-allergy-evaluation/

75. Li, *supra* note 45.

76. *Celiacs Disease – Genetics Home Reference*, U.S. NAT'L LIBRARY MED., https://ghr.nlm.nih.gov/condition/celiac-disease (accessed Mar. 13, 2020).

77. *Id.*

78. WEBMD, *supra* note 2.

79. *Allergy Tests*, AM. ACAD. OF ALLERGY, ASTHMA & IMMUNOLOGY (July 2012) https://www.choosingwisely.org/patient-resources/allergy-tests/ (citing that a blood test for food allergies may run from hundreds of dollars up to the thousands).

80. EVERLYWELL, *supra* note 3 (showing these tests will still run an individual about $159, however generally are not covered by insurance but may be covered by an HSA or FSA).

Looking long term though, this has a negative effect on the health of the population. Individuals are cutting foods out of their diet that are in turn impacting their nutrition.[81] Studies have shown that following a gluten-free diet, without necessity, actually leads to health concerns due to lack of proper nutrition.[82] Over time this has more costly and serious concerns, than going the proper route in the first place.[83]

This is all concerning. But none of this falls within the realm of the Food and Drug Administration, Federal Trade Commission, the federal Clinical Laboratory Improvement Amendments Act or other state administration.[84] As such, there is a profound lack of regulation surrounding these direct-to-consumer tests, where the FTC could get involved and provide some guidance and regulation.[85]

REGULATION

The FDA regulates certain, but not all, direct-to-consumer tests.[86] In general the FDA will not review direct-to-consumer tests regarding non-medical, overall wellness, or low risk medical issue.[87] Instead, the FDA reviews tests for moderate to high-risk medical purposes to determine validity.[88] In reviewing tests, the FDA looks at whether the test can accurately and reliably measure what it claims, whether the measurement is predictive of health, and what a company says about their tests and how well it works.[89] Additionally, the FDA looks at whether the test offers accurate descriptive information.[90] Given this, the FDA is not required to monitor any direct-to-consumer food intolerance testing.[91] Subsequently, the FDA does not currently regulate any of these tests. In fact, they currently only regulate genetic testing kits.[92]

CLIA governs diagnostic testing,[93] which requires clinical laboratories to

81. Scott Gavura, *IgG Food Intolerance Tests Continue to Mislead Consumers into Unnecessary Dietary Restrictions*, SCIENCE-BASED MEDICINE (Nov. 15, 2018) https://sciencebasedmedicine.org/igg-food-intolerance-tests-continue-to-mislead-consumers-into-unnecessary-dietary-restrictions/.

82. Bond, *supra* note 24.

83. *Id.*

84. McClurg *supra* note 52; Fantozzi, *supra* note 52.

85. *Infra* part Regulation.

86. *Direct-to-Consumer Tests*, FDA (Dec. 20, 2019) https://www.fda.gov/medical-devices/vitro-diagnostics/direct-consumer-tests.

87. *Id.*

88. *Id.*

89. *Id.*

90. *Id.*

91. *Id.*

92. *Id.*

93. Michael H. Cohen, *How are Home Health Kits Regulated Under FDA and State*

be certified by the state as well as the Center for Medicare and Medicaid Services (CMS).[94] All of this must happen before the labs accept any human samples for testing.[95] Three federal agencies are involved in CLIA.[96] The FDA, CMS and the Centers for Disease Control and Prevention (CDC) all work with CLIA for its certification process.[97] FDA categorizes tests, reviews requests and develops the rules and guidance for categorization.[98] CMS issues lab certificates, collect fees, conducts inspections and enforces compliance.[99] The CDC develops technical standards.[100] States may impose certain licensing requirements and rules governing direct-to-consumer tests.[101] Everlywell, and other direct-to-consumer testing kits assure that the laboratories they work with are CLIA-certified.[102] However, this does not mean that the tests themselves are certified. This merely establishes that the testing centers are safe, and accurate to what they are being asked to test for, the IG-gA.[103]

The FTC works to protect consumers and promote competition.[104] The FTC stops unfair, deceptive, or fraudulent practice in the marketplace by conducting investigations, suing companies and people that violate the law.[105] However, in this realm, the FTC currently only regulates genetic direct-to-consumer testing.[106] Arguably, the FTC should be more involved in the realm of food allergy and intolerance testing. Especially as the evidence shows, the tests themselves serve no scientific purpose and merely lead to consumer confusion.[107] Further, physicians have noted that in the long run it ends up costing consumers more money, since they spend up to

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Law, COHEN HEALTHCARE LAW GROUP (Jul. 15, 2015) https://cohenhealthcarelaw.com/2015/07/how-are-home-health-kits-regulated-under-fda-and-state-law/.

94. *Id.*
95. *Id.*
96. *Id.*
97. *Id.*
98. *Id.*
99. *Id.*
100. *Id.*
101. *Id.*
102. EVERLYWELL, *supra* note 3.
103. *Clinical Laboratory Improvement Amendments (CLIA),* CMS.GOV, https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA (accessed Mar. 13, 2020).
104. *A Brief Overview of the Federal Trade Commission's Investigative, Law Enforcement, and Rulemaking Authority*, FED. TRADE COMM'N (Oct. 2019) https://www.ftc.gov/about-ftc/what-we-do/enforcement-authority.
105. *Id.*
106. *Id* (The FTC cite lists all of their regulations, noticeably the direct-to-consumer tests used for food allergy tests are missing.).
107. Bond, *supra* note 24.

$250 on the direct-to-consumer test, and then have to go to the doctors and spend even more on a test that shows proper data.[108]

CONCLUSION

As food allergies and intolerances become more prevalent, the importance and desire for easy and effective testing is growing. Consequently, the concept of direct-to-consumer testing is theoretically wise and beneficial for the population. However, the technology used today is not accurate and not regulated. This leads to consumer confusion and potential health issues. Even though these tests could be helpful, the FTC should be more involved in regulation in order to reduce public confusion and increase consumer awareness. The public should be aware of how food allergies affect an individual, how at home testing kits work, and the pitfalls of direct-to-consumer testing.

108. *Id.*

Mobile Health Apps and Wearable Technology: Addressing Emerging Risks Without Derailing Chronic Care Management

Alayna M. Frauhiger

INTRODUCTION

Today technology is transforming the healthcare industry so that it can meet the challenges of the 21st century.[1] One important challenge ahead is the rate of chronic diseases which are "present in half the adult population and responsible for 86% of United States (US) healthcare costs and seventy percent of deaths."[2] As a nation, the US has "performed poorly in managing chronic disease," but new "opportunities exist as a result of recent advances in home-based wireless devices, [mobile applications (apps)] and wearables[3], enabling health delivery systems to monitor disease metrics in near real time."[4] Utilizing technology can help patients engage in the management of their disease, and has helped healthcare organizations meet the growing demands and deliver better patient care by operating more efficiently.[5] As the world population continues to age, mobile health apps and wearable technology will offer new and better ways to identify diseases and improve patient care for chronic diseases.[6]

The increased prevalence of chronic diseases in high-income countries is

1. Richard V. Milani et. al., *The Role of Technology in Chronic Disease Care*, 58 PROGRESS IN CARDIOVASCULAR DISEASES 579-83 (2016); Kylie Watson, *Predictive Analytics in Health Care: Emerging Value and Risks*, DELOITTE INSIGHTS (July 19, 2019), www2.deloitte.com/us/en/insights/topics/analytics/predictive-analytics-health-care-value-risks.html.

2. *Id* at 579.

3. "Wearable devices interface with smartphones and personal computer software to collect a wide variety of data. Wearable devices include dedicated health monitors, fitness bands, and smartwatches." Liezel Cilliers, *Wearable Devices in Healthcare: Privacy and Information Security Issues*, HEALTH INFO. MGMT. J. 1-7 (May 2019) (citing Farnell et. al., *The effect of a wearable physical activity monitor (Fitbit One) on physical activity behavior in women: a pilot study*, 12 J. OF HUM. SPORT & EXERCISE 1230-1237 (2017)).

4. *Id.*

5. Bernard Marr, *The 9 Biggest Technology Trends That Will Transform Medicine and Healthcare in 2020*, FORBES (Nov. 1, 2019), www.forbes.com/sites/bernardmarr/2019/11/01/the-9-biggest-technology-trends-that-will-transform-medicine-and-healthcare-in-2020/#772e6e7072cd.

6. *Id*.

attributable to the convergence of an aging population with the persistence of several risk factors, including physical inactivity, use of tobacco and alcohol, high blood pressure and cholesterol, stress, depression, and overweight and obesity.[7] However, many of these risk factors can be mitigated by health interventions, education, and communication tools used to support a healthy lifestyle and behavior change.[8] For instance, in the past ten years, there has been an increase in the "use of digital technologies to support these changes" because they enable users to monitor their health status and activity levels, while encouraging individuals to make good lifestyle choices.[9] This is why the incorporation of communication tools[10] and mobile health apps into chronic disease management is expected to grow in practice and importance as more people communicate online.[11] Although many anticipate an increase use of technology in health care, the "collection of personal data in unprecedented volumes does raise privacy and security concerns for the user."[12]

As our society becomes increasingly connected through wireless devices and accustomed to sharing private data such as health metrics with others online, new challenges and opportunities will arise in utilizing this information in a safe, dynamic, and timely manner.[13] Since wearable devices must collect data to be useful, it is the centralization of data which presents a serious risk in terms of security of the data.[14] After an app or wearable device collects health data, these values are usually "transferred wirelessly to a database where these data can be analyzed using statistics."[15] "Information can then be shared via the Internet with healthcare providers to make informed decisions about the user's healthcare."[16] Given this increased amount of data, often stored in servers or otherwise accessible via the internet, there is the persistent threat of hacking from individuals with

7. Eugenio Santoro et al., *Social Media and Mobile Applications in Chronic Disease Prevention and Management*, 6 FRONTIERS PSYCH., May 2015, at 1, 1.

8. *Id.*

9. *Id.* (citing Gianluca Castelnuovo et al., *TECNOB: Study Design of a Randomized Controlled Trial of Multidisciplinary Telecare Intervention for Obese Patients with Type-2 Diabetes*, 10 BMC PUB. HEALTH., Apr. 2010, at 1, 1, https://doi.org/10.1186/1471-2458-10-204); Cilliers, *supra* note 3, at 1.

10. *See Session 8: Communication Tools*, Santa Clara University, www.scu.edu/mobi/business-courses/starting-a-business/session-8-communication-tools/ (last visited Feb. 15, 2020). There are a wide variety of communication tools available including mail, email, smartphones, video, social networking and web conferencing tools, *id.*

11. SANTORO ET AL., *supra* note 7, at 2.

12. Cilliers, *supra* note 3, at 1.

13. SANTORO ET AL., *supra* note 7, at 2.

14. Watson, *supra* note 1, at 3.; Cilliers, *supra* note 3, at 2.

15. Cilliers, *supra* note 3, at 2.

16. *Id.*

malicious intent.[17] Finally, given the role the technology plays in a patient's daily interactions and the overall outcome of their care, it is critical to protect this data since "health information is regarded as the most confidential of all types of personal information."[18]

In response to the increasing use of technology in healthcare, Congress introduced the Stop Marketing and Revealing the Wearables and Trackers Consumer Health Data Act, known as the Smartwatch Data Act (the Smartwatch Data Act or the Act).[19] The Act was introduced by Democratic Senator Jacky Rosen and Republican Senator Bill Cassidy on November 18th, 2019.[20] Their hope in introducing the bill was to ensure health data collected through fitness trackers, smartwatches, and health apps, would not be sold without consumer consent.[21] Essentially, the Act is designed to fill in a gap left by the privacy rule of the Health Insurance Portability and Accountability Act (HIPAA).[22] While the HIPAA Privacy Rule prohibits the disclosure of protected health information (PHI) in certain instances, there is no prohibition on use, sharing, or selling health data that is collected, stored, and transmitted by fitness trackers, wearable devices, and health apps.[23]

To combat the ongoing, and rapidly growing privacy and security consumer risks, Congress should pass the Act. Although the Act does not give the patient total control over their information, the bill does address a current "gap in privacy" and is a comprehensive start to increasing privacy protection which congressional legislators should pass.[24] Part I of this article addresses the regulatory challenges of incorporating mobile health devices or apps in the treatment of chronic illnesses. Part II analyzes how the Act creates greater transparency for consumer data and can positively impact the treatment of chronic illnesses. Part III establishes the types of data privacy regulation, including federal and state law, necessary to protect how consumer data is collected and used in treating chronic illnesses.

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17. Watson, *supra* note 1, at 3.

18. *Id.*; Cilliers, *supra* note 3, at 2.

19. Stop Marketing and Revealing the Wearables and Trackers Consumer Health Data Act, S.2885, 116th Cong. (2019).

20. *Id.*

21. *Congress Introduces the Smartwatch Data Act*, COMPLIANCY GRP., (Nov. 25, 2019) https://compliancy-group.com/congress-introduces-the-smartwatch-data-act/.

22. 45 C.F.R. § 160 (2013).

23. *Summary of the HIPAA Privacy Rule*, OFF. FOR C. R., (July 26, 2013) www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html.

24. *Id.*; *see Congress Introduces the Smartwatch Data Act, supra* note 21.

ANALYSIS

Mobile technology has the potential to make a huge impact on the management of chronic disease.[25] By connecting patients and healthcare providers, technology can improve access to medical records, update caregivers on how their loved ones feel, monitor treatment adherence, and work in countless other ways.[26] Furthermore, technology will not only allow health care to change and become more personalized, but technology can also make a huge difference in successfully preventing or delaying the complications of many chronic conditions.[27]

Specifically, some research has shown that mobile health applications are useful and can improve shared decision-making in diagnostic and treatment decisions between patients and physicians.[28] One 2016 study focused on the management of hypertension through mobile health apps and showed that accurate medical information on smartphone applications empowered patients.[29] Keeping the patient's information up-to-date is now possible with features on apps that automatically upload information to the servers and integrate the newest medical evidence into the program's software.[30] Although technology is not unique to healthcare, there are significantly

25. Steven R. Steinhubl et al., *The Emerging Field of Mobile Health*, 7 SCI. TRANSLATIONAL MED. 1 (Apr. 15, 2015), stm.sciencemag.org/content/7/283/283rv3.short; *see generally* Santoro ET AL., *supra* note 7, at 2.

26. Matt Clemente, *Technology is Changing the Way We Manage Chronic Diseases*, MOBI HEALTH NEWS (Oct. 30, 2018), www.mobihealthnews.com/sponsored-content/technology-changing-way-we-manage-chronic-diseases; *see* C. Lee Ventola, *Mobile Devices and Apps for Health Care Professionals: Uses and Benefits*, 39 PHARM. & THERAPEUTICS 356, 358 (May 2014).

27. *How Technology is Changing How We Manage Chronic Conditions*, SANOFI: SCI. & INNOVATION (June 29, 2018), www.sanofi.com/en/science-and-innovation/how-technology-is-changing-how-we-manage-chronic-conditions ("This is particularly important for people with diabetes, because when the condition is not well managed, patients are at increased risk of serious complications.").

28. Samira Abbasgholizadeh Rahimi et al., *Are Mobile Health Applications Useful for Supporting Shared Decision Making in Diagnostic and Treatment Decisions?*, 10 GLOBAL HEALTH ACTION 37-38 (May 2, 2017) ("[Shared decision making] is defined as a collaborative process that allows patients and their providers to make healthcare decisions together, taking into account the best scientific evidence available as well as the patient's values and preferences."); Renee Purcell et al., *Telemonitoring Can Assist in Managing Cardiovascular Disease in Primary Care: A Systematic Review of Systematic Reviews*, 15 BMC Family Practice 43 (2014).; Paul J. Heinzelmann et al., *Beyond EHRs: How Technology Can Help You Treat Chronic Illness*, 15 FAM. PRAC. MGMT.: TECH. & CHRONIC ILLNESS 32 (March 2008).

29. PAUL J. HEINZELMANN ET AL., *supra* note 28, at 38; Stefano Omboni et el., *Telemedicine and M-Health in Hypertension Management: Technologies, Applications and Clinical Evidence*, 23 HIGH BLOOD PRESSURE & CARDIOVASCULAR PREVENTION 187-196 (2016).

30. PAUL J. HEINZELMANN ET AL., *supra* note 28, at 38.

more important quality and safety measures that need to be considered.[31] In spite of all these benefits of technology in chronic care management, there are also far-reaching implications for the economy, security, and the environment to be considered.[32] Not only will technology change the consumer-based market and long-established roles in regulatory healthcare but it could also increase consumer risks. Depending on how long it takes for the rules under the Act to be deployed, there could be a lag in enforcement despite the technology being readily used in the real world.

REGULATORY CHALLENGES

It is necessary to establish data privacy regulations to protect how consumer data is collected and used. "Currently [there is] no regulation of mobile health devices or apps and no guarantee that they are providing [. . .] accurate information" to the consumers. [33] The US Food and Drug Administration (FDA) has released regulations for the marketing the mobile health apps that meet the definition of medical devices "whose functionality could pose a risk to a patient's safety if the mobile app were to not function as intended."[34] However, these recommendations are currently non-binding and will not prevent a health app from being made available since most apps are made available to patients directly via public app stores, without passing through regulatory gatekeepers to ensure their safety and effectiveness.[35] The clinical use of these devices and apps to collect highly sensitive information needs to be regulated in a similar way to how other medical interventions are already regulated by the FDA.[36] The regulation of mobile health products would help to minimize privacy violations as Regulators start to deal with the increasingly globalized nature of health data.[37] Therefore, the regulators need to start the development of an

31. Yasser K. Alotaibi & Frank Federico, *The Impact of Health Information Technology on Patient Safety*, 38 SAUDI MED. J. 1173-80 (2017) ("Patient safety is a subset of healthcare and is defined as the avoidance, prevention, and amelioration of adverse outcomes or injuries stemming from the processes of health care.").

32. *The Rise of Artificial Intelligence: Future Outlook and Emerging Risks*, *supra* note 32, at 11-13.

33. Adrian Carter et al., *Mobile Phones in Research and Treatment: Ethical Guidelines and Future Decisions*, 3 JMIR MHEALTH UHEALTH 4, 5 (2015), https://mhealth.jmir.org/2015/4/e95/.

34. *Id.*; U.S. Food & Drug Admin., POLICY FOR DEVICE SOFTWARE FUNCTIONS AND MOBILE MEDICAL APPLICATIONS: GUIDANCE FOR INDUSTRY & FOOD & DRUG ADMINISTRATION STAFF (2019).

35. U.S. FOOD & DRUG ADMIN., *supra* note 34 ("This guidance. . .does not establish any rights for any person and is not binding on FDA or the public."); CARTER ET AL., *supra* note 33, at 5.

36. CARTER ET AL., *supra* note 33, at 5-6.

37. *Id*.

approval system for these devices and mobile health apps as these technologies become more prevalent.[38]

ISSUES OBTAINING CONSENT

Before collecting and releasing medical information, businesses, or any entity collecting data from a consumer, should seek and obtain the consent from consumers.[39] Though the Federal Trade Commission (FTC) has been examining the privacy implications of mobile devices since 2000, many app developers still have privacy policies that do not provide appropriate and easily accessible disclosures.[40] A FTC study of privacy policies found that "consumers do not know or understand current information collection and use practices occurring on mobile devices."[41] The FTC also believes, that many consumers have limited attention spans and would benefit from short form privacy notices similar to the concept of "nutrition labels" on foods.[42] Moreover, within these notices, consumers must also be informed of the risks[43] and benefits of using these technologies.[44] They also need to make a free and uncoerced decision about whether to participate.[45] A challenge in mobile health apps is communicating the complex nature of the risks raised by this technology and negotiating the risks that individuals are willing to face.[46]

Consumers should also be aware of how the data will be used, stored, how it will be shared and for how long, as well as what will happen to their data if they were to choose to stop using an app.[47] Currently, given the complicated mobile system, devices can do anything from sharing data with third parties (including but not limited to: manufactures, developers, companies and advertisers) to storing data for an unlimited amount of time,

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38. *Id*.

39. *Id.* at 3; *see* HEALTH DATA IN THE INFORMATION AGE: USE, DISCLOSURE, AND PRIVACY, Chapter 2 (Molla S. Donaldson & Kathleen N. Lohr eds., 1994).

40. *Mobile Privacy Disclosures Building Trust Through Transparency*, FED. TRADE COMM'N (Feb. 2013), www.ftc.gov/sites/default/files/documents/reports/mobile-privacy-disclosures-building-trust-through-transparency-federal-trade-commission-staff-report/130201mobileprivacyreport.pdf.

41. *Id*.

42. *Id*.

43. Including sensitive information that may be shared or sold to third parties, for example, "to send consumers behaviorally targeted advertisements," *id*.

44. *Id*.

45. CARTER ET AL., *supra* note 33, at 3.

46. *Id*.

47. *See id.*; *see also* Louise Matsakis, *The WIRED Guide to Your Personal Data (and Who Is Using It)*, WIRED: BUS. (Feb. 15, 2019 7:00 AM), www.wired.com/story/wired-guide-personal-data-collection/.

leaving consumers concerned of their privacy.[48] A nationwide survey indicated that "fifty-seven percent of all app users have either uninstalled an app over concerns about having to share their personal information, or declined to install an app in the first place for similar reasons."[49] Therefore, a balance needs to be struck between maximizing technology utility and protecting consumer privacy.[50] It is preferable to only collect data sufficient for the purpose of the mobile app, rather than all data routinely.[51] More disclosure in the privacy notices will increase participants' understanding of the risks involved with this technology and enable them to make more informed decisions.[52]

PRIVACY, SECURITY, AND DATA OWNERSHIP

Privacy is the ability to control the recording and sharing of personal information with others.[53] This requires knowledge of what will be recorded, how it will be used and for how long, who will have access to this information, and what the risks are of discovery and misuse by third parties.[54] Patients expect that any health information revealed will be used exclusively for the purpose of providing care, and it will be kept confidential.[55] However, the security of data collected via mobile phones and devices cannot be guaranteed, since mobile health apps are not required to adhere to strict health record regulations such as the United States Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rule.[56]

Normally, health information collected for the treatment of chronic conditions is protected under HIPAA which regulates the use and disclosure of the individually identifiable health information.[57] However, HIPAA only protects health information for entities that are considered a "covered entity" under the regulation.[58] A "covered entity" for HIPAA purposes

48. *Mobile Privacy Disclosures Building Trust Through Transparency*, *supra* note 40.

49. *Id., (*citing Pew Internet & American Life Project, Privacy and Data Management on Mobile Devices (Sept. 5, 2012), available at www.pewresearch.org/internet/2012/09/05/privacy-and-data-management-on-mobile-devices/).

50. CARTER ET AL., *supra* note 33, at 4.

51. *Id.*

52. *Id.*

53. *Id.* at 2.

54. *Id*.

55. *Id*. at 3.

56. *Covered Entities and Business Associates,* available at www.hhs.gov/hipaa/for-professionals/covered-entities/index.html.

57. *HIPAA for Professionals*, available at www.hhs.gov/hipaa/for-professionals/index.html.

58. *Covered Entities and Business Associates, supra* note 56.

includes providers such as doctors, hospitals, insurance companies, and pharmacies.[59] Since mobile health apps nor devices are considered a "covered entity," these technologies do not necessarily need to protect consumers' information in accordance with HIPAA.[60] Thus, there is no expectation of the same HIPAA privacy protections for information provided to mobile health apps even if they still collect, use, and transmit health information.[61] Therefore, in the current scheme of privacy practices, information being shared with these mobile apps may be stored and transferred using methods that are not compliant with the normal protection standards required for the use of electronic medical records.[62]

Moreover, since the mobile health apps do not need to follow HIPAA security provisions, there are potentially "many security threats that [consumers] are exposed to when making use of" these technologies.[63] One investigation found threats to security of collecting health data from a wearable device including: "data in transit between the device and software program and storage of the aggregated data in a database." Simply put, this information about potential security risks in transferring and storing this data can be helpful "in order to develop a higher degree of awareness and understanding of the security threats" associated with the collection of consumer health data.

Another issue is the ownership of the data that is collected from the consumer.[64] "Currently, the data are not owned by the [consumer] but rather by the company" that produces the mobile health app or wearable device.[65] The individual typically only has access to a "summary of their data, while the raw data can be sold to third parties."[66] Consumers may not be aware of their lack of ownership rights to the data and should be concerned that they "will not have control over" the data they are providing to the apps and device.[67]

SMARTWATCH DATA ACT

The perceived need to protect medical data needs to be met with real life consumer privacy protections.[68] Although there are laws enforcing the use

59. *Id*.
60. *Id*.
61. *Id*.
62. *Id.*
63. Cilliers, *supra* note 3, at 2.
64. *Id*.
65. *Id*.
66. *Id*.
67. *Id*.
68. Nass et al., *Institute of Medicine (US) Committee on Health Research and the Privacy of Health Information: The HIPAA Privacy Rule*, NAT'L ACADS. PRESS (2009).

of privacy policies, consumers still might not understand the true use of the data they are disclosing which creates the need for perceived protections of medical data to be met with new up-to-date privacy restrictions.[69] Currently, the Smartwatch Data Act is in the first stage of the legislative process[70] and will need to be considered by committee before possibly being reviewed.[71] In preparation of this bill becoming a law, privacy departments at technology companies producing mobile apps and medical devices that collect "Consumer Health Information" will need to prepare new policies to ensure compliance with the new protections.[72]

To address this sharing of consumer's information, the Smartwatch Data Act prohibits the transfer, sale, sharing, or access to any non-anonymized, or de-identified,[73] consumer health information, or other individually identifiable health information, that is: "Collected, Recorded, or Derived from personal consumer devices."[74] As the number of mobile health apps and devices increase to treat chronic care, it will be critical to get an understanding of the new privacy practices as soon as possible. The privacy policies will need to be changed need to reflect the language of the bill and allot more protections to consumer information then many policies currently do.[75]

The Smartwatch Data Act would also expand the current definition of PHI by "treating all health data collected through apps, wearable devices, and trackers as protected health information."[76] The Act, however, would

69. *Congress Introduces the Smartwatch Data Act, supra* note 21.

70. *The Legislative Process*, available at www.house.gov/the-house-explained/the-legislative-process. ("Laws begin as ideas. First, a representative sponsors a bill. The bill is then assigned to a committee for study. If released by the committee, the bill is put on a calendar to be voted on, debated or amended.").

71. Stop Marketing and Revealing the Wearables and Trackers Consumer Health Data Act, S.2885, 116th Cong. (2019).

72. *Congress Introduces the Smartwatch Data Act, supra* note 21. ("The term "consumer health information" means any information about the health status, personal biometric information, or personal kinesthetic information about a specific individual that is created or collected by a personal consumer device, whether detected from sensors or input manually. The term "kinesthetic information" means keystroke patterns or rhythms, gait patterns or rhythms, sleep information, and other data that relates to the personal health of an individual.")

73. *See*, Guidance Regarding Methods for De-Identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, available at, www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html#rationale. The process of de-identification, by which identifiers are removed from the health information, mitigates privacy risks to individuals and thereby supports the secondary use of data for comparative effectiveness studies, policy assessment, life sciences research, and other endeavors, *id*.

74. *Id.*

75. *Id*.

76. *Congress Introduces the Smartwatch Data Act, supra* note 21.

not expand the definition of "covered entity" to include "app developers and wearable device manufacturers that collect, store, maintain, process, or transmit consumer health information."[77] Therefore, the Act would not extend HIPAA regulations to cover these app developers, instead the legislation applies to the data itself.[78] Since compliance with the HIPAA is not required by these app developers, the Act is the first measure being discussed to ensure the privacy of patient data in the mobile app and device area.[79] Congress will need to push enforcement to ensure that all companies falling under the regulation are compliant with the increased protection given to the consumers. Without enforcement measures taken, the increase in potential privacy breaches and consumer information hacks will have the potential to increase as more individuals use technology to manage their chronic conditions.

STEPS AFTER THE SMARTWATCH ACT IS PASSED

While significant amounts of private information have "advanced at a rapid pace, the privacy and information security concerns of the user have not kept pace with these developments." Currently, several federal and state statutes protect the confidentiality of medical information that fall within the HIPAA definition.[80] However, there has yet to be established a uniform requirement for the assurance of confidentiality and protection of privacy rights for personally identifiable health data specific to mobile apps and devices.

The Smartwatch Data Act is the first federal bill to propose any such consumer protections. The Federal legislation should be expected to encourage standard setting in such areas where large amounts of confidential information are being collected. Setting privacy standards from a federal level will help to protect consumer information and potentially enable individuals to understand their participation in the use of these mobile health apps.

In other parts of the world, countries have taken it upon themselves to pass privacy laws from a national level that allot more protection to consumers. The General Data Protection Regulation (GDPR) for instance, effective in the EU in May 2018, has been instrumental in advancing

77. *Id*.
78. *Id*.
79. *Id.*
80. HIPAA created a baseline of privacy protections but leaves in effect other laws that are more privacy protective, *see Health Information Privacy Law and Policy*, available at www.healthit.gov/topic/health-information-privacy-law-and-policy. Under this legal framework, health care providers and other implementers must continue to follow other applicable federal and state laws that require obtaining patients' consent before disclosing their health information, *id*.

consumer-centric approaches to privacy.[81] The GDPR has also been instrumental in "resetting" approaches to privacy in the U.S. One such approach is the initiation of the California Consumer Privacy Act (CCPA), which governs privacy rights of California consumers.[82] Some additional states are following suit with the introduction to "CCPA copycat" bills. However, given this patchwork of state legislation, it would be better if Congress proposed a bill in addition to The Smartwatch Data Act, to harmonize these differing state laws.[83]

CONCLUSION

It is critical that the United States have protections in place for consumer's who utilize these apps to improve their health and wellbeing "since mobile applications are accessible, affordable, and easy to use for patients."[84] The promise of this technology—the ability to collect, analyze, and communicate vast amounts of personal data almost immediately to research and clinical teams— creates a developing interest for patients and healthcare providers who want to utilize these mobile health apps. Mobile health apps essentially can empower patients and encourage greater participation of patients in medical decision-making.[85] However, along with these new promises come privacy and security concerns that need to be managed while minimizing potential risks of harm.[86] While the issues of privacy and security are not unique to mobile health apps, specific solutions are needed that address the particular challenges raised with the highly confidential health information.[87]

The development of robust protections for these mobile health apps and wearable devices will optimally address the privacy challenges and will require early and ongoing engagement with consumers and other relevant stakeholders.[88] Accordingly, Congress should start protecting health information collected by health apps and wearable devices by enacting the Stop Marketing and Revealing the Wearables and Trackers Consumer

81. Tom Kulik, *Happy New Year: 3 Hot Topics for Technology and The Law In 2020 (& Beyond)*, ABOVE THE LAW (Jan. 13, 2020, 11:28 AM), https://abovethelaw.com/legal-innovation-center/2020/01/13/happy-new-year-3-hot-topics-for-technology-and-the-law-in-2020-beyond/.

82. *Id.*

83. *Id.*; *see* Adam D. Thierer, *The Internet of Things and Wearable Technology: Addressing Privacy and Security Concerns Without Derailing Innovation*, 21 RICHMOND J. L. & TECH. 116 (Sept. 12, 2014).

84. RAHIMI ET AL., *supra* note 28, at 39.

85. *Id.*

86. CARTER ET AL., *supra* note 33, at 6.

87. *Id.*

88. *Id.*

Health Data Act. Furthermore, Congress should also continue to explore additional privacy concerns and pursue additional legislation that tackles the privacy and security concerns not covered by the proposed law.[89]

89. *Id.*

An Analysis of U.S. Legislation, Healthcare and Litigation: Expanding Ovarian Cancer Prevention Access for American Women

Mehgan Keeley

INTRODUCTION

Ovarian cancer severely threatens the health of American women and the stability of the American economy and healthcare system.[1] In 2020, approximately 21,750 women in the U.S. will be diagnosed with ovarian cancer and about 13,940 will lose their battles.[2] Cancer research development has discovered its most significant risk factors.[3] However, the U.S. healthcare and legal systems fail to adequately provide women access to preventative measures.

Although the U.S. has made progress in recent years to better protect women at risk for developing ovarian cancer, there remains a need for improvement. This article addresses how litigators and victims' advocates can expand access to prevention for women through class action litigation and policy reform. Part II is an overview of the detrimental effects ovarian cancer on women and the economy. Part III discusses the current state of U.S. law, litigation, and healthcare related to ovarian cancer and progress made thus far to protect women at risk. Part IV makes a proposal for how litigators and victims' advocates can expand access to prevention through class action litigation, state legislative reform, and public awareness.

1. *See Key Statistics for Ovarian Cancer,* AMER. CANCER SOC'Y, (Apr. 11, 2018), www.cancer.org/cancer/ovarian-cancer/about/key-statistics.html (approximating that, in 2020, 21,750 women will be diagnosed with ovarian cancer and 13,940 will lose their lives to it); *See* AMER. CANCER SOC'Y, ECONOMIC IMPACT OF CANCER (Jan. 3, 2018) (stating the $80.2 billion medical cost of cancer in 2015 and, in 2016, nine percent of Americans were uninsured).

2. *Id.*

3. *See Ovarian Cancer Risk Factors*, AMER. CANCER SOC'Y (Apr. 11, 2018), www.cancer.org/cancer/ovarian-cancer/causes-risks-prevention/risk-factors.html (outlining risk factors including, but not limited to, infertility, using in vitro fertilization, a history of endometriosis, and talcum powder use).

OVARIAN CANCER: A THREAT TO U.S. WOMEN AND THE LEGAL AND HEALTHCARE INDUSTRIES

A. Ovarian Cancer's Threat to Women

The most obvious and sobering consequence of an ovarian cancer diagnosis is its physical and emotional effect on the patient and her loved ones. The traumatic journey of battling ovarian cancer threatens a shorter and often reduced quality of life.[4] Treatment expenses destabilize a family's finances and force them to make difficult decisions, such as adjusting or delaying treatment.[5] The average cost of care for a patient's first year after surgery is $100,000, with patients paying approximately three-percent out-of-pocket.[6]

Ovarian cancer causes more deaths than any other gynecologic cancer among woman.[7] After a woman is diagnosed, doctors develop customized treatment plans based on the stage of diagnosis and the patient's age, desire to preserve fertility, and other existing health conditions.[8] Ovarian cancer treatment can include but is not limited to surgery, chemotherapy, and radiotherapy.[9] Many patients face a difficult "health-related quality of life," affecting their physical emotional and social well-being because of the intense treatment that follows diagnosis.[10] Navigating the healthcare industry as a newly-diagnosed patient is complicated; It includes choosing a gynecologic oncologist, obtaining second or third opinions, and deciding which treatment options suit the patient's comfort level, needs, financial flexibility, and insurance coverage.[11] Oncologists and patients must also decide whether to explore clinical or experimental trials.[12]

Managing the course of treatment is another challenge for both healthcare providers and patients.[13] Chemotherapy and radiation therapy are

4. Dana M. Chase & Lari Wenzel, *Health-related quality of life in ovarian cancer patients and its impact on clinical management*, 11 EXPERT REV. OF PHARMACOECONOMICS & OUTCOMES RESEARCH 421, 421–22 (2011) (explaining the patient's health-related quality of life encompasses her domains of physical, emotional, functional and social wellbeing).

5. *Id*.

6. Alexandra S. Bercow et al*., Cost of Care for the Initial Management of Ovarian Cancer*, 130 OBSTETRICS & GYNECOLOGY 6, 1269 (2017).

7. *Ovarian Cancer Screening Guidelines,* MEM. SLOAN KETTERING CANCER CTR. (last visited Jan. 25, 2020), www.mskcc.org/cancer-care/types/ovarian/screening/screening-guidelines-ovarian.

8. *Ovarian Cancer Guide for Newly Diagnosed Women*, NAT'L OVARIAN CANCER COALITION, 6 (2012).

9. *Id*.

10. Chase & Wenzel, *supra* note 4, at 421–22.

11. NAT'L OVARIAN CANCER COALITION, *supra* note 8, at 7.

12. *Id*. at 9.

13. *Id*. at 14.

often accompanied by difficult side effects such as fatigue, anemia, infections, pain, hair loss, or memory problems.[14] Furthermore, there are several health care disparities among ovarian cancer patients from different socioeconomic backgrounds.[15] Research demonstrates different treatment options are offered or available based a variety of the patient's socioeconomic and demographic factors, language barriers, or geographic barriers.[16] These varying treatment plans impact survival rates.[17] Other barriers to health care—such as lack of insurance—prevent many women from accessing quality treatment and thereby increase her long-term costs of care.[18] This is particularly alarming in regard to newly diagnosed low-income women and Medicare beneficiaries without supplemental insurance, who on average incur $8,115 in out-of-pocket expenses annually.[19] Their expenses are significantly higher than the median $2,988 out-of-pocket cost for all patients during their first year of treatment.[20]

B. Ovarian Cancer's Threat to the U.S. Economy

Ovarian cancer also negatively impacts the U.S. economy industry.[21] In 2018, ovarian cancer cost the U.S. $5,862,600.[22] Direct medical costs for cancer care are generally fifty-two percent for outpatient services and thirty-eight percent for inpatient hospital stays.[23] The economic burden of cancer on society and families is reflected not only in loss of monetary resources but also the loss of time, human capital and willingness to pay.[24] Patients and their caregivers spend less time in public activities or marketing local businesses.[25] Productivity drops when patients and family members or caregivers are forced to quit or take leave from their jobs.[26]

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14. *Id.* at 14–20.

15. Matthew Kaufman et al., *A review of the effects of healthcare disparities on the experience and survival of ovarian cancer patients of different racial and ethnic backgrounds*, 5 J. OF CANCER METASTASIS & TREATMENT 1 (2019).

16. *Id.*

17. *Id*.

18. AMER. CANCER SOC'Y, ECONOMIC IMPACT OF CANCER (Jan. 3, 2018).

19. Bercow et al, *supra* note 6, at 1274.

20. *Id*.

21. NAT'L CANCER INST., FINANCIAL BURDEN OF CANCER CARE (Feb. 2019) (addressing the national economic burden of cancer care and estimating that care for cancer survivors amounted to $137.4 billion in medical care expenditures in 2010).

22. *Id.*

23. AMER. CANCER SOC'Y, *supra* note 18.

24. K. Robin Yabroff et al., *Economic Burden of Cancer in the U.S.: Estimates, Projections and Future Research*, 20(10) CANCER EPIDEMIOL BIOMARKERS PREV. 1, 4 (Oct. 2011).

25. *Id.* at 4.

26. *Id.* at 1, 4.

Cancer further drains resources from the medical industry and society.[27] An ovarian cancer diagnosis demands a high volume of treatment services and, although preventative services may cost the government and health insurance providers in the short-run, they can significantly reduce the financial burden of ovarian cancer in the long-run.[28] Increased access to preventative measures can reduce ovarian cancer's harmful impact on families, healthcare, and the economy.

C. Prevention

Cancer researchers have discovered several risk factors which increase a woman's chance of developing ovarian cancer.[29] The most common risk factors include giving birth after the age of 35, infertility and using in vitro fertilization, a history of endometriosis, using post-menopausal hormone replacement therapy, using talcum powder, obesity and an unhealthy diet high in red meat and processed foods.[30]

Most women are diagnosed with ovarian cancer after it has developed to Stage III or IV because symptoms are often silent or value in the early stages.[31] Stages III and IV considered "advanced" stages and are correlated with lower survival rates.[32] For instance, the relative five-year survival rate of a Stage I diagnosis is ninety percent while the relative five-year survival rate of a Stage IV diagnosis is seventeen percent.[33] Researchers distinguish women in the general population from those with an increased or inherited risk of developing ovarian cancer.[34] Women with an increased risk are three- to six- times more likely to develop ovarian cancer than the general population and women with an inherited risk are greater than six times more likely.[35] Nevertheless, lack of an increased or inherited risk is not an absolute shield against cancer development and preventative measures are critical for all women.

Ovarian cancer is typically screened by transvaginal ultrasounds for

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27. *Id.* at 2.

28. *Economic Impact of Cancer*, THE UNIV. OF IOWA PUB. POLICY CTR., http://ppc.uiowa.edu/health/study/economic-impact-cancer (last visited March 18, 2020).

29. AMER. CANCER SOC'Y, *supra* note 3.

30. *Id.*; MEM. SLOAN KETTERING CANCER CTR., *supra* note 7.

31. *How am I Diagnosed with Ovarian Cancer?* NAT'L OVARIAN CANCER COAL., www.ovarian.org/about-ovarian-cancer/how-am-i-diagnosed (last visited March 18, 2020).

32. *Id.*; *Staging*, OVARIAN CANCER RESEARCH ALL., https://ocrahope.org/patients/about-ovarian-cancer/staging/ (last visited Mar. 14, 2020).

33. *Id.*

34. Women with an increased risk have a first-degree relative diagnosed with ovarian cancer or have a personal history of breast cancer before the age of fifty. Women with an inherited risk are those with an altered or mutated BRCA 1 or BRCA 2 gene. MEM. SLOAN KETTERING CANCER CTR., *supra* note 7.

35. *Id.*

women at high risk, with abnormal pelvic exam results, or after women notice unusual symptoms.[36] However, health care providers advise women with an inherited risk to undergo the BRCA gene test, a blood test which analyzes DNA to identify mutated BRCA genes.[37] Genetic tests for BRCA mutations can screen women with a family history of ovarian cancer before they are diagnosed with or even develop ovarian cancer.[38] Although the presence of a mutated BRCA gene does not guarantee the patient will develop ovarian cancer, it identifies her risk and informs her of whether she should take preventative measures earlier in her life.[39] Medical professionals predict that the development of genetic testing will lead to more effective and personalized medical treatment, thereby leading to more accurate diagnoses and higher quality treatment strategies.[40]

OVARIAN CANCER PREVENTION UNDER THE CURRENT SYSTEM

A. The Law

Cancer genetic research development has been largely optimistic but also carries consequences. When genetic testing became available, some employers and health insurers took adverse action against employees' or insureds' based on their genetic information.[41] For example, an individual with a genetic predisposition of ovarian cancer might have received different employment benefits from an employer or have been denied or charged higher premiums by health insurance providers.[42] As a result, many women hesitated to undergo genetic testing in fear of adverse action by their employers or health insurers.[43]

Congress enacted the Genetic Nondiscrimination Act ("GINA") in 2008 as a response to misuse of genetic information.[44] GINA prohibits discrimination based on genetic information by health insurers and

36. MEM. SLOAN KETTERING CANCER CTR., *supra* note 7; NAT'L OVARIAN CANCER COAL., supra, note 31.

37. *BRCA gene test for breast and ovarian cancer risk*, MAYO CLINIC (Sep. 12, 2019), www.mayoclinic.org/tests-procedures/brca-gene-test/about/pac-20384815.

38. *Id.*

39. *Id.*

40. Rob Wyse, *Genetic testing, particularly to determine risk or early detection of cancer, is becoming more prevalent and available yet, in economic terms, supply outstrips demand*, MedCity News (Mar. 5, 2019), https://medcitynews.com/2019/03/genetic-testing-supply-for-cancer-diagnosis-and-care-outstrips-demand/?rf=1.

41. Amanda K. Sarata & Jody Feder, The Genetic Information Nondiscrimination Act of 2008 (GINA), CONG. RES. SERV., 1 (2015).

42. *Id.* at 3.

43. *Id.* at 4.

44. *Id.* at "Summary"; The Genetic Information Nondiscrimination Act, Pub. L. No. 110-233, 122 Stat. 881 (2008).

employers.[45] "Genetic information" includes information about a person's genetic tests, her family members' tests and whether her family members manifest a disease or disorder.[46] GINA protects both cost and access to health insurance and employment benefits.[47] GINA further protects individuals' privacy by prohibiting the use of genetic information in employment decisions like hiring, assigning tasks, promotion, or termination.[48]

GINA amended other federal laws like the Employee Retirement Income Security Act, the Public Health Service Act, the Internal Revenue Code, and the Social Security Act to aid its purpose to end genetic information discrimination.[49] Federal agencies including the Department of Health and Human Services, the Department of the Treasury, and the Department of Labor promulgated rules to implement and enforce GINA.[50] The Affordable Care Act ("ACA") overlaps with GINA to prohibit private health insurers from using health status or factors to discriminate against persons when renewing or issuing policies.[51] Medicaid and Medicare bar the use of genetic information as a condition of eligibility.[52]

U.S. law prohibiting genetic information discrimination have made significant progress in expanding access to ovarian cancer prevention. The public policy behind current U.S. laws and regulations values genetic testing opportunities and protecting from discriminatory use of that technology.[53]

B. Litigation

Women's lack of access to prevention and deceptive use of risk factors have led to individual and class action lawsuits on behalf of women and their families.[54] In 1998, the Ninth Circuit foreshadowed the public policy behind GINA which Congress would enact ten years later.[55] In *Norman-*

45. *Id*.

46. 42 U.S.C. 2000ff(4) (2008), as applied to employers; 29 U.S.C. 1191b (2008), as applied to health insurers.

47. Perry W. Payne, Jr. et al., *Health Insurance and the Genetic Information Nondiscrimination Act of 2008: Implications for Public Health Policy and Practice*, 124 PUB. HEALTH REP. 328, 329 (2009).

48. 42 U.S.C. 2000ff-1 (2008).

49. Sarata & Feder, *supra* note 41, at 10.

50. *Id.* at 8.

51. The Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010).

52. Payne et al., *supra* note 47, at 329.

53. *Id.* at 330.

54. *See* Ingham v. Johnson & Johnson, 2018 WL 3471489 (Mo. Cir. Ct. July 12, 2018) (where diagnosed women sued Johnson & Johnson for deceptively using and advertising baby powder made with talcum).

55. *See* Norman-Bloodsaw v. Lawrence Berkeley Laboratory, 135 F.3d 1260 (9th Cir.

Bloodsaw v. Lawrence-Berkeley Labratory, the court acknowledged health and genetic information discrimination in its holding that blood tests for sickle cell traits gave rise to a claim under Title VII of Civil Rights Act.[56] The Ninth Circuit emphasized that the constitutionally-protected privacy interest against disclosure of personal matters includes medical information and its confidentiality.[57]

In 2013, the United States Supreme Court struck down the validity of patents on mutated BRCA genes in *Association for Molecular Pathology v. Myriad Genetics, Inc*.[58] Myriad Genetics, Inc. obtained patents on its discovery of the location and sequence of BRCA genes which it used to detect BRCA mutations and, thus, a patient's risk for developing ovarian or breast cancer.[59] The Court struck down the patents because they were products of nature.[60] This holding was seminal to the molecular genetics industry because it opened the door for competition in technology of BRCA genetic screening, and thus, increased the availability of and patient access to high-quality, more accurate BRCA tests.[61]

Further, victims have begun to fight back against companies and manufacturers who deceptively sell and advertise products made with contaminants which increase the risk of ovarian cancer.[62] In 2018, twenty-two women brought a class action lawsuit against Johnson & Johnson in Missouri state court.[63] The *Ingham* plaintiffs alleged they developed ovarian cancer as a result of the carcinogens—including talc, asbestos, and arsenic—in Johnson & Johnson's products.[64] The women asserted they used the powder products regularly in reliance on Johnson & Johnson advertisements encouraging daily use.[65] They also alleged Johnson & Johnson concealed or misrepresented its performance testing findings detecting detected asbestos in their products, failed to properly test all products, and made false public assurances by labeling the products as safe

1998) (holding blood tests for genetic traits interfered with individuals' protected privacy interest against disclosing their medical information).

56. Norman-Bloodsaw, 135 F.3d at 1272.

57. *Id*. at 1269.

58. Assoc. for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).

59. *Id.* at 579–80.

60. *Id.* at 580.

61. Robert T. Neff et al., *BRCA mutation in ovarian cancer: testing, implications and treatment considerations*, 9 THERAPEUTIC ADVANCES IN MED. ONCOLOGY 519, 521 (2017).

62. See Ingham v. Johnson & Johnson, 2018 WL 3471489 (Mo. Cir. Ct. July 12, 2018) (where diagnosed women sued Johnson & Johnson for deceptively using and advertising baby powder made with talcum).

63. *Id.*

64. *Id*.

65. *Id.*

for all uses.[66] Six of the women lost their lives to ovarian cancer which had allegedly developed from their talcum powder use.[67] A six-person jury found Johnson & Johnson guilty for strict liability and negligence and made headlines when it awarded plaintiffs $550 million in compensatory damages and $4.14 billion in punitive damages.[68] The evidence presented at trial revealed Johnson & Johnson may have been aware of the link between talcum powder and ovarian cancer since the 1970s.[69]

EXPANDING ACCESS TO PREVENTION

U.S. law and litigation have progressed access to cancer prevention, as demonstrated by the enactment of GINA and class action litigation like *Ingham*. However, many women remain without access to prevention and improvement can be made by developing state legislation, class action litigation and public awareness on insurance coverage and genetic information protection.

A. State Legislation and Class Action by Litigators

GINA creates a threshold of protection but, notably, does not preempt state laws that offer greater protection.[70] It is also noteworthy that GINA only applies to employment and health insurance settings.[71] Women with genetic predispositions for ovarian cancer are not protected from discrimination in other settings, such as short- or long-term disability and life insurance.[72] GINA was debated in Congress for thirteen years, and protections in short- and long-term disability and life insurance plans were eliminated as a legislative compromise.[73] The result is that individuals who face discrimination by disability or life insurers are unprotected unless they live in a state with an applicable nondiscrimination law.[74] Another result is that some individuals at high risk may not undergo genetic testing in fear that it will interfere with their ability to obtain life or disability insurance.[75]

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66. *Id*.

67. *Id*.

68. *Id.*; Rachel Casey & Timothy P. Larkin, *Ovarian Cancer and "Tainted Talc": What Treating Physicians Need To Know*, 116 MO. MED. 83 (2019).

69. Casey & Larkin, *supra* note 68, at 84.

70. Payne, *supra* note 47, at 330.

71. 42 U.S.C. 2000ff(4) (2008), as applied to employers; 29 U.S.C. 1191b (2008), as applied to health insurers.

72. *See* Sarata & Feder, *supra* note 41, at 21; Payne, *supra* note 47, at 330.

73. Payne, *supra* note 47, at 330.

74. *Id*.

75. Michelle Andrews, *Genetic Tests Can Hurt Your Chances of Getting Some Types of Insurance*, NPR (Aug. 7, 2018), www.npr.org/sections/health-shots/2018/08/07/636026264/genetic-tests-can-hurt-your-chances-of-getting-some-types-of-

States can better protect women by expanding their discrimination laws to protect women with genetic predisposition for ovarian cancer in all settings, including short- and long-term disability and life insurance. Some states have passed genetic nondiscrimination laws offering further protection.[76] California's Genetic Information Nondiscrimination Act is an optimistic example: it expands GINA to prohibit genetic discrimination in employment, education, mortgage lending, and housing, and allows employees to seek unlimited damages for genetic discrimination by their employers.[77]

State legislation can also expand access to prevention specifically for low-income women. Limitations on insurance coverage for BRCA tests impairs patients and healthcare providers from creating effective treatment plans before ovarian cancer manifests at a lethal stage.[78] In 2018, 8.5 percent of people in the U.S. did not have health insurance as compared to 7.9 percent in 2017.[79] BRCA testing can cost a patient between $300 and $5,000.[80] Medicare covers BRCA testing for individuals with personal histories of cancer but not for those with a family member who has a known BRCA gene mutation.[81] Further, even where a health insurance provider covers part of BRCA testing, the patient frequently owes out-of-pocket costs like co-pay, co-insurance fees, and costs to reach deductibles, making BRCA testing even less accessible for low- or middle-income women.[82]

GINA leaves room for states to enact legislation expanding access to ovarian cancer prevention for all women. States can and should enact legislation to fill in the gaps not covered by GINA, such as by mandating coverage for genetic testing for women with increased or inherited risks or barring health insurers from requesting individuals undergo genetic testing

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insurance.

76. *Id*.

77. Marjorie Soto & Kristen Peters, *Scary as Dinosaurs: California's Genetic Information Discrimination Code*, Seyfarth (June 14, 2017), www.calpeculiarities.com/2017/06/14/scary-as-dinosaurs-californias-genetic-information-discrimination-code/.

78. *See* Wyse, *supra* note 40 (stating BRCA testing allows healthcare providers and patients to create more individualized and effective treatment plans); *Genetic Testing Facilities and Cost*, BREASTCANCER.ORG (June 23, 2016), www.breastcancer.org/symptoms/testing/genetic/facility_cost (stating BRCA testing can up to $5000).

79. EDWARD R. BERCHICK ET AL., HEALTH INSURANCE COVERAGE IN THE UNITED STATES: 2018, UNITED STATES CENSUS BUREAU 2 (2019).

80. BREASTCANCER.ORG, *supra* note 78.

81. *Insurance and Costs, Basser Center for BRCA*, PENN MED. (2020), www.basser.org/patients-families/insurance-and-costs#toc-does-insurance-cover-brca-testing-.

82. *Id*.

for research purposes.[83]

Furthermore, the *Ingham* jury made an important example of Johnson & Johnson and for future litigation advocating for the rights of ovarian cancer victims.[84] Legal scholars predict a rise in asbestos litigation initiated by women who worked in buildings contaminated with asbestos and were diagnosed with ovarian cancer.[85] Increased class action litigation against manufacturers which contribute to ovarian cancer risk factors may nudge legislators to expand GINA or enact a new law to ensure product transparency and expand access to prevention.

B. Public Policy Reform and Raising Public Awareness by Victim Advocates

GINA is a complex piece of legislation that, on paper, can be difficult to interpret by the general public.[86] Many people simply do not know they have genetic information rights under GINA or that the law exists at all.[87] Despite the opportunities made available by genetic testing development, some economists note that the supply of genetic testing is greater than the demand.[88] The low demand is likely due to lack of awareness about testing costs, lack of health insurance coverage, and the availability of or access to genetic testing.[89] Many women who may be at high risk for ovarian cancer but unaware of GINA are less likely to undergo BRCA testing in fear that their health insurance provider or employer will take adverse action.[90]

Public education about GINA is critical to protecting Americans at high risk for ovarian cancer.[91] This may include creating more information materials with consumer-friendly language made available at doctors' offices or hosting community information meetings for women who have a family history of ovarian cancer and want to learn more about their options for prevention.

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83. Payne, *supra* note 47, at 329.

84. Tim Larkin, *Toxic Tort Monitor: Looking Ahead: The Future of Ovarian Cancer Litigation*, Tech., Manuf. & Transp. Industry Insider (Aug. 26, 2019), www.tmtindustryinsider.com/2019/08/looking-ahead-the-future-of-ovarian-cancer-litigation/.

85. *Id*.

86. Payne, *supra* note 47, at 330.

87. *See* Sarata & Feder, *supra* note 41, at 21 n. 102 (where only 77% of Americans in 2010 were not certain they were protected by a genetic information or privacy law).

88. Wyse, *supra* note 40.

89. *Id.*

90. Sarata & Feder, *supra* note 41, at 21.

91. *Id.*

CONCLUSION

Increasing access to ovarian cancer prevention requires an expansion in state laws, class action litigation and public awareness by victims' advocates. Laws prohibiting discrimination based on genetic information in settings beyond employment and health insurance will encourage more women to undergo genetic testing and learn their risks. An open door to class action litigation will provide victims and their families legal relief for corporate entities that irresponsibly—and, sometimes, knowingly—increase women's risk of developing ovarian cancer. Broader access to BRCA mutation testing will allow healthcare providers to create more effective treatment strategies for patients before the onset of ovarian cancer. Expanding access to ovarian cancer prevention will critically improve the physical and emotional health of patients and their families as well as the American economy and healthcare industry.

Regulating Ads to Regulate the Waistline

Damyan Kolomayets

INTRODUCTION

Chronic diseases affect about 133 million people in the United States.[1] They are the most prevalent and expensive conditions in the nation and amount to about $3.7 trillion in annual health care costs.[2] Of the $3.7 trillion, about $1.4 trillion are attributed to costs connected to obesity, which as of 2013 the American Medical Association (AMA) designated as a chronic disease.[3] Additionally, obesity can lead to other chronic diseases such as diabetes and heart conditions.[4] Many efforts to curb the costs associated with obesity revolve around prevention, especially aimed towards younger generations in hopes of laying a foundation for a healthy lifestyle.[5]

One prevention tactic used is regulating marketing and advertising of unhealthy foods to children and teens ages two to nineteen years old.[6] On a federal level, the United States does not have any regulations on marketing and advertising of unhealthy foods, although industry leaders have joined together in a self-regulation program.[7] Similarly, most states do not have

1. Wullianallur Raghupathi & Viju Raghupathi, *An Empirical Study of Chronic Diseases in the United States: A Visual Analytics Approach to Public Health,* 15 INT. J. ENVIRON. RESEARCH & PUBLIC HEALTH 431, 431 (2018).

2. HUGH WATERS & MARLON GRAF, THE COST OF CHRONIC DISEASES IN THE U.S.: EXECUTIVE SUMMARY 2 (2018).

3. HUGH WATERS & ROSS DEVOL, WEIGHING DOWN AMERICA 3 (2016); Melody Covington, *Why Is Obesity a Disease?*, OBESITY MED. ASS'N (Feb. 8, 2017), https://obesitymedicine.org/why-is-obesity-a-disease/.

4. Harvard T.H. Chan Sch. of Pub. Health, *Economic Costs*, OBESITY PREVENTION SOURCE, www.hsph.harvard.edu/obesity-prevention-source/obesity-consequences/economic/ (last visited Apr. 30, 2020).

5. Mike Lean et al., *ABC of Obesity: Strategies for Preventing Obesity*, 333 BMJ 959, 961 (2006).

6. *See* THE FOOD FOUNDATION, UK'S RESTRICTIONS ON JUNK FOOD ADVERTISING TO CHILDREN 5 (2017); Carmen Chai, *Ad bans lead to less fast food eating in Quebec, study says*, GLOBAL NEWS (Dec. 15, 2017), https://globalnews.ca/news/209938/ad-bans-lead-to-less-fast-food-eating-in-quebec-study-says/ (showing examples of regulations on marketing unhealthy foods to children and teens).

7. AM. HEART ASS'N, UNHEALTHY AND UNREGULATED: FOOD ADVERTISING AND MARKETING TO CHILDREN 1 (2019); CHILDREN'S FOOD AND BEVERAGE ADVERTISING INITIATIVE (CFBAI), https://bbbprograms.org/programs/cfbai/about-cfbai (last visited Apr. 30, 2020).

restrictions on marketing and advertising unhealthy foods to children, but the few that do have found some successes.[8] In contrast, some foreign countries such as the United Kingdom and Canada have implemented government regulations with differing degrees of success.[9]

Because obesity is extremely burdensome on the healthcare system, there should be a stronger focus on prevention efforts, especially as it pertains to children. While most obese adults were not obese as children, many obese children grow up to be obese adults.[10] Prevention efforts focused on children are motivated by the thinking that early intervention can foster healthier lifestyle habits in the future.[11] In order to make a dent in the rising healthcare costs associated with obesity, the Federal Trade Commission (FTC) should be allowed to regulate food and beverage advertising practices directed towards children.[12] First, I will address how obesity has become a costly chronic disease in the United States and how food and beverage marketing towards children contributes to high obesity rates in the country. Next, I will analyze how current regulations of such marketing in the United States are inadequate. Finally, I will discuss how the United States could benefit from implementing regulations similar to those in the United Kingdom and Canada.

CHRONIC DISEASE

Chronic disease is defined as a "condition that last[s] 1 year or more and require[s] ongoing medical attention or limit[s] activities of daily living or both."[13] Unfortunately, chronic diseases affect about 133 million people in the United States.[14] Furthermore, they hardly exist in isolation – about a quarter of adults in the United States have two or more chronic diseases, and it is not uncommon to see three or more chronic diseases in the elderly.[15] On average, about seven out of ten deaths in the United States

8. *See* Cameron St. Germain, *California Targets Childhood Obesity with New Advertising Regulations*, HUNTER COLL. N.Y.C. FOOD POLICY CTR. (Nov. 21, 2017), www.nycfoodpolicy.org/14603-2/ (outlining a California law aimed at restricting junk food marketing in schools).

9. THE FOOD FOUNDATION, *supra* note 6; Chai, *supra* note 6.

10. Lean et al., *supra* note 5.

11. *Id.*

12. *See* Nadia Arid, *Food Marketing to Children: A Complicated and Tense History*, FOOD LAW LAB HARVARD LAW SCH., https://foodlawlab.org/perspective/ftc-regulations-on-food-marketing-to-children-a-complicated-and-tense-history/ (last visited Apr. 30, 2020) (showing the history of the FTC and food marketing regulations towards children).

13. Ctrs. for Disease Control, *About Chronic Diseases*, CTRS. FOR DISEASE CONTROL & PREV., www.cdc.gov/chronicdisease/about/index.htm (last visited Apr. 30, 2020).

14. Raghupathi & Raghupathi, *supra* note 1 at 431.

15. *Id.* at 432.

result from chronic disease.[16] This amounts to more than 1.7 million people every year.[17]

Unsurprisingly, because of their prevalence, chronic diseases are expensive to treat. They not only burden the healthcare system with direct costs resulting from outpatient and inpatient health services, but they also burden the economy with indirect costs.[18] Indirect costs are considered "resources forgone as a result of a health condition," and they can include the value of reduced economic productivity, inability to work, and lost wages.[19] In 2005, more than seventy-five percent of the $2 trillion spent on public and private healthcare were used towards treating chronic diseases.[20] Since then, the cost has risen.[21] In 2016, direct costs amounted to $1.1 trillion, equal to 5.8 percent of the United States' gross domestic product (GDP).[22] When factoring in the indirect costs related to chronic disease, the total ballooned to $3.7 trillion, equal to 19.6% of the United States' GDP.[23] In 2018, that cost amounted to about $5,300 per person annually.[24] The high cost and prevalence of these diseases account for ninety-six cents per dollar for Medicare spending and eighty-three cents per dollar for Medicaid spending.[25]

OBESITY

In 2013, the AMA officially designated obesity as a chronic disease.[26] Despite this recent designation, obesity has often been linked to chronic disease such as diabetes, heart disease, osteoarthritis, and some cancers.[27] According to the Obesity Medicine Association, obesity is a "chronic, relapsing, multi-factorial, neurobehavioral disease, wherein an increase in body fat promotes adipose tissue dysfunction and abnormal fat mass physical forces, resulting in adverse metabolic, biomechanical, and psychosocial health consequences."[28] In other words, obesity is "a condition in which fat accumulates in the body to a point where it is a risk factor or

16. *Id.*
17. *Id.*
18. WATER & GRAF, *supra* note 2.
19. *Id.*
20. Raghupathi & Raghupathi, *supra* note 1 at 432.
21. WATER & GRAF, *supra* note 2.
22. *Id.*
23. *Id*.
24. Raghupathi & Raghupathi, *supra* note 1.
25. *Id*.
26. Covington, *supra* note 3.
27. Harvard T.H. Chan Sch. of Pub. Health, *supra* note 4.
28. Covington, *supra* note 3.

marker for a number of chronic diseases."[29] Although it is not a precise metric, the Centers for Disease Control and Prevention (CDC) measures obesity using Body Mass Index (BMI).[30] BMI is calculated by dividing a person's weight in kilograms by the square of their height in meters.[31] According to the CDC, an adult with a BMI of thirty or higher is considered obese.[32] Children, on the other hand, use a BMI scale that is age and sex specific.[33] Children above the ninety-fifth percentile for their age and sex are considered obese.[34]

There has been an increase in obesity in the youth of the United States seen from 1999-2016.[35] About 18.5 percent of the youth (ages two through nineteen) in the United States are obese.[36] Within this demographic, the prevalence of obesity among adolescents (ages twelve through nineteen) in the United States is 20.6 percent.[37] The prevalence of obesity in school-aged children (ages six through eleven) is slightly lower at 18.4 percent.[38] Lastly, the prevalence of obesity in preschool-aged children (two through five years old) was even lower at 13.9 percent.[39] Obesity in boys tends to occur more than in girls between the ages of two through eleven years old, while obesity occurs more in girls than in boys from twelve through nineteen years old.[40]

As obesity became more prevalent, it took a larger toll on the healthcare system and the economy. Based on data from the United States Medical Expenditure Panel Survey, in 1998 expenditures on treating obesity were responsible for about six percent of all medical costs, amounting to about $42 billion.[41] In 2006, costs rose to ten percent or nearly $86 billion a year.[42] In that same year, spending on obesity treatment and obesity related

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29. Maximilian Tremmel et al., *Economic Burden of Obesity: A Systematic Literature Review*, 14 INT'L. J. ENVTL. RES. AND PUB. HEALTH 435, 435 (2017).

30. Ctrs. for Disease Control and Prevention, *Defining Adult Overweight and Obesity*, CTRS. FOR DISEASE CONTROL & PREV., www.cdc.gov/obesity/adult/defining.html (last visited on Apr. 30, 2020).

31. *Id.*

32. *Id*.

33. Ctrs. for Disease Control and Prevention, *Defining Childhood Obesity*, CTRS. FOR DISEASE CONTROL & PREV., www.cdc.gov/obesity/childhood/defining.html (last visited on Apr. 30, 2020).

34. *Id.*

35. CRAIG M. HALES ET AL., PREVALENCE OF OBESITY AMONG ADULTS AND YOUTH: UNITED STATES, 2015-2016 1 (2017).

36. *Id.*

37. *Id.*

38. *Id.*

39. *Id.*

40. *Id.*

41. Harvard T.H. Chan Sch. of Pub. Health, *supra* note 4.

42. *Id.*

conditions accounted for 8.5 percent of Medicare spending and 11.8 percent of Medicaid spending.[43] More recent data shows that obesity-related costs accounted for 47.1 percent of the total cost of chronic diseases totaling $480.7 billion in direct costs and $1.24 trillion in indirect costs.[44] Costs will continue to rise without stronger obesity prevention efforts.

PREVENTION

An added emphasis on prevention efforts focused on the youth in the United States can lead to significant mitigation of healthcare spending in the future. A study showed that an incremental change from being obese to overweight can result in savings of an average of $17,655 in direct costs over an individual's life.[45] The savings would be even more pronounced, averaging $28,020 in savings, from going from being obese to a healthy weight.[46] A recent cost-effectiveness study by the Robert Wood Johnson Foundation analyzed certain prevention efforts to better understand the savings certain methods could achieve.[47] Examples of prevention efforts include a sugar-sweetened beverage tax, removing tax deductibility of food and beverage advertising, the Nutrition and Physical Activity Self-Assessment for Child Care (NAP SACC), and the Hip Hop to Health Jr. program.[48] For example, by removing the tax deductibility of advertising unhealthy foods and beverages to children, savings of an average of $260 million could be achieved by 2025.[49]

MARKETING

Focusing on the way food and beverages are marketed to the youth in the United States should be a larger point of emphasis in the effort to prevent obesity. The food and beverage industry spends about $13.5 billion a year marketing to children.[50] Almost all of the food advertisements seen by children are for products that contain high amounts of fat, sugar, or

43. *Id.*

44. WATER & GRAF, *supra* note 2.

45. Sarah Rebbert, *Losing Weight At Any Age Leads to Cost Savings, John Hopkins Study Suggests*, HUB (Sep. 25, 2017), https://hub.jhu.edu/2017/09/26/weight-loss-costs-savings-hopkins-study/.

46. *Id.*

47. E. Kenney et al., THE COST EFFECTIVENESS OF INTERVENTIONS FOR REDUCING OBESITY AMONG YOUNG CHILDREN THROUGH HEALTHY EATING, PHYSICAL ACTIVITY, AND SCREEN TIME 1 (2019).

48. *Id.* at 2-3.

49. *Id.* at 3.

50. AM. HEART ASS'N, UNHEALTHY AND UNREGULATED: FOOD ADVERTISING AND MARKETING TO CHILDREN 1 (2019).

sodium.[51] The largest spenders on food and beverage advertising towards children are the fast food industry ($714 million), the carbonated beverage industry ($395 million), and the breakfast cereal industry ($186 million).[52] The money spent by these industries goes towards marketing to children on a variety of platforms.[53] A child watches an average of over ten food-related ads on television a day, which translates to about 4,000 advertisements a year.[54]

Despite the large volume of television advertisements seen by children, only about 35.4 percent of advertising expenditures directed towards children by the food and beverage industry were spent on television ads.[55] The remaining 64.6 percent is spent on digital food marketing.[56] Digital food marketing works in tandem with traditional forms of marketing by integrating websites, mobile applications, viral marketing techniques and location-based tactics to get children to request and consume products.[57] Digital food marketing is problematic because of the difficulty children have recognizing its persuasive intent compared to a traditional television ad.[58] In a 2013 study, adults were able to identify all advertisements embedded in a mock webpage, whereas six-year-olds were only able to identify a quarter of them, eight-year-olds were able to identify about half of them, and ten-year-olds were able to identify three quarters of them.[59] It becomes even harder for children to recognize advertisements when they come in the form of engaging, interactive websites and mobile applications.[60] Thus, children are at a greater risk of being unfairly influenced because of their inability to recognize persuasive intent.[61] Because such an unfair influence has been considered a deceptive trade practice in news and marketing towards adults, the same sentiment should be expanded to cover more vulnerable populations such as children.[62]

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51. Prevention Inst., *The Facts on Junk Food Marketing and Kids*, PREVENTION INST., www.preventioninstitute.org/facts-junk-food-marketing-and-kids (last visited Apr. 30, 2020).
52. *Id.*
53. *Id.*
54. *Id.*
55. AM. HEART ASS'N, *supra* note 50.
56. The Public Health Advocacy Institute, STATE LAW APPROACHES TO ADDRESS DIGITAL FOOD MARKETING TO YOUTH 5 (2013).
57. *Id.*
58. *Id.*
59. *Id.*
60. *Id.*
61. *Id.*
62. *Id.*

REGULATION IN THE UNITED STATES

Unlike many countries around the world, the United States does not control or ban food advertising and marketing targeting children at the federal level.[63] Such regulations would fall under the purview of the Federal Trade Commission (FTC), which has unsuccessfully attempted to create such a regulation in the past.[64] In 1978, the FTC recognized the detrimental effect food marketing had on the youth in the nation.[65] The FTC commenced a public hearing after determining that advertising to children who could not distinguish the selling purpose of an advertisement was inherently unfair and deceptive.[66] The agency received enormous backlash from the food and beverage industry, and eventually food and beverage lobbyists got Congress involved.[67] In 1980, the industry and lobbyists prevailed by having Congress pass the Federal Trade Commission Improvement Act, which removed the FTC's rulemaking ability regarding addressing "unfair" advertising towards children.[68]

A second attempt at regulating food marketing towards children arose in 2009 with the bipartisan legislation creating the Interagency Working Group (IWG) on Food Marketed to Children.[69] The IWG was tasked with providing recommendations based on "robust, science-based nutrition principles."[70] Its proposals included adding a meaningful amount of healthy food such as fruits and vegetables to food products marketed to children, lowering the amount of sodium, saturated fat, and added sugar in food products, and restricting certain marketing practices based on an FTC study.[71] Many of these recommendations were met with resistance from industries saying the recommendations were unreasonable, and ultimately the IWG's efforts failed.[72]

Currently, the food and beverage industry has taken its own initiative to regulate marketing to children.[73] In 2007, food and beverage industry leaders created the Children's Food and Beverage Advertising Initiative

63. AM. HEART ASS'N,K, *supra* note 50.
64. Arid, *supra* note 12.
65. *Id.*
66. *Id.*
67. *Id.*
68. *Id.*
69. AM. HEART ASS'N, *supra* note 50.
70. *Id.*
71. William H. Dietz, *New Strategies To Improve Food Marketing To Children*, 32 HEALTH AFFAIRS 1652, 1654 (2013).
72. AM. HEART ASS'N, *supra* note 50.
73. CHILDREN'S FOOD AND BEVERAGE ADVERTISING INITIATIVE (CFBAI), https://bbbprograms.org/programs/cfbai/about-cfbai (last visited Apr. 30, 2020).

(CFBAI).[74] Participants pledge to advertise only foods or beverages that meet the Uniform Category Specific Nutrition Criteria.[75] A CFBAI administrator monitors child targeted ads for compliance in addition to participants submitting an annual self-assessment.[76] If the administrator finds non-compliance, the participant will be given notice and an opportunity to bring its conduct into compliance.[77] Failure to comply can result in dismissal from the program and/or referral to a regulatory agency.[78]

Although it is a step in the right direction, the CFBAI has been found to be fairly ineffective.[79] First, because it is a voluntary program, not all members in the industry are mandated to participate. As of 2019, the program only has nineteen participants.[80] Second, the soft penalties for non-compliance do not incentivize the participants to comply. In 2013, 75.3 percent of advertisements from CFBAI participants featured products deemed to be in the least healthy Health and Human Services (HHS) nutrition category.[81] Additionally, an overwhelming majority of all food advertisements from members and non-members were for unhealthy food products (80.5% of advertisements).[82] Such data suggests a more effective regulatory scheme should come from the government.

While the federal government and industry have been ineffective at regulating food marketing to children, state governments have had minor successes. For instance, in 2017 California passed AB 841 – Ban on advertising unhealthy foods in California schools.[83] This law bans schools from advertising unhealthy foods or beverages on campus during school hours, which includes corporate incentive programs that involve foods and beverages.[84] This not only covers traditional advertisements, but also programs such as the Box Tops for Education program, which despite rewarding schools for collecting box tops, the clippings usually come from products that are highly processed and full of added sugar, salt, and fat.[85] Initiatives, such as the one in California, could serve as a baseline on how to more effectively prevent obesity at the state level.

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74. *Id.*
75. *Id.*
76. *Id.*
77. *Id.*
78. *Id.*
79. Dale L. Kunkel et al., *Evaluating Industry Self-Regulation of Food Marketing to Children*, 49 AM. J. PREVENTIVE MED. 181, 181 (2015).
80. CFBAI, *supra* note 73.
81. Kunkel et al., *supra* note 79 at 184.
82. *Id.* at 183.
83. Assemb. B. 841 2017-2018 Reg. Sess. (Cal. 2018).
84. St. Germain, *supra* note 8.
85. *Id.*

REGULATION OUTSIDE OF THE UNITED STATES

Unlike the United States, other countries have had success in regulating food marketing to children at the federal level, which could provide a blueprint for future United States regulations. One example is the United Kingdom. In 2007, the United Kingdom passed the UK Code of Broadcast Advertising.[86] This code prohibits advertisements promoting high fat, sugar, and/or salt (HFSS) foods during and immediately before or after "programs commissioned for, principally directed at or likely to appeal particularly to audiences below the age of 16."[87] In 2017, the Committee of Advertising Practice (CAP) extended the restrictions to non-broadcast media such as the internet.[88] The rules apply to any media where the audience comprises at least twenty-five percent children and targets both direct and indirect promotion.[89] As of July 4, 2018, Cadbury, Chewits, and Squashies became the first companies to have an online advertisement banned by the new policy.[90] The banned activities included the use of an online storybook which featured children hunting for eggs, Facebook posts featuring a cartoon mascot, and an application featuring an advergame.[91]

In Canada, provincial efforts akin to the current situation in the United States where state laws find more success than federal government regulation have had some successes. In 1980, Quebec passed legislation that banned print and electronic advertisements for toys and fast food targeting children under thirteen years old.[92] Since then, the drop in spending on fast food has been estimated to be equivalent to $88 million USD in 2010.[93] Despite obesity among Canadian youths aged two through seventeen years old almost tripling in the past twenty-five years, Quebec has consistently had one of the lowest rates of childhood obesity of all the provinces showing that there may be merit in the policy.[94] A large caveat to this data is that it was compiled during the Internet's infancy, before it contained the data it has today.[95] Concerns of how to police such a

86. THE FOOD FOUNDATION, UK'S RESTRICTIONS ON JUNK FOOD ADVERTISING TO CHILDREN 5 (2017).

87. *Id.*

88. Cameron St. Germain, *Junk Food Advertising Restrictions for Youth, United Kingdom: Urban Food Policy Snapshot*, HUNTER COLL. N.Y.C. FOOD POLICY CTR. (Aug. 8, 2017), www.nycfoodpolicy.org/junk-food-advertising-restrictions-youth-united-kingdom-urban-food-policy-snapshot/.

89. *Id.*

90. BBC News, *First Ads Banned Under New Junk Food Rules*, BBC NEWS (July 4, 2018), www.bbc.com/news/uk-44706755.

91. *Id.*

92. Chai, *supra* note 6.

93. *Id.*

94. *Id.*

95. Phil Ciciora, *Study: Quebec Ban on Fast-Food Ads Reduced Consumption of Junk*

regulation applying to the Internet have been voiced.[96] One researcher suggested that the policy would be applicable to the United States, but only on a national level, stating

> [w]hat we found is that advertising bans are most effective when children live in an isolated media market, and it's only because they're in an isolated media market that they're getting these effects. If any state on their own decided to do this it would be problematic. If the U.S. as a whole decided to do it, our research indicates that such a ban could be successful.[97]

This would require the FTC to regain its regulatory power over advertisements directed at children.

CONCLUSION

Obesity continues to be prevalent in the United States, which in turn causes it to have an immense impact on the healthcare system directly and indirectly.[98] This burden is unsustainable. Therefore, prevention efforts to instill healthy habits in youth is paramount in reducing the economic impact of obesity.[99] More emphasis should be placed on regulating food marketing to children. Just as the FTC can declare marketing practices aimed at adults as unfair or deceptive, this authority should be expanded and strengthened by Congress to apply to children and teens.[100] By granting the FTC this power, the United States could set more effective regulations, similar to those in the United Kingdom and Quebec, than those set up by the CFBAI.[101]

Food, ILL. NEWS BUREAU (Jan. 19, 2012 9:00 AM), https://news.illinois.edu/view/6367/205158.

96. *Id.*
97. *Id.*
98. WATERS & DEVOL, *supra* note 3.
99. Lean et al., *supra* note 5.
100. The Public Health Advocacy Institute, *supra* note 56.
101. THE FOOD FOUNDATION, *supra* note 6; Chai, *supra* note 6; CFBAI, *supra* note 73.

Working for Whom?: How the Medicaid Work Requirements Leaves Those with Chronic Neurological Diseases Vulnerable and Fails to Increase Employment

Karin Long

Medicaid is a cornerstone of the American healthcare system—as the nation's largest health insurance provider for low-income persons, it can be the only mechanism standing between these individuals and the choice of financial ruin or denial of medical care.[1] The individuals that it supports include those with life-threatening illnesses, chronic illnesses, and disabilities.[2] For decades, Medicaid has had no relationship to an individual's employment status: the program was separated from welfare in the mid-1980's and became "a cornerstone of the welfare reform movement" because it allowed low-income individuals to maintain health insurance whether they were working or on welfare.[3] Beneficiaries had long felt they had to choose between jobs without insurance and Medicaid-backed healthcare, and thus the separation allowed Medicaid to stand alone as a health insurance option for those in need, regardless of employment or welfare status.[4] In 2018, Medicaid and employment re-entered the national conversation when the Trump administration introduced guidance for a

1. Robin Rudowitz et al., *10 Things to Know about Medicaid: Setting the Facts Straight,* KAISER FAMILY FOUNDATION (Mar. 6, 2019), https://www.kff.org/medicaid/issue-brief/10-things-to-know-about-medicaid-setting-the-facts-straight/?gclid=Cj0KCQiAsvTxBRDkARIsAH4W_j89F4YG2F1Amc (stating that Medicaid is the United States' largest health insurance program for people with low income, covering one in five Americans, many who have "complex and costly needs for care" and that the vast majority of Medicaid recipients lack access to other affordable health insurance).

2. Rudowitz, *supra* note 1 (stating that Medicaid covers forty-five percent of nonelderly adults with special needs, randing from Alzheimer's to traumatic brain injuries).

3. Drew Altman & Dennis F. Beatric, *Perspective on the Medicaid Program*, HEALTH CARE FINANCING REVIEW HEALTH CARE FINANCING ADMINISTRATION (1990) (stating that "welfare recipients almost always cite the fear of losing health insurance as a major disincentive to leaving weldare and going to work").

4. Altman, *supra* note 3.

work requirement which states could attach to their Medicaid programs.[5] The administration's proposed work requirement should be rejected because it will harm individuals with chronic neurological illnesses and fail to increase employment.[6] Studies have shown that those with chronic illnesses affecting the neurological system, such as Multiple Sclerosis (MS) and Parkinson's Disease, face higher rates of unemployment[7] and are thus disproportionately affected by such a contingency to Medicaid. While individuals with certain medical issues can be exempted when they cannot work, the current exemptions fail to protect these individuals from losing coverage.[8]

Historically, conservatives have viewed safety net public assistance programs as mechanisms to bridge the gap between periods of self-sufficiency, developing each program as a short-term solution to a short-term problem.[9] Accordingly, Republicans hold out work requirements as mechanisms to encourage unemployed, able-bodied beneficiaries to rejoin the workforce, achieve self-sufficiency, and no longer rely upon Medicaid.[10] But chronic diseases that have no cure like MS, a disease of the

5. RACHEL GARFIELD ET AL., KAISER FAMILY FOUNDATION 1 (2019).

6. Benjamin D. Sommers et al., *Medicaid Work Requirements — Results from the First Year in Arkansas*, N. ENGL. J. MED. 8 (2019), www.nejm.org/doi/full/10.1056/NEJMsr1901772?url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org&rfr_dat=cr_pub%3Dpubmed (stating that implementation of the Trump administration's Medicaid work requirement in 2018 was associated with significant losses in health insurance coverage in the initial six months of the policy but no significant change in employment); Lisa Rapaport, *Medicaid work rules likely to penalize chronically ill: study*, REUTERS (May 10, 2019), www.reuters.com/article/us-health-medicaid-work/medicaid-work-rules-likely-to-penalize-chronically-ill-study-idUSKCN1SG2H8

(statint that opponents to the work requirement "argue that cutting off benefits for people too sick to work prevents them from getting healthy enough to hold down jobs").

7. L.B. Strober & R.M. Callahan, *Unemployment in multiple sclerosis across the ages: How factors of unemployment differ among the decades of life,* J. OF HEALTH PSYCHOLOGY ONLINE (2019) (stating that rates of unemployment among those with MS are between forty and eighty percent compared to over ninety percent before the onset of their disease); Anette Schrag & Pauline Banks, *Time of loss of employment in Parkinson's disease*, 21 MOVEMENT DISORDERS 1839, 1840 (2006) (stating that in a study of 151 and 308 patients with Parkinson's disease fifty-two percent and fifty-six percent of patients had retired early due to Parkinson's, sixteen and five percent of patients were unemployed, and eight and eleven percent were part-time–employed).

8. Judith Solomon, *Medicaid Work Requirements Can't Be Fixed*, CENTER ON BUDGET AND POLICY PRIORITIES (Jan. 10, 209), https://www.cbpp.org/research/health/medicaid-work-requirements-cant-be-fixed (stating that many Medicaid adults lose coverage because the system is complicated and difficult to navigate).

9. Rapaport, *supra* note 6 (stating that "proponents of a Medicaid work requirements maintain that benefits are only meant to be temporary and that employment will help people move out of poverty").

10. Michael Strain, *What's so 'cruel' about Medicaid work requirements*, AMERICAN ENTERPRISE INSTITUTE (Jan. 17, 2018), www.aei.org/health-policy/whats-so-cruel-about-

central nervous system caused by an autoimmune disorder, and Parkinson's, a degenerative neurological disease,[11] have higher instances of unemployment and early retirement, most often because these individuals cannot return to work due to their illness.[12] Accordingly, the goal of Medicaid should be to support those who have low or no income by providing them necessary health insurance. In its current state, the system is difficult to navigate, making it challenging for individuals to keep the benefits to which they are entitled, and leaving vulnerable individuals without the critical medical care that they need at worst.[13] For those reasons and others, the Trump administration's work requirement guidance should be rejected and work requirements should not be a condition of Medicaid entitlement.

THE ROLE OF MEDICAID

Medicaid is a public assistance program designed to provide health insurance to those are categorically needy, based on income.[14] It is a joint federal and state program: the federal government provides funding and guidance, and the states tailor their programs as they see fit.[15] One method

medicaid-work-requirements/ (maintaining that the work requirements are "completely reasonable" because they allow exceptions for some parts of the population and do not force states to impose them).

11. *See* MedlinePlus, *Neurological Diseases*, https://medlineplus.gov/neurologicdiseases.html (last seen Apr. 15, 2020) (stating that Parkinson's is a neurological disease); *see also* Columbia Neurology, *Multiple Sclerosis*, www.columbianeurology.org/neurology/staywell/document.php?id=33922 (last seen Apr. 15, 2020) (stating that Multiple Sclerosis is a central nervous system autoimmune disorder); *see also* National Health Service, Treatment: Multiple Sclerosis, www.nhs.uk/conditions/multiple-sclerosis/treatment/ (last seen Apr. 15, 2020) (stating that while Multiple Sclerosis can be managed through medicines, there is no cure); *see also* MayoClinic, *Parkinson's disease*, https://www.mayoclinic.org/diseases-conditions/parkinsons-disease/diagnosis-treatment/drc-20376062 (last visited Apr. 15, 2020) (stating that Parkinson's has no cure).

12. *See* Strober *supra* note 7, at 3 (study examined rates of unemployment and risks of unemployment in individuals in multiple sclerosis); *see* Schrag *supra* note 7, at 1840 (article examined time to loss of employment in two U.K.-based studies of 151 and 308 patients with Parkinson's disease).

13. *See* Rapaport, *supra* note 9 (stating that poor health can make it difficult for people to find and keep a job); *see also* Solomon *supra* note 8 (stating that many Medicaid adults lose coverage because the system is complicated and difficult to navigate).

14. Center on Budget and Policy Priorities, *Policy Basics: Introduction to Medicaid*, www.cbpp.org/research/health/policy-basics-introduction-to-medicaid (last updated Aug. 16, 2016).

15. Rapaport, *supra* note 6; *see also* MARYBETH MUSUMECI & ROBIN RUDOWITZ, THE KAISER COMMISSION ON MEDICAID AND THE UNINSURED 1 (2015) (The most prominent recent example of a waiver program is the Affordable Care Act, which established that states that wished to receive increased federal funding for their Medicaid programs would be required to "expand" Medicaid coverage to everyone under 138 percent of the Federal poverty Line. States then had the option to apply for Section 1115 waivers to receive more

by which states individualize their programs is through Section 1115 waivers.[16] These waivers must further "an experimental, pilot, or demonstration project which, in the judgment of the Secretary, is likely to assist in promoting the objectives of [Medicaid]," but in practice the waivers fall into two categories—expanding coverage and restricting coverage.[17] Liberal policymakers have historically supported expansion, arguing that the goal of Medicaid is to provide health insurance to any low-income individual who needs it.[18] Conversely, conservative policymakers have historically supported limitations on coverage through waivers with mechanisms like work requirements and higher income requirements to limit dependence on Medicaid as a long-term health insurance option.[19]

In 2019, the Center for Medicare and Medicaid Services (CMS) under the Trump administration issued guidance for states to apply for waivers to add a work requirement as a condition of eligibility for Medicaid.[20] As of March 2020, Indiana and Utah's waivers were approved and implemented; Arizona, Ohio, and Wisconsin's were approved and not implemented; ten states' were pending; and four states' waivers were set aside by a court, including Kentucky, whose case was decided in March of the previous year.[21] Conservative policymakers argue that the work requirement will lead to higher employment among the Medicaid population and maintain that the proposed exemptions for those who cannot work are adequately protecting them from losing coverage.[22] However, the negative effects of these waivers are already becoming clear: in Arkansas, the first state to implement the work requirement waiver, over 18,000 beneficiaries have

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flexibility within each individual program.)

16. Mary Leto Pareja, *Humanizing Work Requirements for Safety Net Programs*, 39 PACE L. REV. 833, 852 (2019) (stating that states can apply for a waiver of certain aspects of the Medicaid program under Section 1115 of the Social Security Act).

17. *Id*. at 852-53.

18. *Id.* at 833-34 (stating that politicians on the left have been proposing various forms of universal, or expanded, health care).

19. *Id.* at 834 (stating that politicians on the right to condition the receipt of much publicly financed health care on work).

20. GARFIELD, *supra* note 5.

21. Keiser Family Foundation, *Medicaid Waiver Tracker: Approved and Pending Section 1115 Waivers by State* (Apr. 7, 2020), www.kff.org/medicaid/issue-brief/medicaid-waiver-tracker-approved-and-pending-section-1115-waivers-by-state/ (tracking the status of each state's waiver and stating that Alabama, Georgia, Idaho, Mississippi, Montana, Nebraska, Oklahoma, South Dakota, Tennessee, Virginia have pending waivers); *Stewart v. Azar*, 366 F. Supp. 3d 125 (D.D.C. 2019) (vacating Kentucky's waiver approval and remanding to Health and Human Services to consider how the waiver would help furnish medical assistance consistent with Medicaid program objectives).

22. Doug Badger, *Medicaid Work Requirements Could Help the Poor*, THE HERITAGE INSTITUTE (Jan. 9, 2019), www.heritage.org/medicaid/commentary/medicaid-work-requirements-could-help-the-poor.

lost Medicaid coverage and will likely become uninsured.[23] Implementing a work requirement that is difficult for employed beneficiaries to fulfill[24] and difficult for those who are not-able-bodied to seek exemption from[25] leaves states with large populations of uninsured individuals and exposes vulnerable individuals to losing the healthcare upon which their lives depend.[26]

WORK REQUIREMENTS AS A CONDITION OF PUBLIC ASSISTANCE

The work requirement was first introduced as a condition to receiving public assistance when Republicans and other conservatives attached it to food assistance programs in the mid-1980's and housing assistance programs in the mid-1990's.[27] Historically, both Democrats and Republicans have supported "welfare to work," a phrase indicating that welfare was to be the step before earning an income.[28] Between 1995 and 1996, Congress passed the Personal Responsibility and Work Opportunity Reconciliation Act and replaced Aid to Families with Dependent Children with Temporary Assistance to Needy Families ("TANF"), establishing work requirements for existing cash assistance programs.[29] The legislation resulted in a decline in TANF and welfare caseloads, which conservatives hoped indicated that their program had succeeded.[30] However, data published by authors at the University of Kentucky's Department of Economics shows that more than a decade after TANF, individuals in the population affected became employed and gained income, but that those gains in income were "more than offset by losses in transfer income," meaning that their after-tax income fell overall.[31]

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23. Jessica Schubel, *Arizona Should Reconsider Policies That Will Take Away Medicaid, Increase Hardship*, CENTER ON BUDGET AND POLICY PRIORITIES (January 18, 2019, 5:15 PM), www.cbpp.org/blog/arizona-should-reconsider-policies-that-will-take-away-medicaid-increase-hardship.

24. *Id.* (stating that many working Arizonans will be unable to meet the eighty-hour requirement because they work in industries like retail, home health, and construction where hours fluctuate from month to month and there is little flexibility, resulting in any illness, family emergency, or disruption in child care or transportation costing their jobs).

25. *Id.* (stating that people with disabilities or serious illnesses may lose coverage because they don't meet the standards to qualify for exemptions, don't know they qualify, or have a hard time providing the necessary documentation).

26. *Id.* (stating that Arizona seems ready to implement the work requirement despite mounting evidence that many of those losing coverage will be working people and people with serious health needs who cannot overcome the red tape that these policies create).

27. Allyson Baughman, *A History of Work Requirements*, PUBLIC HEALTH POST (Feb. 12, 2018), www.publichealthpost.org/viewpoints/history-of-work-requirements/.

28. *Id.*

29. *Id.*

30. *Id.*

31. Chris Bollinger et al., *Welfare reform and the level and composition of income* (Sep.

Although work requirements have been attached to cash assistance programs like TANF for decades, their addition to safety net programs like Medicaid is unprecedented.[32] Again, conservatives' goal for Medicaid is that it be a stop-gap program, and they thus argue that work requirements will encourage those who can work to do so, ultimately gaining independence and no longer needing Medicaid.[33] Conversely, liberals' goal for Medicaid is to provide health insurance to low-income individuals.[34] A work requirement will thus not only do nothing to help achieve liberals' goal, but will arguably pose a new obstacle to achieving it, a point illustrated by a recent study on the outcome of the Trump administration's work requirement's first year of implementation.[35] The study found that "implementation of the first-ever work requirements in Medicaid in 2018 was associated with significant losses in health insurance coverage in the initial six months of the policy but no significant change in employment."[36]

While supporters of work requirements aim to push beneficiaries to independence through higher employment, data shows that these requirements do not actually increase employment among Medicaid beneficiaries.[37] Sixty-three percent of "Medicaid adults," or non-elderly adults who rely on Medicaid but not social security benefits, are already working.[38] Among those Medicaid adults who are not working, many report illness and disability as barriers to work.[39] Adding to the policy's failure, the Trump administration's work requirement guidance does nothing to target Medicaid adults who are able to work but are unemployed, which describes just seven percent of the Medicaid population.[40] Rather than being tailored to target that seven percent, the requirement applies to all Medicaid adults and relies on the establishment of exceptions to the requirement to protect those who cannot work.[41] Further, the guidance provides no resources to connect able-bodied, unemployed Medicaid adults with

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2007), www.researchgate.net/publication/228360525_Welfare_reform_and_the_level_and_composition_of_income (DOI: 10.1017/CBO9780511605383.004).

32. Pareja, *supra* note 16, at 834.

33. Rapaport, *supra* note 6.

34. Thomas Bodenheimer, *The Political Divide in Health Care: A Liberal Perspective*, 24 HEALTH AFFAIRS 6 (Nov. 2005), www.healthaffairs.org/doi/full/10.1377/hlthaff.24.6.1426.

35. Sommers, *supra* note 6.

36. *Id.*

37. GARFIELD, *supra* note 20, at 18.

38. *Id.* at 2.

39. *Id.*

40. *Id.*

41. *Id.*

employment to achieve the policy's goal.[42] Accordingly, the broad application of the requirement puts non-able-bodied Medicaid adults at risk of losing coverage, and does little to actually increase employment among the narrow population that is unemployed, able-bodied Medicaid adults.[43]

Although exemptions are available for those who cannot work, they often involve great lengths of bureaucracy that can be difficult for individuals on public assistance—often with less education, time, and support to navigate the system—to utilize to their full extent.[44] Donald Moynihan, a professor of public affairs at the University of Wisconsin-Madison, told the New York Times: "Without being tremendously well organized, it can be easy to fail. These sorts of little barriers are ways in which humans get tripped up all the time when they're trying to do something that might benefit them."[45] In Medicaid specifically, research has found that an increase in complications leads to a decrease in sign-ups, and thus a decrease in coverage.[46] The general complexity that exists for individuals navigating government programs is exacerbated for low-income individuals who lack access to reliable transportation, a bank account, and the internet, which is particularly concerning for Medicaid beneficiaries.[47] Advocates for the work requirement argue that it will "help teach low-income people to take more responsibility for their health"[48]—yet this leads one to ponder, when did teaching responsibility become a goal of the sole federal program providing health insurance to the categorically needy?

ARIZONA: ILLUSTRATING THE POLICY'S FAILURES

Arizona provides an example of the work requirement's pitfalls when implemented in its original form.[49] In December of 2017, Arizona submitted a Section 1115 waiver request to CMS which would allow Arizona's Medicaid program to deny coverage to or disenroll individuals who did not meet its proposed work requirement.[50] This policy required that individuals between the ages of nineteen and fifty-four years old spend at

42. Solomon, *supra* note 8 (noting that work requirements do not accurately identify those who can work but are not working, nor do they assess their needs or provide them with supports).

43. *Id.*

44. Rapaport, *supra* note 9.

45. Margot Sanger-Katz, *Hate Paperwork? Medicaid Recipients Will Be Drowning in It*, N.Y. TIMES (Jan. 18, 2018) www.nytimes.com/2018/01/18/upshot/medicaid-enrollment-obstacles-kentucky-work-requirement.html.

46. *Id.*

47. *Id.*

48. *Id.*

49. DOUGLAS A. DUCEY, ARIZONA HEALTH CARE COST CONTAINMENT ASSOCIATION, 3 (2017).

50. *Id.*

least twenty hours per week working, attending school, attending an Employment Support and Development Program, or a combination of those three.[51] Before its implementation, it was estimated that 120,000 adults in Arizona would be affected by the waiver, which would lead to a decline in health outcomes for low-income adults. and cause thousands of residents to "face greater financial insecurity."[52]

Arizona's waiver application offered fourteen exemptions intended to protect certain populations from losing coverage.[53] Health-related exemptions exist for groups such as individuals currently receiving temporary or permanent long-term disability benefits from a private insurer or from the government and individuals who were determined to be "medically frail."[54] The waiver application and policy proposal provided no information on how to apply for exemptions,[55] and as noted by Mental Health America of Arizona, provided no definition for "able-bodied."[56] Due to this extensive red-tape, people with chronic illnesses were at risk of losing coverage because they failed to meet the standards to qualify for exemptions, did not know they could qualify, or had trouble providing the necessary documentation.[57] Since CMS granted the waiver request, Arizona's work requirement has been suspended due to "the evolving national landscape concerning Medicaid. . .and ongoing litigation regarding the topic."[58] The litigation referred to is *Stewart v. Azar*, in which a federal judge blocked Medicaid work requirements in Arkansas and Kentucky for failing to consider the number of Medicaid recipients who would lose coverage under the policy and deeming the granting of the waivers "arbitrary and capricious."[59]

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51. *Id.* at 7.

52. Schubel, *supra* note 23.

53. DUCEY, *supra* note 49, at 12 (noting that criteria ranges from age to American Indian status to homelessness to caregiver status).

54. *Id.* at 5.

55. Ariz. Rev. Stat. 36-2903.09 (The law states that exemptions are to be "allowed for" if a person is at least nineteen years of age but is still attending high school as a full-time student, is the sole caregiver of a family member who is under six years of age, or is currently receiving temporary or permanent long-term disability benefits from a private insurer or from the government, but makes no mention of how one would apply for said exemption.)

56. AHCCCS, LETTER FROM KRISTINA SABATTA TO AHCCCS 172 (Feb. 17, 2017). (Letter requesting, among other things, that "able-bodied" to be defined.)

57. Schubel, *supra* note 23.

58. LETTER FROM DIRECTOR JAMI SNYDER TO ADMINISTRATOR CALDER LYNCH 1 (Oct. 17, 2019).

59. Dylan Scott, *Federal judge blocks Medicaid work requirements in Arkansas and Kentucky*, Vox (Mar. 27, 2019), www.vox.com/policy-and-politics/2019/3/27/18284501/arkanas-kentucky-medicaid-work-requirement-judge-ruling; see also *Stewart v. Azar*, 366 F. Supp. 3d 125 (D.D.C. 2019) (holding that "weighing the harms these persons will suffer from leaving in place a legally deficient order against the

CHRONIC NEUROLOGICAL DISEASES & EMPLOYMENT

The Centers for Disease Control and Prevention (CDC) defines chronic illnesses as conditions that last one year or more and require ongoing medical attention or limit activities of daily living or both,[60] and thus this population is especially in need of health insurance coverage. Individuals who have chronic neurological diseases like Parkinson's and MS have higher unemployment and early retirement rates because the effects of these diseases make working difficult or impossible; these effects include poor balance and difficulty walking, incontinence, fatigue, and cognitive difficulties for those with MS.[61]

For those who are categorically needy and cannot work, Medicaid is not a stop-gap program, but instead is one in five of Americans' only option for health insurance.[62] Further, it is a program relied upon by almost half of all disabled adults: in a typical state, 45% of non-elderly adults with disabilities are covered by Medicaid.[63] For those with chronic illnesses who cannot work and thus receive employer insurance, government-sponsored insurance is their only option.[64] This is significant because as of 2018, the Federal Reserve reported that thirty-nine percent of Americans cannot afford a $400 bill,[65] and as of 2019, a study found that 137 million Americans reported medical financial hardship in the last year.[66]

Thus, cracks left by poor exemption structures in Medicaid work requirements leave those with chronic diseases like MS and Parkinson's who are categorically needy especially vulnerable. These diseases have a variety of physical and mental effects and often, as with many other

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disruptions to the State's data-collection and education efforts due to vacatur renders a clear answer: the Arkansas Works Amendments cannot stand").

60. Centers for Disease Control & Prevention, *About Chronic Diseases* (Oct. 23, 2019), www.cdc.gov/chronicdisease/about/index.htm.

61. Strober, *supra* note 7 (stating that rates of unemployment among those with MS are between forty and eighty percent compared to over ninety percent before the onset of their disease).

62. Rudowitz, *supra* note 1.

63. *Id.* (stating that nonelderly adults with disabilities includes physical disabilities, developmental disabilities such as autism, traumatic brain injury, serious mental illness, and Alzheimer's disease).

64. HEALTHCARE.GOV, *Health coverage options if you're unemployed*, https://www.healthcare.gov/unemployed/coverage/ (last visited Apr. 15, 2020) (stating that if you are unemployed, you may be able to get health insurance through the Marketplace, Medicaid, or CHIPS, all government-operated options).

65. THE FEDERAL RESERVE, *Dealing with Unexpected Expenses*, https://www.federalreserve.gov/publications/2019-economic-well-being-of-us-households-in-2018-dealing-with-unexpected-expenses.htm (last updated May 28, 2019).

66. K. Robin Yabroff et al., *Prevalence and Correlates of Medical Financial Hardship in the USA*, 34 J. GEN. INTERNAL MED. 1494 (2019), https://link.springer.com/article/10.1007/s11606-019-05002-w.

disabilities, lead to higher rates of unemployment and early retirement.[67] The Department of Labor reported in 2018 that the unemployment rate for the general population was 3.7%, while the rate for those with disabilities was over double that at eight percent.[68] For those with disabilities, specifically chronic neurological diseases, Medicaid is not "welfare to work"—it is the safety net they need to afford the healthcare they require to survive.

Studies have shown that for many neurological diseases, employment is adversely affected, and many individuals must leave work while still of working age or retire early.[69] While most people with MS report being gainfully employed before their diagnosis, a study conducted by Dr. Lauren Strober, PhD, a Senior Research Scientist at the Center for Neuropsychology and Neuroscience Research,[70] found that forty to eighty percent of those with MS have reported becoming unemployed during their working years after their diagnosis as a consequence of the disease.[71] Additionally, Dr. Anette Schrag, PhD, of the University College of London Queen Square Institute of Neurology, and Pauline Banks, PhD, of the University of Glasgow,[72] found that of those with Parkinson's who were diagnosed before the age of sixty-five, the unemployment rate was higher than that of the general population: in studies of 151 and 308 patients with Parkinson's, fifty-two and fifty-six percent retired early due to Parkinson's Disease, sixteen and five percent were unemployed, and eight and eleven percent were employed part-time.[73] Accordingly, those with chronic neurological diseases like MS and Parkinson's are at risk to be unable to meet the work requirement either because they have permanently left the work force, or because they are forced to work part-time and cannot meet the number of hours mandated by the Trump administration's guidance.[74]

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67. *See* Strober, *supra* note 7 (stating that rates of unemployment among those with MS are between forty and eighty percent compared to over ninety percent before the onset of their disease); *see also* Schrag *supra* note 7, at 1840 (stating that in a study of 151 and 308 patients with Parkinson's disease fifty-two percent and fifty-six percent of patients had retired early due to Parkinson's, sixteen percent and five percent of patients were unemployed, and eight percent and eleven percent were part-time–employed).

68. Bureau of Labor Statistics, *Persons with a Disability: Labor Force Characteristics—2018*, U.S. DEPARTMENT OF LABOR (Feb. 26, 2019) at 1.

69. Strober, *supra* note 7 (stating the findings in a study of individuals with MS); Schrag *supra* note 7, at 1840 (stating the findings in a study of individuals with Parkinson's).

70. Strober, *supra* note 7.

71. *Id.*

72. Schrag, *supra* note 7, at 1839.

73. *Id.* at 1840.

74. *See* Strober, *supra* note 7 (stating that rates of unemployment among those with MS are between forty and eighty percent compared to over ninety percent before the onset of their disease); *see also* Schrag, *supra* note 7, at 1840 (stating that in a study of 151 and 308 patients with Parkinson's disease fifty-two and fifty-six percent of patients had retired early

The waiver guidance includes exemptions intended to protect coverage for those who are unable to work based on disability, but the process of applying for an exemption is complex and time-consuming, leading to disabled beneficiaries losing the coverage to which they are entitled.[75] Studies show that making one's way through this system requires time, education/knowledge, and ability, privileges which those who are categorically poor and disabled or chronically ill often lack.[76] The exception process requires even more paperwork and red tape than simply applying for Medicaid, and efforts to educate beneficiaries are bound to fall short as they historically have.[77] For example, Arkansas, the first state to implement work requirements for Medicaid, has shown that many who are working and meet the requirement still have difficulty obtaining and maintaining coverage.[78] Many whose income meets the Medicaid income requirement are working low wage jobs that have volatile hours, and accordingly even some of those who work have difficulty meeting the intricacies of the work requirement.[79] Thus not only are those who cannot work put at risk by a work requirement, but even those who are working and fulfilling the goals of conservatives are at risk to lose their health insurance.[80] For those foregoing reasons, in order to protect beneficiaries of Medicaid, the work requirement should be rejected as a Section 1115 waiver and employment in the Medicaid population should be tackled instead with targeted programs that do not put their coverage at risk.

CONCLUSION

While work requirements have been useful and supported by liberals and conservatives alike for cash assistance programs, their addition to Medicaid as a safety net program would cause a myriad of issues. Those with chronic neurological diseases would be adversely impacted because they experience unemployment and early retirement in higher figures than the general population. And because the states who were initially granted waivers have not had clear paths to applying for exemptions, Medicaid beneficiaries with less resources face significant hurdles to maintaining coverage. Further, the requirement does not do enough to achieve the conservatives' goal: increasing employment. Thus, the Trump administration's waiver guidance

due to Parkinson's, sixteen percent and five percent of patients were unemployed, and eight percent and eleven percent were part-time–employed).

75. *See* Solomon, *supra* note 8 (stating that many Medicaid adults lose coverage because the system is complicated and difficult to navigate).

76. *Id.*

77. *Id.*

78. *Id.*

79. *Id.*

80. *Id.*

adding a work requirement to Medicaid should be rejected.

Diabetes Increases Health Care Costs in the United States: How Focusing on Self-Management & the Patient-Physician Relationship Will Curb Costs

Sunaina Ramesh

INTRODUCTION

Chronic diseases are highly prevalent in the United States.[1] Chronic diseases are " conditions that last one year or more and require ongoing medical attention and/or conditions that limit activities of daily living."[2] Common chronic diseases and conditions such as heart disease, cancer, diabetes, stroke and arthritis leads to a higher chances of death and disability.[3] Individuals with chronic conditions tend to use more health care services.[4] Additionally, they account for ninety-one percent of all prescriptions filled and seventy-six percent of all physician visits.[5]

Individuals over sixty-five years old make up the largest portion of the diabetic population.[6] In 2020, the cost of diabetes is projected to reach $3.4 trillion.[7] Type 2 diabetes can result from both genetic and lifestyle factors.[8] Older adults and those with conditions including obesity, high blood pressure, family members with diabetes, gestational diabetes are at a higher

1. Laura Jost, *Identifying the Most Prevalent and Costly Chronic Conditions in Medicaid*, AJMC (Nov. 28, 2017), https://www.ajmc.com/newsroom/identifying-the-most-prevalent-and-costly-chronic-conditions-in-medicaid.

2. About Chronic Diseases, CENTERS FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/chronicdisease/about/index.htm (last visited Apr. 12, 2020).

3. *Chronic Diseases and Conditions*, NY STATE DEP'T OF HEALTH, https://www.health.ny.gov/diseases/chronic/ (last visited Mar. 15, 2020).

4. PARTNERSHIP TO FIGHT CHRONIC DISEASE, THE GROWING CRISIS OF CHRONIC DISEASE IN THE UNITED STATES, https://www.fightchronicdisease.org/sites/default/files/docs/GrowingCrisisofChronicDiseaseintheUSfactsheet_81009.pdf (last visited Apr. 12, 2020).

5. *Id*.

6. Jennifer Berry, *Statistics and facts about type 2 diabetes*, MEDICALNEWSTODAY (April 1, 2019), https://www.medicalnewstoday.com/articles/318472.php.

7. *Diabetes costs projected to soar to $3.4 trillion by 2020*, ENDOCRINE TODAY (Dec. 2010), https://www.healio.com/endocrinology/diabetes/news/print/endocrine-today/%7B8bc9192b-3a62-43ba-9835-ba74937a1f18%7D/diabetes-costs-projected-to-soar-to-34-trillion-by-2020.

8. Berry, *supra* note 6.

risk for type 2 diabetes.[9] Diabetes is currently the seventh leading cause of death in the United States, with most deaths resulting from complications of the disease.[10]

This article will specifically focus on how the healthcare system must focus on self-management of type 2 diabetes through physician-patient communication and urging preventative care, which will be paramount to curbing the rising healthcare costs contributed by diabetes. First, the article will discuss the general costs of treating diabetes. Next, the article will discuss the role of self-management programs to assist in curbing growing health care costs. Lastly, the article will discuss the importance of the patient-physician relationship through information technology and self-care to lower costs overall.

TYPE 2 DIABETES

Diabetes is one of the most expensive chronic disease in the United States[11], given both the high medical costs and reduced productivity associated with the disease.[12] Most of the costs are covered by government insurance programs, such as Medicare and Medicaid.[13] The rest of the costs are covered by private insurance or by the uninsured.[14] By 2050, it is estimated that between twenty-five and thirty-three percent of American adults could have diabetes, whether it be diagnosed or undiagnosed.[15]

Type 2 diabetes mellitus is a chronic condition that keeps the body from effectively using insulin to bring glucose into the cells.[16] About ninety to ninety-five percent people diagnosed with diabetes are diagnosed with type 2 while five percent are diagnosed with type 1.[17]

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9. *Id*.

10. *Id*.

11. *Top 10 Most Expensive Chronic Diseases for Healthcare Payers*, HEALTHPAYERINTELLIGENCE, https://healthpayerintelligence.com/news/top-10-most-expensive-chronic-diseases-for-healthcare-payers (last visited Apr. 30, 2020).

12. American Diabetes Association, *Economic Costs of Diabetes in the U.S. in 2017*, 41 DIABETES CARE 917, 917 (Mar. 22, 2018).

13. *The Cost of Diabetes*, AM. DIABETES ASS'N (Mar. 2018), https://www.diabetes.org/resources/statistics/cost-diabetes.

14. *Id*.

15. Sara Lindberg, *Cost of Type 2 Diabetes*, HEALTHLINE (Oct. 25, 2018), https://www.healthline.com/health/cost-of-diabetes#1.

16. Ann Pietrangelo, *Understanding Type 2 Diabetes*, HEALTHLINE (May 28, 2019), https://www.healthline.com/health/type-2-diabetes#symptoms.

17. Berry, *supra* note 6; *See* Melissa Conrad Stöppler, *Type 1 vs. Type 2 Diabetes: Which One Is Worse*, MEDICINENET, https://www.medicinenet.com/type_1_vs_type_2_diabetes_similarities_differences/article.htm#what_is_diabetes (last visited Apr. 12, 2020) (noting that type 1 diabetes is where the patient does not have insulin in their body).

COSTS OF TREATING DIABETES

The costs begin to rise for patients once they are diagnosed with diabetes. Those with diabetes must pay for necessary medical supplies, doctor's visits, hospital care, and prescription medications.[18] Diabetes-related costs drivers include the high-costs of managing common diabetes-related comorbidities, "which can affect patient's daily functioning and quality of life and may increase mortality risk."[19] An average of $16,572 per year is spent on medical costs by diabetic patients.[20] Over a lifetime, these costs can range between $55,000 to $130,000.[21] These direct medical costs include inpatient care, prescription medications to treat complications, diabetes supplies and physician office visits.[22] An average hospital stay for a diabetes patient in California costs about $2,200 more than for a patient without diabetes.[23]

Common complications associated with diabetes significantly affects the cost of treatment.[24] Diabetes-related complications include chronic kidney disease, end-stage renal disease, peripheral neuropathy and retinopathy and macro/microvascular disease.[25] Treatment of these additional complications add onto the already high-costs associated with diabetes, often resulting in a 70 to 150 percent increase in costs.[26]

Treating diabetes often involves insulin therapy[27], however the cost of insulin is expensive.[28] In the United States, the rising costs of insulin is

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18. Jennifer Dorsey, *Cost of Diabetes- Insurance, Insulin Prices and Complications,* HEALTHE DEALS (Jul. 5, 2018), https://www.healthedeals.com/blog/save/diabetes-costs/.

19. Vincent J. Willey et al., *Estimating the Real-World Cost of Diabetes Mellitus in the United States During an 8-Year Period Using 2 Cost Methodologies*, 11 AM. HEALTH & DRUG BENEFITS 310, 311 (2018). *See The Comorbidity of Two Disorders*, VERYWELLMIND (Feb. 21, 2020), https://www.verywellmind.com/what-is-comorbidity-3024480 (explaining comorbidities as the presence of more than one disorder in the same person).

20. Dorsey, *supra* note 18.

21. Marlene Busko, *Lifetime Cost of Treating Diabetes in US: Around $85,000*, MEDSCAPE (Aug. 13, 2013), https://www.medscape.com/viewarticle/809547.

22. AM. DIABETES ASS'N, *supra* note 13.

23. Anthony Cannon et al., *Burden of Illness in Type 2 Diabetes Mellitus*, 24 SUPP. J. MANAGED CARE & SPECIALTY PHARMACY S5, S8 (2018).

24. Wenya Yang et al., *Economic Costs of Diabetes in the U.S. in 2017*, 41 DIABETES CARE 917, 918 (2018) ("Diabetes also increases the cost of treating general conditions that are not directly related to diabetes.")

25. Cannon, *supra* note 23, at S5.

26. Li et al., *Medical Costs Associated With Type 2 Diabetes Complications and Comorbidities*, 19 AM. J. MANAGED CARE 1, 1 (2013).

27. *Insulin Therapy for Type 2 Diabetes*, WEBMD, https://www.webmd.com/diabetes/type-two-diabetes-insulin-therapy (last visited Apr. 28, 2020).

28. Danielle K. Roberts, *The Deadly Costs of Insulin*, AJMC (Jun. 10, 2019), https://www.ajmc.com/contributor/danielle-roberts/2019/06/the-deadly-costs-of-insulin.

being referred to as the "insulin crisis."[29] Patients tend to pay around $300 to $800 out-of-pocket a month for their insulin prescription.[30] The average out-of-pocket monthly diabetes cost of insulin and other diabetic supplies is $360.[31] In countries such as India, Japan, the United Kingdom and Italy, insulin prices are three to four times less than in the United States.[32] The high costs can be attributed to the free market approach towards pharmaceuticals.[33] In the free market approach, pharmaceuticals have almost full control over pricing which in turn leads to price surges.[34]

These costs often have a negative financial impact on the individual, alongside all the other costs, leading to insulation rationing.[35] Patients who ration their insulin take smaller doses or skip their doses, leading to deathly results.[36] Individuals who ration insulin have higher rates of complications and provide higher overall costs absorbed by the health care system.[37] Therefore, a diagnosis of diabetes is very costly: it leads to higher costs for both patients and the health care system.

FOCUSING ON SELF-MANAGEMENT TO REDUCE COSTS

The American Diabetes Association reports that the "United States health care system will be unable to afford the high costs of care unless incidence rates and related complications are reduced."[38] Healthcare costs for chronic conditions are rising because of the costs related to diabetes, however, there are proven methods to reduce the costs as well as improve patient well-being.[39] Methods such as self-management emphasizes patient responsibility and "acting in concert with the provider community, representing a promising strategy for treating chronic conditions."[40] Self-

29. *Id*.
30. *Id.*
31. Ritu Prasad, *The Human Cost of Insulin in America*, BBC NEWS (Mar. 14, 2019), https://www.bbc.com/news/world-us-canada-47491964.
32. *Id.*
33. Julia Belluz, *The Absurdly High Cost of Insulin, Explained,* VOX (Nov. 7, 2019), https://www.vox.com/2019/4/3/18293950/why-is-insulin-so-expensive.
34. *Id.*
35. Mary Caffrey, *Gathering Evidence on Insulin Rationing: Answers and Future Questions*, AJMC (Sept. 26, 2019), https://www.ajmc.com/journals/evidence-based-diabetes-management/2019/september-2019/gathering-evidence-on-insulin-rationing-answers-and-future-questions.
36. *Id.*
37. *Id.*
38. *Diabetes Self Management Education*, AM. DIABETES ASS'N, https://www.professional.diabetes.org/diabetes-self-management-education (last visited Apr. 13, 2020).
39. Carol A. Brownson et al., *Cost-effectiveness of Diabetes Self-management Programs in Community Primary Care Settings*, DIABETES EDUCATOR 1, 2 (2009).
40. Patricia A. Grady & Lisa Lucio Gough, *Self-Management: A Comprehensive*

management allows patients to gain the necessary skills to manage their diabetes effectively through checking their own blood sugar, eating well and being active.[41] Patient self-management includes education classes, support groups, patient-centered staging and counseling and one-on-one self-management sessions with specific diabetes educators.[42] Self-management in a primary care setting can help reduce long-term complications and associated costs by $3,385 per patient.[43]

Physicians should require patient participation in diabetes self-management education (DSME) because it focuses on promoting healthy behaviors and lifestyle changes.[44] The most successful programs utilize registered nurses, registered dietitians, and registered pharmacists as instructors for the self-management programs.[45] An example of an effective program is the Better Choices Better Health Diabetes (BCBH-D) program.[46] BCBH-D is a series of six consecutive sessions, two and half hours each, that consist of online workshops where patients complete exercises, read materials and interact with other patients in their group.[47] The BCBH-D program has led to a decrease in the number of medical claims associated with comorbid illnesses, and a reduced utilization of both emergency department visits and outpatient services.[48] An effect was seen on health care costs post-intervention of the self-management program, in which there was significantly lower costs for inpatient and outpatient services.[49] Overall, medical costs for all were lower.[50]

Self-management education interventions have shown to have a positive impact on patients with diabetes in controlling the presence of diabetes-related complications and in lowering health care utilization.[51] These in turn can help lower costs for the health care system, and especially for patients.[52] Specifically, these programs have been found to improve A1C by as much

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Approach to Management of Chronic Conditions, 104 AM. J. PUB. HEALTH e25, e25 (2014).

41. *Managing Diabetes,* CENTERS FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/learnmorefeelbetter/programs/diabetes.htm (last visited Apr. 13, 2020).

42. Brownson, *supra* note 3939, at 3.

43. *Id.* at 1.

44. Turner et al., *Evaluation of a Diabetes Self-Management Program: Claims Analysis on Comorbid Illnesses, Health Care Utilization, and Cost*, 20 J. MED. INTERNET RES. 1, 2 (2018).

45. Martha M. Funnel et al., *National Standards for Diabetes Self-Management Education*, 33 DIABETES CARE S89, S89 (2010).

46. Turner et al., *supra* note 44, at 2.

47. *Id*.

48. *Id* at 6.

49. *Id*. at 9.

50. *Id*.

51. Brownson, *supra* note 39, at 1.

52. *Id*.

as 1 percent in type 2 diabetes and have had "a positive effect on other clinical, psychosocial, and behavioral aspects of diabetes."[53]

BARRIERS TO SELF-MANAGEMENT SAVINGS

Providers may face challenges in attracting patients to engage in self-management programs due to lack of participation in the programs and high costs.[54] Although DSME programs provide a great opportunity for patients to manage their diabetes and cut costs for the health care system overall, these programs may be too costly for patients to attend.[55] While physicians should strongly encourage participation in the DSME programs, they should be mindful that costs of attending could exceed $1,000 and may be a detriment to some patients without insurance.[56] One way to reduce this barrier is to reconsider cost-sharing for DSME.[57] Cost-sharing refers to the out-of-pocket costs owed by a patient under his or her insurance plan.[58]

Self-management, in addition to programs and workshops, includes careful management of the patient's own blood glucose levels.[59] The current status of DSME programs show that most public and private insurance plans are required by the law to cover DSME.[60] However, patient participation is low even when DSME programs are covered by insurance.[61] Only fifty-eight percent of diabetes patients ever receive education on their diabetes.[62] Lack of education results in a lower volume of patient participation and is a significant barrier to decreasing overall costs.

Greater participation in these programs can lead to better health outcomes in patients, eventually decreasing costs for the health care system. This is where reconsidering cost-sharing comes into play.[63] Not only would

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53. Grady, *supra* note 40, at 27. A1C is a blood test which measures the patient's blood sugar level to determine how well the patient is managing their diabetes. *A1C*, MEDLINEPLUS, https://medlineplus.gov/a1c.html (last visited Apr. 28, 2020).

54. *See* Julie Appleby, *Hospitals Lure Diabetes Patients With Self-Care Courses, But Costs Can Weigh Heavily*, KAISER HEALTH NEWS (Apr. 26, 2018), https://khn.org/news/hospitals-lure-diabetes-patients-with-self-care-courses-but-costs-can-weigh-heavily/ (Noting that one of the most expensive DSME group courses that included two hours sessions with a dietitian and a diabetes educator cost $1,700 in Washington State).

55. *Id*.

56. *Id*.

57. Katie Garfield et al., *Reconsidering Cost-Sharing For Diabetes Self-Management Education: Recommendation For Policy Reform*, CTR. FOR HEALTH L. & POL'Y INNOVATION, 1 (2015).

58. *Cost Sharing*, HEALTHCARE.GOV, https://www.healthcare.gov/glossary/cost-sharing/ (last visited Apr. 13, 2020).

59. Garfield, *supra* note 57, at 4.

60. *Id*. at 5.

61. *Id.*

62. *Id.*

63. *Id.* at 6.

this save money for patients, but it would certainly save money for insurers as well.[64] Medicare Part B covers only ten hours of DSME out of the total hours the patient participates in the initial year of participation.[65] A 2015 Harvard Study on reducing cost-sharing for DSME programs found that public insurers would realize cost-savings if they reduced the amount of cost-sharing with their insured.[66] The study also urged private payers to consider providing DSME with little to no cost-sharing because it is "a cost-effective way to improve care for their beneficiaries."[67]

Through this policy, the change in cost-sharing could generally happen through a statutory change on the federal level.[68] Public insurance programs must make a change in order to reduce costs to insurers and patients as well as the health care costs overall. Accordingly, advocates may urge Congress to change U.S.C. §13951(a) and (b) to establish that Medicare would pay one hundred percent of the cost of DSME including out-of-pocket deductibles.[69] The upside of this would be that patients would have even more encouragement to participate in the diabetes education programs, improve their health outcomes and lower costs.

STRENGTHENING THE PHYSICIAN-PATIENT RELATIONSHIP TO REDUCE COSTS

Along with self-management education, physicians must also urge self-care through the physician-patient relationship and increased physician-patient education. Self-care includes nutrition therapy, daily home blood glucose monitoring and regular exercise to reduce insulin resistance and to correct lipid metabolism.[70] Self-care, unlike self-management education, are to be done by the patient at their home.[71] These activities are difficult to comply with because they require skill and time, and effectiveness of self-care depends greatly on consistent participation throughout a patient's lifetime.[72] A patient-physician relationship could improve compliance with self-care. Patients tend to have substantially better association and recollection when physicians give memorable information along with their recommendation for self-care diabetes management.[73]

64. *Id.* at. 10.
65. *Id.* at 9.
66. *Id.* at 10.
67. *Id.* at 11.
68. *Id.*
69. *Id*.
70. Ragnhild Bundesmann & Stan A. Kaplowitz, *Provider Communication and Patient Participation in Diabetes Self-Care*, 85 PATIENT EDUC. & COUNSELING 143, 143 (2011).
71. *Id*.
72. *Id*.
73. *Id*. at 146.

INFORMATION TECHNOLOGY AND SELF-CARE

One way that could reduce costs is through information technology working alongside self-care. The goal of both self-care and self-management education is to prevent complications related to diabetes, which would further reduce costs. One of the physician's top goals for diabetic patient is to decrease A1C levels, which have been shown reduce future healthcare costs.[74] The Information Technology Enabled Diabetes Management (ITDM) has been found to lower costs in managing care for diabetes.[75] This, in addition to collaboration with health care providers to enhance self-care goals and compliance with the recommended guidelines, can "assist with the identification of patients, data synthesis for population and individual patient health status reports, and with patient education for effective self-care."[76] The ITDM program could be implemented by targeting the patient-physician relationship.[77] Physicians utilize ITDM to create diabetes registries, clinical decision support systems and electronic medical records.[78] Providers utilize ITDM through automated phone systems to provide reminders or educational content to patients, electronic diaries to collect information and online resources such as peer support groups.[79] Lastly, the system is utilized by payers through payer systems' interfaces with electronic claims systems to track diabetic-specific information.[80]

The utilization of ITDM resulted in lower health care utilization and lower incidence of diabetes related complications.[81] Through the implementation methods, ITDM allows providers to empower patients to actively participate in provider decisions and allows these decisions to be effective.[82] Specifically, the provider-patient system was most successful in cost-savings, saving the United States healthcare system $16.9 billion.[83] If providers use the ITDM to facilitate their communications with patients to manage their diabetes, the United States healthcare system could realize higher savings.

Conclusion

Diabetes has cost the United States billions of dollars because of the high

74. Kathleen Wyne, *Information Technology for the Treatment of Diabetes: Improving Outcomes and Controlling Costs*, 14 SUPP. J. MANAGED CARE PHARMACY S12, S13 (2008).
75. *Id*. at S14.
76. *Id*.
77. *Id*. at S15.
78. *Id*.
79. *Id*.
80. *Id*.
81. *Id*.
82. *Id*.
83. *Id*. at S16.

prevalence of other chronic diseases that frequently accompany a diabetes diagnosis. If the costs associated with diabetes are lowered, the overall health care system will also likely realize saving. Reducing costs for diabetes must focus on both the physician and the patient. From a patient perspective, the focus should be centered around self-management education programs coupled with self-care practices. From a physician perspective, the patient-physician relationship is the middle point for these practices to be recognized by patients, specifically through physician communication and the establishment of information technology services. If these areas are improved by the current health care system, lower costs will be achieved.

The Introduction of Biosimilars in the United States: The Impact of Non-medical Switching

Natasha Shukla

Chronically ill patients are reliant on their prescribed medication regimens to maintain a stable quality of life. Non-medical switching[1] deprives chronically ill patients of a quality standard of living by disrupting established disease management routines. Insurance companies can classify non-interchangeable biosimilar products in non-medical switching mechanisms, despite the Food and Drug Administration's ("FDA's") lack of approval for interchangeable biologic products. This continued practice will place the quality of healthcare for chronically ill patients at risk. In the face of increased approval of biosimilars, public and private payors should not equate available biosimilar products to preexisting medicinal therapies in their formularies, especially when employing the ineffective mechanism of non-medical switching.

INTRODUCTION

Costs associated with managing chronic disease often result from systemic barriers to access to medication, which include access and insurance coverage for the medication, the complexity of payor formularies, and administrative processes among others.[2] Thus, increasing proper medication utilization and adherence to prescribed treatment is effective in managing chronic disease conditions.[3] Practices employed by insurance companies and physicians that compel patients to make changes to their established regimen can place an unnecessary financial burden on patients with chronic diseases and pose additional health risks.[4]

1. INSTITUTE FOR PATIENT ACCESS, *infra* note 50 (Non-medical switching practices occur when a health plan causes patients on stable medical regimens to switch from their current medication to a less expensive alternative. It can occur several different ways: by changing the list of approved drugs, by incentivizing pharmacists or physicians to switch a patient's medication, or by limiting or eliminating the use of co-pay coupons that patients need to afford their medication).

2. Socha, *infra* note 38.

3. Balkrishnan, *supra* note 38, at 517.

4. Christopher Parkin and Jerry Meece, *CED Non-Medical Switching Help Your Patients Know their Rights*, AADE IN PRACTICE 17 (2017).

While non-medical switching[5] is intended to be a cost-cutting mechanism that can help reduce overall healthcare costs, it often results in the reemergence of chronic disease symptoms and may increase overall treatment costs for the patient with the chronic disease.[6] When insurers increase the costs of therapies that have stabilized a patient's symptoms, non-medical switching severely limits the access that patients with chronic illness have to prescription drugs, including biologics, like insulin, and places treatment decisions in the hands of the payer instead of patients and their physicians.[7] The introduction of biosimilars[8] into the pharmaceutical market is another effort in cutting costs and increasing access for patients with chronic disease.[9] While these biosimilars provide a new avenue of treatment for patients with chronic disease, patients and physicians have several doubts regarding their safety and efficacy.[10] Therefore, in the face of increased approval of biosimilars, public and private payors should not equate available biosimilar products to preexisting medicinal therapies in their formularies, especially when employing the ineffective mechanism of non-medical switching.[11]

Part I of this article will focus on the significance of biosimilars in the health care market and the regulatory process required for approval. Part II will address certain concerns that physicians and patients may have regarding the use of newly approved biosimilars in therapies. Part III of this article will examine the process of non-medical switching and discuss the demonstrated ineffectiveness of legislative action to limit this procedure for biosimilars. Finally, Part IV will conclude with the suggestion that biosimilars should not be classified as interchangeable and alternative therapies to preexisting medicinal treatments, but that the decision should be one made by patients, in conjunction with an endorsement by their

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5. *See* supra 1 (defining nonmedical switching).

6. *See generally id* (IfPA brief compares the costs per patient of those who do not switch, switch, and switch treatments multiple times).

7. Parkin, *supra* note 4, at 18.

8. PHRMA, BIOLOGICS AND BIOSIMILARS, *infra* note 16 (Biologics are medicines made from living organisms through highly complex manufacturing processes that are used to treat prevent, treat or cure a disorders, including chronic diseases. Biosimilars are highly similar to preexisting biologic products but may differ from their reference biologics by virtue of having different clinically inactive components).

9. Smeeding et al., *Biosimilars: Considerations for Payers*, 42(2) P&T 54, 59 (2019).

10. Bruce N. Cronstein, *The Benefits and Drawbacks of Biosimilars*, 13(10) CLINICAL ADVANCES IN HEMATOLOGY & ONCOLOGY, 639, 640 (Oct. 2015).

11. INSTITUTE FOR PATIENT ACCESS, COST-MOTIVATED TREATMENT CHANGES AND NON-MEDICAL SWITCHING (2017) (Non-medical switching is ineffective and often increases costs due to patient concerns of ineffective treatments); Bruce N. Cronstein, *The Benefits and Drawbacks of Biosimilars*, 13(10) CLINICAL ADVANCES IN HEMATOLOGY & ONCOLOGY, 639, 640 (Oct. 2015) (The novelty of biosimilars elicits physician and patient concerns as to the safety and effectiveness of such treatments).

physician.

PART I: FROM FDA APPROVAL TO AVAILABILITY IN THE MARKET

The increased availability of biosimilars may provide additional biologic drug options to patients who cannot afford originator biologic therapies, resulting in increased access and decreased costs.[12] The predicted mechanism behind the success of biosimilars is that they are expected to increase market competition by providing a substitution for biologic treatments, such as Amgen's biosimilar Kanjinti in place of Roche's Herceptin for cancer,[13] thereby reducing health care expenditures.[14] Biologic therapies are manufactured using living cells, and are used in the treatment of chronic, inflammatory diseases and cancer.[15] Thus, a high price tag is associated with the production of biologics, which limits access to such treatments for patients.

In 2010, Congress passed an abbreviated approval pathway was created for biosimilars to enter the market through the Biologics Price Competition and Innovation Act ("BPCIA").[16] The goal of the BPCIA was to concurrently foster innovation in the field of biologic medicines, and create more affordable treatment options for patients.[17] Through the BPCIA, the FDA established two types of classifications: non-interchangeable biosimilars and interchangeable biologics.[18] The difference between the two classifications lies in their clinical testing requirements.[19] To obtain an interchangeable biologic designation, the originator product and biosimilar must have the same clinical result without a loss of efficacy, or the formation of additional safety concerns when compared with patients treated continuously with only the originator biologic.[20] As a prerequisite to the interchangeable biologic designation, the manufacturer must conduct clinical switching studies to show that a patient will be able to switch

12. Smeeding, *supra* note 9.
13. Ned Paliarulo, *infra* 55.
14. *Id*. at 54.
15. *Id*.
16. PHRMA, BIOLOGICS AND BIOSIMILARS, https://www.phrma.org/en/Advocacy/Research-Development/Biologics-Biosimilars (last visited Feb. 15, 2020).
17. *Id*.
18. Hillel P. Cohen, *Interchangeable Biologics as Safe, Efficacious as Non-Interchangeable Biosimilars*, HEALIO RHEUMATOLOGY (July 6, 2018), https://www.healio.com/rheumatology/practice-management/news/online/%7B2d477940-cfca-46a3-953e-6027362f8914%7D/interchangeable-biologics-as-safe-efficacious-as-non-interchangeable-biosimilars.
19. *Id*.
20. *Id*.

between the originator drug and the biosimilar without compromising safety, efficacy, or clinical outcomes.[21] To date, twenty-six biosimilars have been approved for use in the United States by the FDA.[22] The FDA has not approved a biosimilar as interchangeable with its originator biologic because while the approval process ensures safety, efficacy, and analogous clinical outcomes required for a drug to be deemed interchangeable, it is more burdensome.[23] The twenty-six therapies approved are new therapies classified as non-interchangeable biosimilars, because these biologics may result in different clinical outcomes than their originator biologics.[24] The FDA has not approved any interchangeable biologics; meaning there has not been an irrefutable showing by a manufacturer that the originator biologic and the approved biosimilar product are equivalent in their clinical outcomes.[25]

PART II: CONCERNS ABOUT BIOSIMILARS AND THEIR BENEFITS

Biosimilars, like generic drugs, are meant to offer a more affordable treatment option to patients;[26] however, the chemical composition of biosimilars makes their market incomparable to the generic drug market.[27] The active ingredients of generic drugs are the same as those of brand name drugs, whereas biosimilars are highly similar to the preexisting name brand biologics, but are not an exact replica of their originator biologic.[28] Additionally, producing a biosimilar is more complicated than replicating a traditional, small-molecule generic drug through chemical synthesis.[29] As a result, switching between biosimilars and their biologic originators poses an inherent risk that generic drugs do not.[30]

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21. *Id*.

22. Judith Stewart, *How many biosimilars have been approved in the United States?*, DRUGS.COM, (Dec. 8, 2019) https://www.drugs.com/medical-answers/many-biosimilars-approved-united-states-3463281/; CENTER FOR DRUG EVALUATION AND RESEARCH, LIST OF LICENSED BIOLOGICAL PRODUCTS WITH (1) REFERENCE PRODUCT EXCLUSIVITY AND (2) BIOSIMILARITY OR INTERCHANGEABILITY EVALUATIONS TO DATE, https://www.fda.gov/media/89589/download (last visited Feb 15, 2020) (more commonly known as the "purple book," this is an FDA-produced guide for pharmacists and physicians that summarizes FDA-approved biosimilars and interchangeable biologics).

23. Stewart, *supra* note 22.

24. *Id*.

25. *Id*.

26. Smeeding, *supra* note 9, at 56.

27. FOOD AND DRUG ADMINISTRATION, BIOSIMILAR AND INTERCHANGEABLE PRODUCTS, https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products (last visited February 15, 2020).

28. *Id*.

29. Smeeding, *supra* note 9, at 56.

30. Stewart, *supra* note 22. (Biologics are not replicated from their reference products like generics are, and thus, without a showing that they have outcomes analogous to their

The abbreviated path for biosimilar approval also allows for extrapolation — a statistical method where information and conclusions from studies performed in one or more groups of patients is then extended to make inferences regarding another population of patients.[31] At the time the FDA draft guidance for the BPCIA was posted for notice and comment review, physicians expressed concern for the use of extrapolation, citing the possibility of inappropriate substitution of a biosimilar where it does not meet the same indications as the originator drug.[32] In addition, physicians also noted that switching to the biosimilar drug could have a detrimental impact on patients that are already stable on preexisting therapies.[33] Since autoimmune disorders are complex chronic diseases and the interchangeability of biosimilars with their originator product may not guarantee the same result.[34] Finally, physicians also expressed the need for post-market evaluation for biosimilars in order to ensure their safety and efficacy.[35] Real-world data through post-market studies will help monitor the safety of the biosimilars, allow for mitigation of any unknown side effects, and allow for determination of the effective uses of the drug in comparison to its originator counterpart.[36]

PART III: PATIENT ADHERENCE TO PRESCRIBED TREATMENTS AND RESERVATIONS ABOUT SWITCHING

Adherence to prescribed medical treatments is associated with lower avoidable healthcare utilization and morbidity across many chronic conditions.[37] While adherence to strict medical regimens is crucial for patients in managing their chronic illness, nearly fifty percent of Americans do not take their medicine as prescribed, thereby increasing health care costs by $290 billion through unnecessary acute patient visits and more involved medical procedures.[38] Patients with chronic disease rely on a

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reference biologic, there is always the risk of achieving different results than the reference biologic).

31. Jackie Syrop, *Physicians Express Concerns About Biosimilar Interchangeability to FDA*, THE CENTER FOR BIOSIMILARS, (June 30, 2017) https://www.centerforbiosimilars.com/news/physicians-express-concerns-about-biosimilar-interchangeability-to-fda.

32. *Id*.

33. *Id*.

34. *Id*.

35. *Id*.

36. *Id*.

37. Balkrishnan, *supra* note 38, at 517.

38. Tori Socha, *Medication Adherence Crucial to Management of Chronic Disease*, FIRST REPORT MANAGED CARE (2011), https://www.managedhealthcareconnect.com/article/medicationadherence-crucial—management-chronic-disease; Rajesh Balkrishnan, *The Importance of Medication Adherence*

sustainable medication regimen to manage their condition, therefore forcing providers to prescribe more affordable alternate therapies, which causes patients to switch to another drug or therapy, that may destabilize their condition.[39] This leads to poorer health outcomes.[40] Additionally, many patients are uninformed about biosimilars.[41] In a study conducted by research branches associated with Pfizer, Inc., in 2016, nearly seventy percent of respondents across the United States and the European Union were unfamiliar with the term "biosimilar."[42]

Patient information and understanding is crucial to adherence to medical regimens,[43] and it is important that the decision to switch from an originator biologic to a biosimilar is made by both the physician and the patient.[44] While patient concerns with biosimilars stem from misinformation, studies[45] conducted on patient attitudes and awareness of biosimilars conducted between 2016 and 2017 show that patients also have reservations about switching to a biosimilar in managing their condition.[46] International studies on patient attitudes and understanding about biosimilars conducted by research branches associated with Pfizer, Inc. have shown that a nearly fifteen percent of respondents would refuse to switch to a biosimilar drug, and half would switch but with reservations.[47] Such hesitancy in switching may have implications on patient choice and their adherence to prescribed treatments if providers facilitate a non-medical switch to biosimilars.[48]

The process of switching a patient's biologic regimen is confusing for both patients and physicians.[49] Non-medical switching is a practice used by

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in Improving Chronic-Disease Related Outcomes: What We Know and What We Need to Further Know, MEDICAL CARE 516, 517 (2013).

39. Christopher Parkin and Jerry Meece, *supra* note 4.

40. Christopher Parkin and Jerry Meece, *supra* note 4.

41. Ira Jacobs et al., *Patient attitudes and understanding about biosimilars: an international cross-sectional survey*, PATIENT PREFERENCE AND ADHERENCE, 937, 940 (May 2016).

42. *Id*.

43. Balkrishnan, *supra* note 38, at 518.

44. Michael Broder, *They Trust You: Patient Perspectives on Biosimilars in Rheumatology*, MEDPAGE TODAY, (May 9, 2019) https://www.medpagetoday.com/resource-centers/biosimilars/they-trust-you-patient-perspectives-biosimilars-rheumatology/2505. (Physician communication about benefits and risks associated with particularly confusing treatments like biosimilars are essential to encouraging adherence to medical regimens).

45. Jacobs, *supra* note 41; Hillel Cohen et al*., Awareness, Knowledge, and Perceptions of Biosimilars Among Specialty Physicians*, ADV THER, 2160–2172 (2016). (These studies assessed physician perceptions about biosimilars and patient attitudes towards being prescribed biosimilar therapies).

46. *Id*.

47. *Id*.

48. *Id* (Patients are more likely to adhere to medical regimens that they understand and developed with their physicians).

49. *Id*.

health care payers intended to reduce health care costs by the following: changing the list of approved drugs in their formularies, incentivizing providers to switch a patient's medication, or limiting or eliminating the use of co-pay coupons that patients need to afford their medication.[50] In the face of increased approval for biosimilars, physicians and providers have expressed concerns that despite the uncertainty associated with switching to biosimilars, the decision will be made for them by virtue of what patients can afford under payor formularies.[51] The Biologics Prescribers Collaborative, which represents member organizations including the American College of Rheumatology, the Endocrine Society, and the American Gastroenterological Association, among others, has addressed these concerns by issuing guidelines to preserve physician-patient interests in the process.[52] These guidelines expressly call for ensuring the best patient outcomes by avoiding switching patients who are stable on a biologic therapy to the biosimilar drug. [53] Given the novelty of biosimilars in the American healthcare system, and reservations that patients and physicians have about switching from originator biologics to biosimilars, forced non-medical switching by insurers could compromise patient choice and trust in medical providers.[54]

PART IV: EFFECTIVENESS OF NON-MEDICAL SWITCHING FOR BIOSIMILARS

As more biosimilars are approved by the FDA in the United States, pharmaceutical companies are seeing a favorable response to biosimilar launches.[55] While biosimilars still need to be prescribed by physicians, insurers like UnitedHealthcare have begun listing biosimilars as "preferred for members covered under its commercial, community and Medicare Advantage plans," encouraging physicians to prescribe biosimilars.[56] Biosimilars can be anywhere from ten to forty percent cheaper for providers to acquire from manufacturers,[57] further serving as a motivator for insurance providers and pharmacy benefit managers to encourage the

50. INSTITUTE FOR PATIENT ACCESS, COST-MOTIVATED TREATMENT CHANGES AND NON-MEDICAL SWITCHING (2017).

51. *See generally* Kelly Davio, *BPC's Nonmedical Switching Guidelines Seek to Preserve Physician–Patient Relationship*, THE CENTER FOR BIOSIMILARS, (May 10, 2018) https://www.centerforbiosimilars.com/news/bpcs-nonmedical-switching-guidelines-seek-to-preserve-physician-patient-relationship.

52. *Id*.

53. *Id*.

54. *See* Broder*, supra* note 44.

55. Ned Paliarulo, *Amgen Biosimilar Debut Boosted by Unitedhealthcare Coverage Switch*, BIOPHARMA DIVE, (AUG. 19, 2019) https://www.biopharmadive.com/news/amgen-biosimilar-debut-boosted-by-unitedhealthcare-coverage-switch/561192/.

56. *Id.*

57. Smeeding, *supra* note 9, at 59.

switch to an interchangeable treatment.[58]

Even though the expedited approval pathway for biosimilars in the United States is relatively new, European countries have had an established framework for regulation of biosimilars since 2005.[59] Thus, while there is no data on how non-medical switching of biosimilars has impacted health care costs in the United States, studies done in European nations can be consulted to determine the impact of non-medical switching on overall healthcare costs.[60] For example, a Danish register-based study conducted by Glintborg in 2019 took into account the effect of mandated switching from an originator to a biosimilar etanercept.[61] This study demonstrated that there was an eight percent increase in outpatient visits after the switch was made.[62] Even though there were no negative impacts of the switch on the patients' disease activities, the study cites a nocebo effect, where patients who were reluctant to switch may have perceived poor performance of the biosimilar drug as a result of a preconceived notion of its ineffectiveness.[63]

Non-medical switching may be a mechanism that is intended to drive down costs associated with prescription biologic drugs; however, it may have the opposite effect in practice.[64] A systematic literature review of studies conducted in England evaluating the economic impact of non-medical switching from originator biologics to biosimilars have shown that patients who were first prescribed originator biologics made more visits to healthcare providers after the switch to biosimilars due to lack of response, low treatment adherence, or adverse events.[65] Even accounting for the

58. Madelaine Feldman, *Prescription Drugs and the Effect on Access to Biosimilars in the US*, RHEUMNOW – RHEUMATOLOGY NEWS & INFORMATION, (July 10, 2019) http://rheumnow.com/blog/prescription-drugs-and-effect-access-biosimilars-us.

59. Martin Schiestl et al., *Ten years of biosimilars in Europe: development and evolution of the regulatory pathways*, DRUG DESIGN, DEVELOPMENT AND THERAPY, 1509, 1509 (2017).

60. Diane S. Aschenbrenner, *First Biosimilar Drug Approved*, American Journal of Nursing 24, 25 (2015);
Schiestl, *supra* note 59 (In contrast to the United States, where the first biosimilar was approved in 2015, biosimilars have been available in Europe for over 10 years, which has allowed large-scale studies evaluating the effect of non-medical switching employed in a biosimilar context on patient treatment).

61. Etanercept is a biologic used in the treatment of inflammatory arthritis. Bente Glintborg et al., *Does a mandatory non-medical switch from originator to biosimilar etanercept lead to increase in healthcare use and costs? A Danish register-based study of patients with inflammatory arthritis*, RMD OPEN, at 1 (2019).

62. *Id*. at 6.

63. *Id*.

64. Yifei, *infra* note 65 (A higher number of visits results in increased utilization of the healthcare system, and therefore increased healthcare costs); *infra* note 67 (Non-medical switching has already been shown to increase healthcare costs in non-biologic contexts).

65. Yifei Liu et al., *Economic Impact of Non-Medical Switching from Originator Biologics to Biosimilars: A Systematic Literature Review,* 36 ADVANCED THERAPEUTICS,

difference between international healthcare systems, these factors will remain because they are driven by the drug's effectiveness rather than the structure of any given healthcare system.[66]

An analysis of non-medical switches made in the United States for non-biologic treatments indicates that the practice of non-medical switching to an ineffective treatment, or one that is perceived to be ineffective, results in higher costs as well.[67] This study suggested that continuity of care for patients with pre-existing prescriptions for their chronic conditions could keep costs low as opposed to cost-motivated treatment changes.[68] Maintaining stable regimens for patients with chronic diseases is the most efficient way to maintain lower costs for these patients in the current American healthcare system.[69]

CONCLUSION

Insurance formularies and legislation allowing automatic substitution should consider the efficacy concerns presented by patients and providers in the case of biosimilars.[70] Currently no substance has a designation of an interchangeable biologic, at least thirty-three states allow for automatic prescription substitution upon the availability of this designation.[71] States should exclude biosimilars from automatic substitutions and consider physician concerns with the safety and efficacy of biosimilars.[72] Due to the inherent differences between a biosimilar, interchangeable biologics, and their originators, there is a risk that switching a patient from a stable medication regimen may result in adverse effects.[73] This assessment of risk is a decision that should be made by a patient in consultation with their physician, who can evaluate treatment decisions on a case-by-case basis.[74] Thus, state legislatures should maintain prescription requirements for

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1871, 1872 (2019).

66. Variances in healthcare systems do not have an impact on the biologic functions of a treatment.

67. INSTITUTE FOR PATIENT ACCESS, *supra* note 6, at 3; Davio, *supra* note 51.

68. INSTITUTE FOR PATIENT ACCESS, *supra* note 6, at 3; Davio, *supra* note 51.

69. INSTITUTE FOR PATIENT ACCESS, *supra* note 6, at 3; Davio, *supra* note 51.

70. Davio, *supra* note 51 (Physicians have advocated for keeping patients on their current biologic treatments); Yifei, *supra* note 65 (Studies have shown that involuntary switches not only result in higher costs for patients, but are also perceived as ineffective treatments).

71. Syrop, *supra* note 31.

72. *See generally supra* note 51. (Automatic substitution negatively impacts patient choice by allowing substitutions in their medical regimen that they may not have consented to. This is more of a concern for biosimilars because unlike generics, biosimilars are not interchangeable with their reference products).

73. Yifei, *supra* note 65.

74. Broder, *supra*, note 44.

biosimilars to preserve patient choice.

Payers should maintain the same coverage for originator biologic products, interchangeable biologics, and biosimilars as patients continue to understand the significance of biologics.[75] Maintaining existing and stable regimens can be the most effective way to keep overall healthcare costs down, as other medical costs increase as a result of a patient's involuntary medication switch intended to reduce healthcare spending.[76] Thus, while biosimilars may be avenues for cost-reduction in the future, the uncertainty associated with their success for patients with chronic diseases make them a poor choice for automatic substitution and nonmedical switching.

75. *Id*. (Patient outcomes are made on an individual basis between patients and their physicians); See Broder, *supra* note 44 (There are large gaps in patient and physician information on the subject of biosimilars).

76. Davio, *supra* note 51.