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ANNALS OF HEALTH LAW

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

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ANNALS OF HEALTH LAW

Advance Directive

Editors' Note

The Annals of Health Law is proud to present the Eighteenth Issue of our online, student-written publication, Advance Directive. Advance Directive aims to support and encourage student scholarship in the area of health law and policy. In this vein, this issue explores a variety of areas that focus on current public health concerns. The CDC Foundation defines public health as "the science of protecting and improving the health of families and communities through promotion of healthy lifestyles, research for disease and injury prevention and detection and control of infectious diseases." The protection of population health lies at the heart of public health. The authors in this volume of Advance Directive examine a variety of public health issues and solutions ranging from food prescription programs targeted to combat chronic illness, to analyzing the growing opioid epidemic, to contraceptive challenges in the United States, to risks associated with the development of self-driving cars.

Our first article begins with a discussion of food prescription programs as a method to combat chronic illness. The author notes how low-income populations are often overcome with issues of chronic disease, and due to their economic situations, cannot afford proper nutrition. As a result, these chronic conditions often exacerbate. The author provides a number of examples, including the Fruit & Vegetable Prescription Program and Food Rx, which have shown promising results in their initial stages in providing healthier options which have helped to improve chronic conditions. The author argues that the success of these programs will rely on systematic collaboration between providers, non-profit hospitals, medical education, and insurers to combat chronic disease and ensuring that food prescription becomes part of normal practice.

The next author discusses motor vehicle accidents as a public health issue. The author begins with a discussion of the causes of motor vehicle accidents and their effect on public health. The author then explores self-driving vehicles, and their potential to remove human error and decrease motor vehicle accidents. Finally, the author discusses the challenges of self-driving vehicles and how these challenges can ultimately be overcome.

The next author discusses the Affordable Care Act's contraceptive mandate and its importance in expanding access to cost-free contraception for women. The author begins with a discussion of the history of contraception coverage, and the application of the contraception mandate to insurance plans. The discussion then explores alternative approaches to the contraception mandate, including employer-based methods, pharmacist prescribed contraception, and over-the-counter options. Finally, the author proposes not only keeping the mandate in place, but expanding it to allow for greater access to affordable contraception.

The next author discusses comprehensive sexual education and the role it plays in reducing teenage pregnancies. The author explores the important role Planned Parenthood and community-based organizations play in providing comprehensive sexual education to youths. The author then compares abstinence-only education to comprehensive sexual education, while discussing how teenage pregnancy should be treated as a public health issue. Finally, the author argues in favor of

comprehensive sexual education models and how organizations like Planned Parenthood should continue to utilize the models considering the current emphasis on abstinence-only education.

Our discussion then turns to an evaluation of the inconsistent, and arguably non-existent, enforcement of the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Act of 2008 (MHPAEA). Here, the author notes that while promising, the MHPAEA's lack of clear guidance for defining parity and procedural enforcement has left the burden of identification and reporting of violations primarily to consumers. The author argues that the primary responsibility for enforcement should shift back to state and federal regulators through plan audits and disclosure of non-confidential enforcement results, but acknowledges that enforcement is severely limited by funding and political will.

The next author addresses the ever present and increasingly alarming epidemic of prescription opioids, discussing faulty studies that suggested that the extended administration of opioids for chronic pain was safe, leading to increased prescription requests by physicians. The article then analyzes how the government's long-term deterrent programs—including state-run Prescription Drug Monitoring Programs and increased drug enforcement—prevent patients from acquiring prescription opioids, leading some to obtain opioids illegally. The author argues that short-term treatment and therapy and research and development for alternatives are underfunded and that lawmakers should continue funding short-term opioid abuse treatment initiatives and while working to make antidote drugs more affordable and readily available.

The next author explores a public health crisis, as defined by the World Health Organization, not often discussed: pornography. The author begins with a discussion of the constitutionality of pornography and its basis on freedom of speech, highlighting landmark cases in the development of the term "obscene." The discussion then turns to the current state of pornography opposition and measures taken to curb exposure and the resulting detrimental effects of pornography. Finally, the author proposes that in order for anti-pornography advocates to attain meaningful success, they must undertake a holistic approach that encompasses both state and federal enforcement mechanisms, improves sex education, and encourages private action in the home.

Finally, we end our issue with a return to the opioid epidemic. The author suggests intervention sites, such as supervised injection facilities, coupled with the current Prescription Drug Monitoring Programs could be the solution. The author first reviews current prescription drug laws, with an emphasis on immunity and mitigation laws and state Prescription Drug Monitoring Programs, and then discusses the international implementation of supervised injection facilities. Finally, the author proposes that by tracking opioid and prescription drug users at state funded facilities and allowing users to have safe haven facilities, the United States could potentially see a three-fold effect: a decrease in death rates from overdoses, the facilitation of safe usage, and encouragement of voluntary cessation or treatment.

We would like to thank Katie Lavin and Jordan Donnelly, our Technical Production Editors, because without their knowledge and commitment, this Issue would not have been possible. We would like to give special thanks to our Annals Editor-in-Chief, Dennis Pangindian, for his leadership and support. The Annals Executive Board Members, Alanna Kroeker,

MaryKathryn Hurd and Mandy Bast provided invaluable editorial assistance with this Issue. The Annals members deserve special recognition for their thoughtful and topical articles and for editing the work of their peers. Lastly, we must thank the Beazley Institute for Health Law and Policy and our faculty advisors, Professor Lawrence Singer, Megan Bess, and Kristin Finn for their guidance and support. We hope you enjoy our Eighteenth Issue of Advance Directive.

Sincerely,

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Advance Directive Editor
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Doctor's Orders: The Food-As-Medicine Movement

Adrienne Testa[*]

I. INTRODUCTION

The United States currently faces a chronic disease crisis. The Center for Disease Control ("CDC") estimates that approximately 191 million Americans live with at least one chronic disease, and that seventy-five million Americans live with two or more chronic diseases.[1] Chronic disease lays a heavy burden on health care, and by extension, all Americans.[2] The *Food as Medicine* movement encourages physicians to rethink traditional prescription practices and prescribe good nutrition as a means to prevent, treat, and potentially reverse chronic disease.[3] Throughout the country, food prescription programs demonstrate the positive health and cost outcomes of utilizing this course of treatment for chronic diseases.[4] However, for food prescription programs and the greater *Food as Medicine* movement to become standard care, the health care industry must embrace nutrition as a remedy. Specifically, non-profit hospitals must implement nutrition-based strategies, insurers must include food prescriptions as a covered service, and the medical community must integrate nutrition into medical training.

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1. PARTNERSHIP TO FIGHT CHRONIC DISEASE, WHAT IS THE IMPACT OF CHRONIC DISEASE ON AMERICA? FACT SHEET (2016), http://www.fightchronicdisease.org/sites/default/files/pfcd_blocks/PFCD_US.FactSheet_FINAL1%20%282%29.pdf.

2. Chronic Disease Overview, CTRS. FOR DISEASE CONTROL, https://www.cdc.gov/chronicdisease/overview (last updated Feb. 23, 2016).

3. ROBERT GREENWALD, FOOD AS MEDICINE: THE CASE FOR INSURANCE COVERAGE FOR MEDICALLY TAILORED FOOD UNDER THE AFFORDABLE CARE ACT (Jan. 2015), http://www.chlpi.org/wp-content/uploads/2013/12/CA-Greenwald-Hunger-Summit-1-26-15.pdf.

4. *See Food as Medicine*, *infra* page 5, and accompanying notes.

This article discusses the rising rates of chronic disease in the United States and the health, medical, and economic burdens that result. Focusing on the experiences particular to low-income households, this article highlights obstacles to pursuing nutrition-based interventions for chronic diseases. This article then proposes the *Food as Medicine* movement, particularly prescription food programs, as a means for preventive, proactive, and effective treatment of chronic conditions, particularly for this patient population. Finally, considering the barriers that inhibit *Food as Medicine* from having its full effect, this article proposes a systemic shift in the health care industry to promote nutrition interventions.

II. CHRONIC DISEASE IN AMERICA

Chronic diseases can be generally defined as ongoing, normally incurable illnesses or conditions; examples include heart disease, arthritis, and diabetes.[5] A growing majority of Americans live with one or more chronic diseases.[6] Today, the majority of American deaths result from chronic diseases; heart disease and cancer together account for nearly half of all deaths.[7] By 2020, the number of Americans with at least one chronic disease is expected to reach an unprecedented 157 million people.[8] These projections intensify when one considers the costs- personally, medically, and economically- of these illnesses.[9] Nationally, the United States spends close to eighteen percent of its GDP on health care alone, and a large majority of

5. ABOUT CHRONIC CONDITIONS, NATL. HEALTH COUNCIL, http://www.nationalhealthcouncil.org/newsroom/about-chronic-conditions (last updated Mar. 21, 2016); CHRONIC DISEASE OVERVIEW, CTRS. FOR DISEASE CONTROL, https://www.cdc.gov/chronicdisease/overview (last updated Feb. 23, 2016).

6. PARTNERSHIP TO FIGHT CHRONIC DISEASE, *supra* note 1.

7. CHRONIC DISEASE OVERVIEW, *supra* note 5.

8. Thomas Bodenheimer et al., *Confronting The Growing Burden Of Chronic Disease: Can The U.S. Health Care Workforce Do The Job?*, 28 HEALTH AFF. 64, 64 (2009).

9. PARTNERSHIP TO FIGHT CHRONIC DISEASE, *supra* note 1; *see also* Jane Turner, *Emotional Dimensions of Chronic Disease*, 172 West J. Med. 124 (2000) (illustrating the mental and emotional health challenges which often accompany chronic disease).

this is spent on chronic disease.[10] The projected total cost of chronic disease in America between 2016 and 2030 is forty-two trillion dollars.[11] The burden of chronic disease most strongly affects ethnic minority and low-income populations, reflecting dual disparities in socioeconomic status and access to quality medical care.[12]

Illustrating the multi-factorial nature of this health disparity is the "hunger-obesity paradox" experienced by many people living in poverty.[13] Food insecurity, particularly in areas where individuals lack affordable healthy food options, often leads to diets comprised of calorie-dense but nutrition-poor food.[14] This poverty-induced malnutrition is associated with chronic conditions like obesity, heart disease, hypertension, and diabetes, and can ultimately lead to early death for poor populations.[15]

Because lifestyle choices play a seminal role in the development,

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10. In 2014, the United States' GDP totaled $17.348 trillion and national healthcare spending totaled $3.0313 trillion of this total, or seventeen and a half percent. *See* HEALTH, UNITED STATES 2015, NATL. CTR. FOR HEALTH STATISTICS 293 (2016), https://www.cdc.gov/nchs/data/hus/hus15.pdf#093; the CDC has continually estimated that chronic diseases account for eighty-six percent of all health care spending. *See* CHRONIC DISEASE OVERVIEW, *supra* note 5 (contending that eighty-six percent of all health care spending in 2010 was for people with one or more chronic medical conditions); *see also At a Glance 2015*, CTRS. FOR DISEASE CONTROL (2015), https://www.cdc.gov/chronicdisease/resources/publications/aag/pdf/2015/nccdphp-aag.pdf (repeating and affirming this eighty-six percent estimation).

11. See PARTNERSHIP TO FIGHT CHRONIC DISEASE, *supra* note 1 (projecting an annual cost of $2 trillion in medical costs and $794 billion in lost employee productivity, over sixteen years).

12. Errol D. Crook & Mosha Peters, *Health Disparities in Chronic Diseases: Where the Money Is*, 335 AM. J. MED. SCI. 266, 266 (2014); Racial and Ethnic Approaches to Community Health (REACH), CTRS. FOR DISEASE CONTROL, https://www.cdc.gov/chronicdisease/resources/publications/aag/reach.htm (last updated Nov. 29, 2016). Demographically, African Americans are forty percent more likely to be diagnosed with high blood pressure and seventy-seven percent more likely to be diagnosed with diabetes than Caucasian Americans. Moreover, Hispanic Americans are sixty-six percent more likely to be diagnosed with diabetes. *Racial and Ethnic Approaches to Community Health (REACH)*, CTRS. FOR DISEASE CONTROL, https://www.cdc.gov/chronicdisease/resources/publications/aag/reach.htm (last updated Nov. 29, 2016).

13. Melissa Biel et al, *Forging Links Between Nutrition and Healthcare Using Community-Based Partnerships*, 32 FAM. COMMUNITY HEALTH 196, 197 (2009).

14. *Id*.

15. *Id*.

exacerbation, maintenance, and improvement of chronic disease, therein lies guidance for prevention and treatment.[16] In fact, food and nutrition can serve as effective interventions in the primary, secondary, and tertiary preventative stages in chronic diseases.[17] However, for the aforementioned low-income populations most burdened by chronic disease, proper nutrition interventions remain elusive remedies in the face of food insecurity.[18] Many low-income families combine public sources of food assistance, such as Supplemental Nutrition Assistance Program ("SNAP"), with private sources, such as local foodbanks, to afford food.[19] Though both food pantries and the SNAP program may incentivize healthy purchases,[20] the central goal of these

16. *See* Academy of Nutrition and Dietetics, *Position of the Academy of Nutrition and Dietetics: The Role of Nutrition in Health Promotion and Chronic Disease Prevention*, 113 J. ACAD. OF NUTRITION & DIETETICS 972, 972 (2013) (stressing the importance of health promotion and disease prevention (HPDP) in delaying premature death, improving quality of life, and lessening the economic burden inherent in chronic disease; the Academy of Nutrition and Dietetics considers nutrition a "cornerstone" in these lifestyle interventions). The CDC estimates that eliminating poor diet, inactivity, and smoking would allow patients to better-manage their chronic diseases while easing the burden on the health system. CTRS. FOR DISEASE CONTROL, NATL. CTR. FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION, THE POWER OF PREVENTION: CHRONIC DISEASE. . . THE PUBLIC HEALTH CHALLENGE OF THE 21ST CENTURY (2009), https://www.cdc.gov/chronicdisease/pdf/2009-power-of-prevention.pdf.

17. In distinguishing the three stages, the Center for Health Law and Policy of Harvard Law School notes that primary stage interventions may prevent "risk factors" linked to the onset of a chronic disease. By contrast, secondary stage interventions can address any early detection of conditions. Finally, tertiary stage interventions amount to "disease management," preempting complications for individuals already diagnosed with a chronic disease. SARAH DOWNER ET AL., CTR. FOR HEALTH LAW & POLICY INNOVATION, FOOD IS PREVENTION: THE CASE FOR INTEGRATING FOOD AND NUTRITION INTERVENTIONS INTO HEALTHCARE 3.

18. *See* Academy of Nutrition and Dietetics, *supra* note 16, at 974, 976 (noting that populations facing lower socioeconomic status are more likely to face general food insecurity and limited access to a variety of affordable and healthy foods; these nutrition and food deficiencies are linked to poor health outcomes).

19. *See* FEEDING AMERICA, FOOD BANKS: HUNGER'S NEW STAPLE 4 (2009), http://www.feedingamerica.org/hunger-in-america/our-research/hungers-new-staple /hungers-new-staple-full-report.pdf (reporting that SNAP and WIC benefits, though crucial to low-income households, may be insufficient and thus supplemented by food pantry visits); Food banks, often very large and centralized, provide perishable and non-perishable foods to 36,000 community-based agencies that distribute the food to individuals at the community level. Biel, *supra* note 13, at 197.

20. Courtney Collins, *Food Pantries Try Nutritional Nudging to Encourage Good Food Choices*, NATL. PUB. RADIO, ALL THINGS CONSIDERED (Nov. 7, 2016, 1:10 PM), http://www.npr.org/sections/thesalt/2016/11/07/499325457/food-pantries-try-nutritional-nudging-to-encourage-good-food-choices; Lauren E.W. Olsho et al., *Rebates to Incentivize Healthy Nutrition Choices in the Supplemental Nutrition Assistance Program*, AM. J.

programs is to combat hunger rather than the chronic diseases which accompany malnourishment.[21] Moreover, SNAP benefits can be used to purchase nearly any foods and beverages,[22] and a Department of Agriculture survey determined that SNAP beneficiaries consume a lower quality diet than nonparticipants.[23] These statistics invite numerous debates on the proper role of food assistance programs and whether there should be strict limits on beneficiaries' food purchases.[24] Regardless of this debate, it remains that food assistance programs centered on alleviating hunger are currently ill-equipped to provide the level of medically-rooted nutritional intervention that could help stave, stall, or reverse the effects of chronic disease for low-income populations.[25]

Food as Medicine initiatives, such as food prescription programs, are better suited to implement nutritional interventions purported to conquer chronic disease. Interventions that address the range of factors causing chronic disease are more likely to be effective in improving health outcomes.[26] Food prescription programs embody this multi-factorial

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PREVENTIVE MED. S161 (2016).

21. Tatiana Andreyeva et al., *Grocery Store Beverage Choices by Participants in Federal Food Assistance and Nutrition Programs*, AM. J. PREVENTIVE MED. 411 (2012); FEEDING AMERICA, WHAT IS A FOOD BANK? (2017), http://www.feedingamerica.org/about-us/how-we-work/food-bank-network/what-is-a-food-bank.html.

22. SNAP's only exclusions are alcohol, hot foods, and ready-made foods meant to be consumed within the store. Andreyeva et al., *supra* note 21.

23. DIET QUALITY OF AMERICANS BY SNAP PARTICIPATION STATUS: DATA FROM THE NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY, 2007-2010 – SUMMARY, U.S. DEPT. AGRIC. 2 (May 2015).

24. Olga Khazan, *Should Food Stamps Buy Soda?*, THE ATLANTIC (Nov. 11, 2013), https://www.theatlantic.com/health/archive/2013/11/should-food-stamps-buy-soda/281342.

25. DIET QUALITY OF AMERICANS BY SNAP PARTICIPATION STATUS: DATA FROM THE NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY, 2007-2010 – SUMMARY, *supra* note 23.

26. Monica Peek et al., *Early Lessons From An Initiative On Chicago's South Side To Reduce Disparities In Diabetes Care And Outcomes*, 31 HEALTH AFF. 177, 177 (Jan. 2012); see also Jeff Loi, Food as Medicine: Improving Access to Healthy Food 13, 14 (2016) (unpublished MURP manuscript), https://noharm-uscanada.org/sites/default/files/documents-files/4123/Food%20as%20Medicine%20-%20Jeff%20Loi%20Report.pdf (arguing the importance of implementing a multifactorial program that could address dietary, behavioral, educational, environmental, and financial barriers to health).

approach, while rooted in the health care delivery model.[27] Discussed at length in the next section, food prescription programs, born out of the *Food as Medicine* movement, reimagine subsidized nutrition as a prescribed remedy for chronic disease.[28]

III. FOOD AS MEDICINE

Food as Medicine refers to a growing movement within healthcare, stemming from the increasing recognition of food and nutrition as valuable tools in medicine.[29] Formally including food in treatment plans presents physicians with an opportunity to shift away from sole reliance on medications.[30] Nevertheless, because poor nutrition represents an underlying cause or exacerbant of chronic diseases, it behooves physicians to subscribe to a philosophy which, by prescribing healthy eating, purports to combat this trend.[31]

A. Food Prescription Programs

A number of food prescription programs specifically target the chronic health crisis that exists throughout the country.[32] Some programs emerge through community-based non-profits, and may involve hospitals or provider initiatives.[33] Generally, food prescription programs create partnerships between health care providers and farmer's markets, food retailers, or Community Supported Agriculture groups.[34] Providers prescribe chronic

27. Monica Peek et al., *supra* note 26.
28. *Id*. at 178.
29. *See* Mat Edelson, *Take Two Carrots and Call Me in the Morning*, HOPKINS MED. (2010), http://www.hopkinsmedicine.org/hmn/w10/feature2.cfm (highlighting gastroenterologists' recommendations of ginger and peppermint to patients suffering with various gut disorders).
30. David Gorn, *Food As Medicine: It's Not Just A Fringe Idea Anymore*, NPR: THE SALT (Jan. 17, 2017), http://www.npr.org/sections/thesalt/2017/01/17/509520895/food-as-medicine-it-s-not-just-a-fringe-idea-anymore.
31. *Id*.
32. See *infra* notes 36, 41, 45 and accompanying text.
33. *Id*.
34. *Id*.

disease patients fresh produce and the patient redeems the prescription with the partnered produce supplier.[35] One such program is Wholesome Wave, a national non-profit which operates its Fruit & Vegetable Prescription Program ("FVRx") in over ten states.[36] Patients can sign up for FVRx upon visiting their participating health clinic; after setting nutrition goals with their physician, participants receive an FVRx prescription.[37] The "prescription" acts as a subsidy for nutritious food equal to $1/day for each participant and household member.[38] FVRx tracks the redemption of these prescriptions at participating retailers, and then participants schedule their next FVRx visit.[39]

City- and provider-specific food prescription programs exist, as well.[40] For example, Detroit's Health Rx Program at the Community Health and Social Services ("CHASS") Center serves low-income patients with chronic disease, as well as caregivers of young children and pregnant women.[41] Similar to FVRx, physicians at CHASS assess and discuss healthy eating at an initial screening.[42] Afterwards, physicians write patients prescriptions to "eat more fruits and vegetables."[43] Patients receive ten dollars per prescription to be redeemed at the weekly, on-site farmers market, where they can also receive nutrition counseling and view cooking demonstrations.[44] Chicago's South Side recently saw the development of its own, provider-specific food prescription program, Food Rx.[45] Food Rx results from

35. WHOLESOME WAVE, *infra* note 36; Hernandez, *infra* note 41; Goddu et al., *infra* note 45.

36. *See* WHOLESOME WAVE, FRUIT AND VEGETABLE PRESCRIPTION PROGRAM, FACT SHEET (2015) (reporting that the FVRx program reached CA, CT, GA, MA, ME, MN, NM, NY, RI, TX, Washington, D.C. and Navajo Nation between 2010 and 2015).

37. *Id*.

38. For example, a family of four would receive up to twenty-eight dollars per week. *Id*.

39. *Id*.

40. Hernandez, *infra* note 41; Goddu et al., *infra* note 45.

41. Dorothy Hernandez, *Fresh Prescription*, HOUR DETROIT (Sept. 22, 2014), http://www.hourdetroit.com/Hour-Detroit/October-2014/Fresh-Prescription.

42. *Id*.

43. *Id*.

44. *Id*.

45. Anna P. Goddu et al., *Food RX: A Community-University Partnership to Prescribe*

collaboration between the University of Chicago researchers, six local health clinics, Walgreens, and a local non-profit farmers market.[46] Food Rx innovators describe their goals for the program in four "prongs:" (1) tapping into the symbolic, persuasive nature of "Doctor's Orders;" (2) providing a coupon for healthy purchases at a Farmers Market and at Walgreens; (3) raising awareness of health and wellness resources on the South Side; and (4) educating patients on healthy choices through shopping guidelines.[47]

B. Program Effectiveness and Barriers

Reflections on these programs demonstrate clear impact. Wholesome Wave reports that between 2011 and 2015, sixty-nine percent of participants increased their fruit and vegetable consumption and forty-five percent of participants decreased their Body Mass Indexes ("BMI"s).[48] Furthermore, ninety-one percent of FVRx participants agreed or strongly agreed that they were happier with their healthy weight or diabetes care because of their participation in FVRx.[49] For families, forty-five percent of patient households reported an increase in food security.[50] For Health Rx in Detroit, ninety-four percent of participants reported an increased consumption of fruits and vegetables and an increased ability to manage their conditions better after participating in the program.[51]

These promising prescription programs also reveal several systemic challenges to food prescription programs and *Food as Medicine* initiatives

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Healthy Eating on the South Side of Chicago, 43 J. OF PREVENTION & INTERVENTION IN THE COMMUNITY 148 (2015).

46. Walgreens' interest in helping pilot a food prescription program stemmed from their effort to grow beyond the "traditional retail pharmacy model." *Id*. Walgreens' expansion efforts included the addition of fresh fruit, vegetables, and other healthy foods, particularly at Walgreens locations in food desert areas. *Id*. at 3.

47. *Id*. at 4–5.

48. WHOLESOME WAVE, *supra* note 36.

49. *Id*.

50. *Id*.

51. Hernandez, *supra* note 41.

having widespread impact on America's chronic disease crisis.[52] First, Food Rx researchers noted that some providers had yet to incorporate the food prescription into their list of routinely administered care for chronic conditions.[53] Though researchers agreed that continued awareness of the program would quell this tendency, this common pitfall speaks to the significant shift implicit in a physician's prescribing of *food*, not medicine.[54]

Second, food prescription programs are non-profit initiatives and they are predominantly funded privately, often through grants.[55] However, maximizing the reach of *Food as Medicine* initiatives would likely require a diversification of funding sources.[56] Most uniquely, Food Rx in Chicago succeeded in forming a partnership with a mega retailer in Walgreens.[57] Though still in its pilot phase, the program's promising results may encourage retailers to join the food prescription movement as a funding source.[58] Even so, Walgreen's private support was not a funding cure-all.[59] Food Rx research funds had to cover the cost of the pilot voucher for the Farmers Market, and researchers conceded that a major limitation to the longevity of the program is the lack of long-term financial support for underserved patients.[60] Ultimately, food prescription programs will require sustainable funding by diverse sources, including insurance, to take permanent hold.[61]

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52. *Infra* notes 53–60 and accompanying text.

53. Goddu et al., *supra* note 45, at 7.

54. *Id*.

55. GREENWALD, *supra* note 3. This Wholesome Wave created FVRx in partnership with the Laurie M. Tisch Illumination Fund and the city's Health and Hospital Corporation, while Health Rx is funded by the Kresge Foundation. Jane Brody, *Prescribing Vegetables, Not Pills*, NY TIMES (Dec. 1, 2014, 2:44 PM), https://well.blogs.nytimes.com/2014/12/01/prescribing-vegetables-not-pills/?_r=0; Hernandez, *supra* note 41.

56. GREENWALD, *supra* note 3.

57. Goddu et al., *supra* note 45, at 3.

58. *Id*. at 8.

59. *Id*. at 4, 9.

60. *Id*.

61. Robert Greenwald & David Waters, *Prescribing Food Like Medicine Would Save Medicare Millions*, WGBH NEWS (Mar. 12, 2014), http://news.wgbh.org/post/prescribing-

IV. *FOOD AS MEDICINE* AND FOOD PRESCRIPTIONS: THE NEW STANDARD

Food prescription programs have potential to address the health care needs of chronic disease sufferers. It follows that health care delivery should incorporate food prescription programs and the greater *Food as Medicine* movement. However, for these interventions to become standard care, it falls on health care providers, payers, and educators to embrace nutrition as a remedy.

A. Non-Profit Hospitals Should Promote Nutrition Through Community Health Needs Assessment

For non-profit hospitals, the Community Health Needs Assessment ("CHNA") provides an opportunity to address its community's nutritional needs.[62] All non-profit hospitals have to demonstrate their "community benefit," or, restated, the initiatives by which the hospital promotes community health.[63] Before the Patient Protection and Affordable Care Act ("ACA"), non-profit hospitals needed only to report a certain quantity of these activities to the Internal Revenue Service ("IRS") in order to maintain their tax-exempt status.[64] The ACA strengthened tax exemption requirements, which were then implemented by the IRS's 2014 Final Rule.[65] Today, hospitals seeking federal tax-exempt status are required to conduct a CHNA, a broad survey of the community's essential health needs performed every three years.[66] Thereafter, the hospital must design and implement a strategy to meet the community's health needs,[67] referred to as the

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food-medicine-would-save-medicare-millions.

62. SARAH DOWNER ET AL., CENTER FOR HEALTH LAW AND POLICY INNOVATION, HOSPITAL COMMUNITY BENEFIT: ADDRESSING NUTRITION AS A PRIMARY COMMUNITY HEALTH NEED 3 (June 2015), http://www.chlpi.org/wp-content/uploads/2014/01/Hospital-Community-Benefit-issue-brief-06.2015-V3.pdf.

63. *Id*.

64. *Id*.

65. *Id*.

66. *Id*. at 15.

67. Examples of "community health needs" include a community's needs to prevent illness and ensure adequate nutrition. *Id*. at 5.

Community Health Implementation Plan ("CHIP").[68] The Final Rule requires hospitals to include the medically underserved, low income, and minority populations living in its defined "community."[69] After determining that its community holds significant nutrition and/or preventive medicine needs, a non-profit hospital must either adopt a program to address such needs or report to the IRS its reasoning for not doing so.[70]

Therefore, non-profit hospitals which discover nutritional deficiencies and/or chronic diseases in their communities should address these needs through nutritional programming.[71] This strategy has already manifested within some non-profit hospitals.[72] For example, in its 2016 CHNA, St. Mary-Corwin Medical Center in Pueblo, Colorado identified chronic diseases, such as obesity and diabetes, as among their top three community health concerns.[73] The CHNA explained that seventeen percent of Pueblo's population was low income, with limited access to decent nutrition.[74] In response, St. Mary-Corwin affirmed its commitment to its own nutritional initiative, SMC Farm Stand, a hospital-run farmer's market which accepts prescriptions for produce.[75] Although the Farm Stand and its food prescription component predated the 2016 CHNA, one point of St. Mary-Corwin's CHIP was to expand healthy food access by expanding the number of clinical food prescription partners in 2017.[76] Food prescription programs

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68. ST. MARY-CORWIN MEDICAL CENTER, *infra* note 76. The CHIP must give special consideration to the input from at least one public health department, members of a medically underserved, low-income, and minority population, and use feedback to adopt an implementation strategy. SARAH DOWNER ET AL., *supra* note 62.

69. *Id*.

70. *Id*.

71. *See* Food as Medicine, *supra* page 5, and accompanying notes (discussing how poor nutrition worsens chronic conditions).

72. *See infra* notes 73, 77, 78, 79 and accompanying text (discussing St. Mary-Corwin Medical Center implementation of a food nutritional program to combat chronic disease).

73. ST. MARY-CORWIN MEDICAL CENTER, COMMUNITY HEALTH NEEDS ASSESSMENT 20 (2016).

74. *Id*. at 24.

75. *Id*. at 25.

76. ST. MARY-CORWIN MEDICAL CENTER, COMMUNITY HEALTH IMPLEMENTATION PLAN

are one example of actions non-profit hospitals can undertake in response to CHNAs, which prioritize chronic disease prevention. Other actions include maintaining urban gardens,[77] working with local schools to provide nutrition education to students,[78] and starting cooking classes.[79] Non-profit hospitals are at liberty to allocate funding ("community benefit resources") to multiple types of nutritional interventions to support its community's wellness needs.[80]

Therefore, it is unsurprising that *Food as Medicine* subscribers and nutrition professionals see the Final Rule's CHNA requirements as an opportunity to pursue and form partnerships with local non-profit hospitals.[81] Food prescription programs particularly stand to gain from these partnerships; these programs are typically non-profits, sustained only through foundation and donor support.[82] Meanwhile, hospitals are "anchor institutions," consistant and increasingly active institutions rooted in a community,[83] playing vital and apparent roles in health care delivery.[84] Partnerships between food prescription programs and non-profit hospitals

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(CHIP) FY 2017-2019, COMMUNITY HEALTH ACTION PLAN (CHAP) FY 2017 5 (2017).

77. LOYOLA UNIVERSITY MEDICAL CENTER, COMMUNITY HEALTH NEEDS ASSESSMENT (CHNA) 13 (2017).

78. KANE COMMUNITY HOSPITAL, COMMUNITY HEALTH NEEDS ASSESSMENT AND COMMUNITY HEALTH STRATEGIC PLAN 21 (June 30, 2016).

79. RIVER FALLS AREA HOSPITAL, COMMUNITY HEALTH NEEDS ASSESSMENT AND IMPLEMENTATION PLAN 2014-2016 18 (2014).

80. SARAH DOWNER, *supra* note 17, at 15.

81. *See* Bina Venkataraman, *Poverty Prescriptions*, BOSTON GLOBE (Feb. 1, 2015), https://www.bostonglobe.com/opinion/2015/02/01/nonprofit-hospitals-have-key-role-play-feeding-america-hungry/esyDBsP34tY2KbjgZv4TrM/story.html (pointing to two *Food as Medicine* organizations, including Wholesome Wave, which actively pursue hospital partnerships to improve healthy food access. The author also notes that these organizations pushed for the adoption of the CHNA requirement).

82. ROBERT GREENWALD, *supra* note 3.

83. David Maurrasse, Anchor Institutions and their Significance to Community and Economic Development, STATE OF THE PLANET (March 8, 2016), http://blogs.ei.columbia.edu/2016/03/08/anchor-institutions-and-their-significance-to-community-and-economic-development.

84. *Leveraging Nonprofit Hospital "Community Benefits" to Create Healthier Communities*, NATL. POL'Y & LEGAL ANALYSIS NETWORK TO PREVENT CHILDHOOD OBESITY 3 (July 2015), http://www.changelabsolutions.org/sites/default/files/Hospital-Community-Benefits_FINAL_20150720.pdf.

promise financial investment, greater stability, and a more direct reach to target populations.[85]

B. Insurers Should Support Food as Medicine Based on Patient Outcomes

Additionally, the benefits of *Food as Medicine* initiatives could be maximized if insurers covered nutrition interventions as a means of preventive care.[86] Potential savings, alone, should entice private and public payers to cover *Food as Medicine* initiatives.[87] Specifically in regards to food prescriptions, prices to "refill" (or rather, to redeem subsidies for) fruits and vegetables pale in comparison to traditional pharmaceuticals.[88] A high-level consideration of the medical costs for people facing chronic diseases like diabetes and obesity reveals shocking numbers.[89] For example, in 2013, per capita medical costs for diabetics totaled just under $15,000, $10,000 higher than people without the disease.[90] The CDC estimated medical costs for obesity-related illnesses to be $147 billion in 2008.[91] Amid such staggering figures, *Food as Medicine* programs present viable options for cost- and medically-effective solutions. One study calculated that an investment of ten dollars per person in community-based lifestyle interventions, those that "increase physical activity, *improve nutrition*, and prevent tobacco use," could save the country more than sixteen billion dollars annually within five years.[92] A smaller, test group study assessed the cost savings for sixty-five chronic disease sufferers who received healthy meals and nutrition

85. SARAH DOWNER, *supra* note 62, at 3, 8.
86. *Id*. at 1.
87. ROBERT GREENWALD, *supra* note 3.
88. SARAH DOWNER, *supra* note 17, at 5–6.
89. Michelle Andrews, *High Cost of Diabetes Drugs Often Goes Overlooked*, NAT'L PUB. RADIO, (Aug. 18, 2015), http://www.npr.org/sections/health-shots /2015/08/18/432621873/high-cost-of-diabetes-drugs-often-goes-overlooked.
90. *Id*.
91. CHRONIC DISEASE OVERVIEW, *supra* note 2.
92. *The Healthcare Costs of Obesity*, THE STATE OF OBESITY, http://stateofobesity.org/healthcare-costs-obesity.

counseling for one year.[93] Compared to their counterparts who did not receive nutritional interventions, this group experienced fewer and shorter hospital stays.[94] Furthermore, the group's monthly healthcare costs fell from $50,000 per person to $17,000 per person.[95] As populations facing chronic disease stand to benefit from primary, secondary, or tertiary nutrition interventions,[96] insurers which promote and cover such initiatives could reap real, quantifiable cost-savings.

Moreover, because *Food as Medicine* initiatives fit compatibly within the Medicare trend towards value-based-payment, insurers adopting such value-based reimbursement models should cover nutrition interventions which improve health outcomes.[97] Value-based payment models eschew the traditional "fee-for-service reimbursement" and reward quality care and positive patient outcomes.[98] Studies demonstrate nutrition interventions' propensity to improve patient outcomes, as well-nourished patients visit the emergency room less frequently, are more likely to adhere to their medication prescriptions, and miss fewer medical appointments.[99] By contrast, malnourished patients experience longer hospital stays and ineffective medication interventions.[100] Furthermore, malnourishment precludes patients from continuing critical treatments, and often increases patient readmission rates.[101] Because *Food as Medicine* initiatives promote long-

93. SARAH DOWNER, *supra* note 17, at 6.
94. *Id*.
95. *Id*.
96. *Id*. at 3.
97. Robert Greenwald *supra* note 61.
98. *Id*.
99. *Id*.
100. *Id*.
101. *Id*.; One such value-based payment model is the Centers for Medicare and Medicaid Services *Hospital Readmission Reduction Program*, providing financial incentives to hospitals to reduce costly and unnecessary hospital readmissions. *The Hospital Readmissions Reduction (HRR) Program*, CTRS. FOR MEDICARE & MEDICAID SERV., https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/HRRP/Hospital-Readmission-Reduction-Program.html.

term health benefits and enhanced quality outcomes for chronic disease patients, it follows that private insurers should design benefit packages which cover nutrition interventions for the treatment of chronic diseases.[102]

C. Medical Education Should Incorporate Nutrition Training

Finally, the necessity for nutrition intervention programs, such as food prescription programs, is underscored by current physicians' minimal understanding of "how" to utilize nutrition in medical treatment.[103] Despite the benefits of nutrition interventions, *Food as Medicine* represents a departure from the standard medical practices acquired in medical training.[104] In order to truly integrate nutrition into the health care delivery model, this integration should be taught.

Today, most physicians graduate from medical school with little-to-no comprehensive understanding of nutrition, disinclining them from offering or subscribing nutrition interventions for chronic diseases.[105] A 2010 study revealed that only one-quarter of medical schools offered classes on nutrition.[106] A 2014 survey of all medical schools similarly determined that over seventy percent of schools fail to provide the recommended minimum twenty-five hours of nutrition education.[107] If medical schools do offer nutrition education, most occurs before any clinical or experiential training, further hindering the future physicians' integration of food and lifestyle choices into their practices.[108] This medical education absent nutrition training marks future physicians ill-prepared to provide comprehensive care

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102. SARAH DOWNER, *supra* note 17, at 16.

103. Allison L. Crawford & Karen E. Aspry, *Teaching Doctors-in-Training About Nutrition: Where Are We Going in 2016?*, RHODE ISLAND MED. J. 23 (2016).

104. Gorn, *supra* note 30.

105. *See infra*, notes 106, 107, 108 and accompanying text.

106. Crawford & Aspry, *supra* note 103.

107. Nearly forty percent of surveyed medical schools provided less than half of that amount. Kelly M. Adams et al., *The State of Nutrition Education at US Medical Schools*, J. BIOMEDICAL ED. 1, 2 (2015).

108. *Id*. at 3; Crawford & Aspry, *supra* note 106, at 24.

to the growing number of Americans experiencing one or more chronic diseases.[109]

Physicians notice this deficiency themselves.[110] One survey of medical residents found that only a small minority felt prepared to provide competent nutrition guidance to their patients.[111] The study also found that fewer than ten percent of primary care providers in the US provide weight-loss counseling to their patients.[112] Upon graduation, fewer than fourteen percent of physicians consider themselves adequately trained in nutrition counselling.[113] Nevertheless, there are signs that nutritional training piques physicians' interests. For example, seventy-one percent of incoming medical students consider nutrition to be clinically important.[114] A 2012 national survey of U.S. primary care physicians indicated that an overwhelming majority of primary care physicians supported nutrition counseling to help them improve their treatment of chronic disease.[115]

On an institutional level, some medical schools have successfully incorporated nutritional education.[116] The University of North Carolina at Chapel Hill has developed an open-access, web-based Nutrition in Medicine program targeting medical students and residents, reportedly administered by a number of residency programs.[117] Loma Linda University School of Medicine is offering specialized training for its resident physicians in Lifestyle Medicine — a formal subspecialty in using food to treat disease.[118]

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109. Adams et al., *supra* note 107, at 5.

110. *Id.*, *What's at stake in nutrition education during med school*, AM. MED. ASS'N, AMA WIRE (July 23, 2015), https://wire.ama-assn.org/education/whats-stake-nutrition-education-during-med-school.

111. Adams et al., *supra* note 107.

112. *Id*.

113. *What's at stake in nutrition education during med school*, *supra* note 110.

114. *Id*.

115. Sara N. Bleich et al., *National survey of US primary care physicians' perspectives about causes of obesity and solutions to improve care*, BMJ OPEN (2012).

116. Crawford, *infra* note 106.

117. *Id*.

118. Gorn, *supra* note 30.

At least ten medical schools have even formed partnerships with culinary schools, utilizing cooking demonstrations to impart practical, real-world nutritional information that the physician can offer to patients.[119] The adoption of such programs demonstrates the medical industry's tacit willingness to embrace the tenets of *Food as Medicine* into medical education.

Congressional leaders sought to further encourage this shift in medical education with the introduction of two possibly key pieces of legislation: the Expanding Nutrition's Role in Curricula and Healthcare (ENRICH) Act and the Education and Training (EAT) for Health Act.[120] The ENRICH Act would provide for a grants program to develop and enhance integrated nutrition and physical activity curricula in medical schools.[121] The bill creates a fifteen million dollar competitive grants program, under which at least thirty medical schools could apply for funding for new or expanded nutrition and physical activity curriculum.[122] Developed curriculum must be designed to address nutrition needs and improve physician preparedness in the prevention, management, and reversal of obesity, cardiovascular, disease, diabetes, and cancer.[123] The EAT for Health Act promotes nutrition training for practicing physicians, mandating at least six hours of continued medical education in nutrition each year.[124]

Regardless of the future of this legislation,[125] conventional health care

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119. *Id*.

120. Expanding Nutrition's Role in Curricula and Healthcare Act, H.R. 1411, 114th Congress (2015); Education and Training (EAT) for Health Act of 2014, H.R. 4378, 113th Congress (2014).

121. Expanding Nutrition's Role in Curricula and Healthcare Act, H.R. 1411, 114th Congress (2015).

122. *Id*.

123. Expanding Nutrition's Role in Curricula and Healthcare Act, H.R. 1411, 114th Congress (2015).

124. Education and Training (EAT) for Health Act of 2014, H.R. 4378, 113th Congress (2014).

125. The ENRICH Act and the EAT for Health Act were reintroduced and assigned to committees in March of 2017. *Nutrition and Diet Bills*, GovTrack,

practices should no longer ignore nutrition as a viable treatment option. If medical training can educate physicians how to provide nutritional counseling, they will emerge from medical school better prepared to address chronic disease from a multi-factorial approach. Without such training, physicians will remain ill-versed in the healing properties of nutrition, and *Food as Medicine* initiatives like food prescriptions will remain untapped or underutilized resources in the providers' administration of care to chronic disease sufferers.

VI. CONCLUSION

Food as Medicine departs from traditional prescriptive practices.[126] However, considering the growing burden of chronic diseases,[127] the medical community should embrace nutrition as a cost-effective and successful treatment. Existing food prescription programs are generating positive outcomes for chronic disease sufferers around the country.[128] However, for *Food as Medicine* to take hold in the modern health care landscape, health care providers and payers must act. Specifically, non-profit hospitals should implement food prescription programs as strategies to address CHNAs, insurers should reimburse nutritional interventions, and medical education should incorporate nutritional training into physicians' curricula.

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https://www.govtrack.us/congress/bills/subjects/nutrition_and_diet/6181 (last visited Apr. 28, 2017).

126. David Gorn, *supra* note 30.

127. *See* Chronic Disease in America, *supra* page 2, and accompanying notes.

128. *See Food as Medicine*, *supra* page 5, and accompanying notes.

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Automation and Motor Vehicles: The End of a Public Health Crisis?

Matthew Kurschisnki[*]

The current wave of system automation poses a myriad of new challenges and new solutions for our collective public health. One of the most striking developments in automation's effect on current public health issues may occur on our roadways, and may drastically reduce the amount of injuries and deaths related to motor vehicle accidents. Public roadways are some of the most complex and dangerous systems humans must interact with.[1] While cost effective and well-tested solutions designed to prevent injuries and deaths on our roadways exist[2], the World Health Organization notes that it is still a neglected public health concern.[3] Technology may provide a novel solution. As technology alters the public health landscape, regulators, legislators, and educators need to be ready for the coming paradigm shift of vehicle automation and undertake educational, legislative, and regulatory action ensuring a smooth transition into automated motor vehicles operating on our roadways Handling this wave of automation efficiently and correctly will provide positive impacts on the public health. This article examines the current public health crisis of motor vehicle accidents, the coming wave of motor vehicle automation, the inherent limitations and harms of automation,

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1. *World report on road traffic injury prevention*, World Health Org. 3 (2004), http://siteresources.worldbank.org/EXTTOPGLOROASAF/Resources/WHO_full_report_en.pdf.
2. *Id*. at 6.
3. *Id*. at 3.

examines what actions have been undertaken to prepare society for the transition to automated motor vehicles, and considers what still must be done to ensure safer roadways in the twenty first century.

I. THE CURRENT PUBLIC HEALTH CRISIS

Motor vehicle accidents are a serious public health concern in the United States. Understanding the real costs and causes of motor vehicle related injuries and deaths illustrates the potential positive impact technology may have on public health. While it may be impossible to entirely eliminate motor vehicle related injuries and deaths, crafting novel solutions to the public health crisis with our ever-advancing technological prowess may drastically reduce the numbers of those injured or killed on our roadways. In 2014, motor vehicle accidents accounted for 10.6 deaths per 100,000 people in the United States, totaling 38,851 deaths.[4] These accidents are the leading cause of deaths for US teens.[5] Furthermore, about ninety percent of all motor vehicle accidents can be attributed to human error.[6] Accordingly, the Centers for Disease Control and Prevention ("CDC") listed motor vehicle injury as a top ten public health concern in the United States.[7]

Thirty-four percent of contributing factors to motor vehicle accidents relate to driver decision errors, including but not limited to, driving too fast for conditions, driving too fast around curves, false assumptions of other driver actions, illegal maneuvers, and misjudgment of gaps or other driver's

4. *Accidents or Unintentional Injuries*, CTRS. FOR DISEASE CONTROL AND PREVENTION (Sept. 15, 2016), https://www.cdc.gov/nchs/fastats/accidental-injury.htm.

5. *Teen Drivers: Get the Facts*, CTRS. FOR DISEASE CONTROL AND PREVENTION (Oct. 13, 2016), https://www.cdc.gov/motorvehiclesafety/teen_drivers/teendrivers_factsheet.html.

6. Bryant Walker Smith, *Human Error as a Cause of Vehicle Crashes*, STANFORD LAW SCHOOL (Dec. 18, 2013, 3:15 PM), http://cyberlaw.stanford.edu/blog/2013/12/human-error-cause-vehicle-crashes.

7. Shannon Barnet, *CDC: 10 most important public health problems and concerns*, BECKER'S HOSP. REVIEW (Mar. 1, 2016), http://www.beckershospitalreview.com/population-health/cdc-10-most-important-public-health-problems-and-concerns.html.

speeds.[8] About forty percent of driver attributable reasons for motor vehicle accidents relate to driver recognition errors, including: inadequate surveillance, internal distractions, external distractions, and inattention.[9] About ten percent of these driver attributable factors relate to performance errors, including: overcompensation, poor directional control, and panic/freezing.[10] Finally, about seven percent of these driver attributable factors result from non-performance error, including sleep or physical impairment (for example, a heart attack).[11]

Other contributory factors, such as texting or drunk driving, result in delayed human responses.[12] At seventy miles per hour, an unimpaired driver has a braking reaction time of .54 seconds.[13] When legally drunk, the driver does not brake until they have traversed an additional four feet beyond the point where an unimpaired driver begins to brake.[14] When a driver is distracted by reading an email, the additional distance traversed increases to thirty-six additional feet until the brakes are applied.[15] When actively sending a text, this distance balloons to an additional seventy feet beyond the point where an unimpaired driver begins to brake.[16]

The current public health crisis of motor vehicle accidents and resulting injury can therefore almost entirely be attributed to human error.[17] Human error, intoxication, distraction, and simple incompetence kill thousands on

8. NAT'L. HIGHWAY TRAFFIC SAFETY ADMIN., NATIONAL MOTOR VEHICLE CRASH CAUSATION SURVEY 24 (July 2008), https://crashstats.nhtsa.dot.gov/Api/Public/ViewPublication/811059.

9. *Id.* at 25.

10. *Id*.

11. *Id*.

12. *See* Phil Lebeau, *Texting and Driving Worse than Drinking and Driving*, CNBC (Jun. 25, 2009), http://www.cnbc.com/id/31545004.

13. *Id*.

14. *Id*.

15. *Id*.

16. *Id*.

17. *See* Smith *supra* note 6.

US roadways every year.[18] Automation provides a potential solution by taking the control away from us.

II. THE PROMISE OF SELF-DRIVING AUTOMATION

The prevalence of human error in motor vehicle accidents poses a challenge for public health educators, legislators, and regulatory bodies, but this challenge may have a novel twenty-first century solution: automation.[19] Automation is a computerized system undertaking all of, or some of, the driving tasks traditionally operated by humans in motor vehicles.[20] The National Highway Traffic Safety Association ("NHTSA") classifies vehicle autonomy by "level," ranging from 1 to 4.[21] Level 1 entails function-specific automation, for example cruise control and automated parallel parking.[22] Level 2 entails combined function automation, such as a function that aids the driver in both cruise control and automatic lane centering.[23] Level 3 is limited self-driving automation, in which drivers cede all safety controls to the onboard computer, and as such do not necessarily have to monitor the roadway at all times.[24] Finally, level 4 is complete full self-driving automation, wherein the vehicle is completely autonomous and performs all functions with minimal human input.[25]

The wave of automation is rapidly advancing, with motor vehicle

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18. *See* Barnet *supra* note 7; *see also* Lebeau *supra* note 12 (discussing the dangers of texting and driving).

19. *See* Smith *supra* note 6.

20. *See generally* Todd Litman, *Autonomous Vehicle Implementation Predictions*, VICTORIA TRANSP. POLICY INST. 3 (Jan. 2, 2017), http://www.vtpi.org/avip.pdf (describing the impact autonomous cars will have on the future of travel).

21. *Id*. at 3.

22. *See id* (discussing how level 1 is the level of automation many motor vehicles currently use for some specific tasks).

23. *See id* (discussing how level 2 entails slight automation, such as your motor vehicle self-centering if the driver begins to drive towards the center line).

24. *See id* (discussing how level 3 entails some applications, like safety device features and emergency braking, being computer prompted with no human input to apply breaks in some situations required).

25. *See id* (discussing how level 4 entails total automation with no human input ever required for any task).

producers predicting the first commercial sales of partially automated vehicles between 2018 and 2020, which may operate autonomously in restricted environments such as freeways.[26] Although further development and testing is needed before unrestricted level 4 autonomous motor vehicles are sold on the commercial market,[27] it is anticipated that fully autonomous vehicles may account for fifty percent of total vehicle travel by the 2040s.[28] This paradigm shift in the motor vehicle market will have important consequences for public health.[29]

With upwards of ninety percent of motor vehicle accidents resulting from human error, complete level 4 automation may radically redefine the public health issues surrounding motor vehicle use, the accidents resulting from motor vehicle use, and the resulting injuries and deaths on US roadways.[30] Human errors[31] could be significantly reduced, if not entirely eliminated, as humans will no longer be responsible for any driver functions.[32] Per decade, it is estimated that upon widespread adoption of self-driving cars in the marketplace 300,000 American lives may be saved.[33]

III. THE CHALLENGES OF SELF-DRIVING AUTOMATION

While it is generally understood that automation of motor vehicles will result in a reduction of fatalities on US roadways, automation itself poses

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26. *See id.* at 10.
27. *Id*.
28. *Id*. at 13.
29. *Id*. at 9.
30. *See id*. at 4.
31. *See* NAT'L. HIGHWAY TRAFFIC SAFETY ADMIN., *supra* note 8 (describing human errors as driver decision errors, driver recognition errors, performance errors, and non-performance errors).
32. Alissa Walker, *Will self-driving vehicles really make cities safer?*, CURBED (Sept. 21, 2016), http://www.curbed.com/2016/9/21/12991696/self-driving-cars-safety-usdot.
33. *See generally* Adrienne Lafrance, *Self-Driving Cars Could Save 300,000 Lives Per Decade in America*, THE ATLANTIC (Sept. 29, 2015), https://www.theatlantic.com/technology/archive/2015/09/self-driving-cars-could-save-300000-lives-per-decade-in-america/407956/ (discussing how driverless cars could could eliminate, "the vast majority of fatal traffic accidents.")

unique challenges to ensuring safety for drivers and pedestrians.[34] As the human element is taken out of the motor vehicle equation, and in its place stands manufactured and programmed electronics and computers, the risk will likewise shift from human error to design error.[35] Human error could potentially be eliminated as the main contributory factor to motor vehicle accidents.[36] Instead, factors such as latent defects, product errors, maintenance errors, and design flaws may become the greatest contributory factors to the loss of life on American roadways.[37]

On May 7th, 2016, a man was killed in a motor vehicle crash while using his Tesla's auto-pilot system.[38] The auto-pilot system Tesla implemented in the vehicle was a level 2 system, combining automated braking, passing, and lane centering abilities without human input, but does require driver attention.[39] Neither the driver, nor the autopilot, engaged a braking maneuver and the vehicle crashed into a truck, killing the driver.[40] The accident resulted in a NHTSA investigation, which ultimately cleared Tesla of any fault and deemed the crash the result of human error.[41] While the investigation cleared Tesla because the system is not designed or advertised as fully autonomous, the accident, and subsequent investigation, highlighted a serious issue for manufacturers and regulators: system failure.[42] Although the system does require human input and is not meant to be a fully autonomous safety system,

34. *See* Litman, *supra* note 20.

35. JASON WAGNER ET AL., TEXAS A&M TRANSPORTATION INSTITUTE, LIABILITY CONSIDERATIONS FOR AUTOMATED AND CONNECTED VEHICLES 6–7 (2015), http://d2dtl5nnlpfr0r.cloudfront.net/tti.tamu.edu/documents/TTI-2015-11.pdf.

36. Walker, *supra* note 32.

37. WAGNER ET AL., *supra* note 35.

38. Neal Boudette, *Tesla's Self Driving System Cleared in Deadly Crash*, N.Y. TIMES, (Jan. 19, 2017), https://www.nytimes.com/2017/01/19/business/tesla-model-s-autopilot-fatal-crash.html?_r=0.

39. *Id*.; *see also* Litman, *supra* note 21 (discussing the impact autonomous cars will have on the future of travel).

40. Boudette, *supra* note 38.

41. *Id*.

42. *See id*.

nonetheless the autopilot system failed to engage the braking mechanism prior to the crash.[43] Regulators, manufacturers, and educators must be aware that even in a world made safer by motor vehicle automation, inherent risks may still lurk in the machines themselves.[44]

Computerized automation also poses the risk of malicious interference, or "hacking."[45] The interference can alter system performance, engage breaks, alter acceleration /deceleration, and ultimately affect any on board computer system device the "hacker" wishes to target.[46] These attacks can be initiated with only an internet connection to the vehicle's computerized systems.[47] Such attacks may be triggered by individuals, criminal enterprises, or even nation states.[48] The results can be devastating, resulting in vehicle accidents and potential fatalities.[49]

Additionally, with automated and computerized vehicle systems and the threat of "hacking" comes the threat of computer viruses infecting automated vehicles.[50] Worldwide, viruses have infected millions of computers.[51] These viruses can be directly targeted, such as the Stuxnet virus, or infect a computer with the goal of spreading the virus to other computer systems .[52]

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43. *Id*.

44. *See id*.

45. Jemima Kiss, *Your next car will be hacked. Will autonomous vehicles be worth it?*, THE GUARDIAN (Mar. 13, 2016, 5:38 PM), https://www.theguardian.com/technology/2016/mar/13/autonomous-cars-self-driving-hack-mikko-hypponen-sxsw.

46. *Seee* Andy Greenberg, *Hackers Remotely Kill a Jeep on the Highway – With Me in it*, WIRED (July 21, 2015), https://www.wired.com/2015/07/hackers-remotely-kill-jeep-highway/.

47. *Id*.

48. Kiss, *supra* note 45.

49. *Id*.; *see also* Greenberg, *supra* note 46 (discussing the dangers of hackers with motor vehicles).

50. Jerry Hirsch, *Hackers can now hitch a ride on car computers*, L.A. TIMES, (Sept. 13, 2015, 6:34 PM), http://www.latimes.com/business/autos/la-fi-hy-car-hacking-20150914-story.html.

51. Sharon Weinberger, *Top Ten Most Destructive Computer Viruses*, SMITHSONIAN (Mar. 19, 2012), http://www.smithsonianmag.com/science-nature/top-ten-most-destructive-computer-viruses-159542266/.

52. *See id.* (discussing how the Stuxnet virus was a malicious attack utilizing computer

In 2011 at Defcon, hackers were already inquiring as to whether car-to-car transmission of computer viruses would soon be a possibility.[53] Real world examples of virus attacks and the interest of the hacking community in car-to-car transmission illustrates a new challenge educators, regulators, legislators, and manufacturers must face as automated motor vehicles became standard on our roadways, malicious interference with the motor vehicle itself.

Automation is not perfect and has its own inherent limitations, such as system error or design flaws, which may contribute to human fatalities on the roadway.[54] Additionally, ceding control of automobiles over to computers creates a host of issues itself, like the potential for malicious hacking.[55] These challenges must be recognized as automation becomes a facet of everyday life on American roadways, the public must be educated about the threats the process of automation itself poses, and legislators need to take action ensuring safety in automation.

IV. DRIVING FORWARD WITH AUTOMATION

Manufacturers, regulators, legislators, and educators must face the threats of computer error, viruses, and hacking. The motor vehicle industry and public health advocates have a robust history of automobile regulation, standards, and educational efforts undertaken to ensure safe motor vehicle use.[56] Regulatory, legislative, and educational efforts designed to address the issues posed by automation should be prioritized as U.S. roadways increasingly become the domain of automated motor vehicles.

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code to shut down an Iranian nuclear facility).

53. *See* Kiss, *supra* note 45 (describing how Defcon, founded in 1992, is the world's largest conference for hackers and computer code enthusiasts).

54. Boudette, *supra* note 38.

55. Hirsch, *supra* note 50.

56. *Achievements in Public Health, 1900-1999 Motor-Vehicle Safety: A 20th Century Public Health Achievement*, CTRS. FOR DISEASE CONTROL AND PREVENTION (May 14, 1999), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm4818a1.htm.

With the passage of the 1966 National Traffic and Motor Vehicle Safety Act, the federal government received authorization to regulate standards for motor vehicles.[57] Federally mandated standards include regulations on minimum sound requirements, rear view visibility, power windows, braking, and emissions.[58] Administrative agencies, such as the NHTSA, are empowered to regulate motor vehicle safety standards.[59] In addition to the federal government, states, such as Illinois, have mandated the use of seatbelts in automobiles.[60] These federal and state legislative and regulatory initiatives are examples of the impact that federal and state agencies can have on motor vehicle manufacturing and use in the US.[61]

Federal and state governments are well situated to exert legislative and regulatory authority and combat the public health issues surrounding automated motor vehicles.[62] The federal government has stopped short of codifying any regulations for driverless cars, but the NHTSA has offered a guideline for driverless car manufacturers.[63] Key concerns addressed in the guidelines are: data recording and sharing; privacy; system safety; cybersecurity; human-machine interface; crash worthiness; consumer education and training; registration; post-crash behavior; the interplay of federal/local/and state laws; ethical considerations; operational design; object

57. 49 U.S.C.A. § 30111 (West 2015).

58. *Id.*; *See also* ENVT'L PROT. AGENCY, *Emission Standards Reference Guide for On-road and Nonroad Vehicles and Engines*, https://www.epa.gov/emission-standards-reference-guide (last visited Feb. 12, 2017) (detailing the guidelines the EPA references when deciding appropriate emissions standards).

59. *National Highway Traffic Safety Administration*, ALLGOV.COM (2016), http://www.allgov.com/departments/department-of-transportation-dot/national-highway-traffic-safety-administration?agencyid=7241.

60. 625 ILCS 5/12-603.1.

61. *Id.;* 49 U.S.C.A. § 30111 (West 2015).

62. CTRS. FOR DISEASE CONTROL AND PREVENTION, *supra* note 56.

63. *See generally Federal Automated Vehicles Policy*, NAT'L. HIGHWAY TRAFFIC SAFETY ADMIN. (Sept. 2016), https://www.transportation.gov/sites/dot.gov/files/docs/AV%20policy%20guidance%20PDF.pdf (detailing the current policies for dealing with automatic vehicles).

and event detection; and risk avoidance (fall back) parameters.[64] The guidelines are a step in the right direction, and will help manufacturers tackle the issues surrounding automated vehicle use.

Through its guidance, the NHTSA signaled that it is cognizant of system failure, hacking, and virus issues.[65] However, the NHTSA cautioned that given the rapid technological advance of automated vehicles, and the fact that the existing regulatory tools at their disposal were created when automated vehicles were only a "remote notion," the regulatory tools at its disposal may be ineffective to deal with the issue of regulating modern automated vehicles.[66] In addition, the federal government must walk the line between under-regulating these new automated vehicles, and over-regulating their use.[67] State governments may provide the regulatory environment necessary to ensure safe automated vehicle use.

Regulation of automated vehicles has increasingly become a concern for state legislatures.[68] In 2015, sixteen states introduced legislation concerning automated motor vehicles and their use.[69] In 2016, twenty states introduced similar legislation, and within the first four months of 2017, this number expanded to thirty-three states.[70] Each year since 2012, the number of state legislatures introducing legislation addressing automated vehicles and their use on US roadways has increased.[71] However, the speed of legislative

64. *Id*. at 15.
65. *Id*.
66. *Id*. at 7–8.
67. Cecilia Kang, *Self-Driving Cars Gain Powerful Ally: The Government*, N.Y. TIMES, (Sept. 19, 2016), https://www.nytimes.com/2016/09/20/technology/self-driving-cars-guidelines.html.
68. Mitchell Russ, *California Regulations for Driverless Cars Stall as Other States Speed Ahead*, L.A. TIMES, (Jan. 26, 2017 12:10 PM), http://www.latimes.com/business/autos/la-fi-hy-driverless-regulations-california-20170126-story.html.
69. *Autonomous Vehicles: Self-Driving Vehicles Enacted Legislation*, NAT'L. CONFERENCE OF STATE LEGISLATURES (April 2017), http://www.ncsl.org/research/transportation/autonomous-vehicles-self-driving-vehicles-enacted-legislation.aspx.
70. *Id*.
71. *Id*.

passage and levels of regulatory oversight imposed within legislation concerning automated motor vehicle use varies by state.[72]

The legislation, or lack thereof, concerning automated motor vehicle use in Michigan and Californian highlights the divide of regulatory efforts concerning automated motor vehicle use at the state level.[73] In Michigan, legislation recently passed ensuring that as soon as driverless cars are commercially available, they will be legal to own and use on all public roadways.[74] Meanwhile, despite passing a law in 2012 directing the state Department of Motor Vehicles to begin the process of establishing regulatory oversight of driverless cars, California has yet to establish any regulations allowing driverless cars on the road.[75] As automation becomes a reality on US roadways, states must exert their regulatory authority to ensure the safe use of automated vehicles. If states fail to address the unique challenges associated with automated vehicle use and provide regulatory oversight over this new industry, it may hamper the positive effects automation may have on the motor vehicle injury public health crisis.

In addition to enhancing legislation and regulation, education is vital, just as it was in efforts to stymie the public health concern of drunk driving.[76] The CDC recommends that in part, public mass media campaigns and instructional classes for students be used to lessen the public health impacts of drunk driving on society.[77] Educational public outreach programs, such as the public mass media campaigns which combated drunk driving, can also help prevent deleterious effects automation could have on human behavior

72. Russ, *supra* note 68.
73. *Id*.
74. *Id*.
75. *Id*.
76. *What Works: Strategies to Reduce or Prevent Drunk Driving*, CTRS. FOR DISEASE CONTROL AND PREVENTION (Mar. 22, 2016), https://www.cdc.gov/motorvehiclesafety/impaired_driving/strategies.html.
77. *Id*.

by informing the public on proper automated vehicle use.[78] The Florida Department of Transportation has undertaken a public outreach program, the Florida Automated Vehicles Program, which seeks to educate the public on automation, conduct research on automated vehicle use, and generally create awareness of these technologies and their impacts on road congestion and human fatalities resulting from car accidents.[79] The Florida program should serve as a model for other states as they address the coming wave of automation.

Education must also alert automated drivers and pedestrians to the fact that an automated vehicle is not a perfectly safe system. Automated vehicle operators may feel safer in their automated vehicles due to the reduction in human error related crashes, and then engage in riskier behavior, such as not wearing a seatbelt.[80] Furthermore, this perception of automated safety may also lead to pedestrians engaging in riskier behavior around and on roadways.[81] These risk taking behaviors due to perceived safety is known as "off-setting" or "risk compensation."[82] The NHTSA recommends that a model approach to automated vehicle policy include federal and state efforts to educate operators.[83] These proposed educational schemes are ideal forums to impart on automated vehicle operators the notion that perceived safety is not a license to engage in risky behavior such as erratic pedestrian movement, the non-use of seatbelts, or "off-setting" generally.[84] Educational programs, like Florida's automated motor vehicle program, will be important assets educating and guiding the public into the coming wave of automation, and

78. Litman, *supra* note 21, at 4.
79. *Florida Automated Vehicles*, FLA. DEP'T. OF TRANSP. (2017), http://www.automatedfl.com/.
80. *Id*.
81. *Id*.
82. FLA. DEP'T. OF TRANSP., *supra* note 79.
83. NAT'L. HIGHWAY TRAFFIC SAFETY ADMIN., *supra* note 63 at 40.
84. *Id*.

will hopefully have a beneficial effect on public health through education that may curb off-setting risk behaviors.[85]

V. CONCLUSION

Traffic fatalities resulting from motor vehicle accidents is currently an American public health crisis.[86] Thousands die on American roadways every year in motor vehicle accidents.[87] The future of automated vehicles on the roadways will likely make drivers safer and the public healthier by drastically reducing the amount of human error on America's roadways, the number one contributory factor to traffic fatalities.[88] However, to discount the risks associated with automated vehicles is an inadequate approach to motor vehicle public health policy.[89] It would be equally inappropriate to assume they will end all human based contributory motor vehicle accident factors.[90] Issues such as risk off-setting, hacking, system failure, and latent design defects must be addressed by educators and legislators to ensure an adequate response to the coming trend of motor vehicle automation.

Moving forward, legislators and regulators should establish substantive legislative and regulatory schemes on both the federal and state levels, as we have with non-automated motor vehicles, promoting safe automated motor vehicle use and creating safer US roadways in the process.[91] Additionally, legislators and regulators should work hand in hand with manufacturers of automated motor vehicles to minimize their inherent risks. Furthermore, establishing educational programs that inform vehicle operators of their proper use and the risks inherent in their use may drastically reduce roadway

85. FLA. DEP'T. OF TRANSP., *supra* note 79.
86. CTRS. FOR DISEASE CONTROL AND PREVENTION, *supra* note 4.
87. *Id*.
88. Smith, *supra* note 6.
89. Litman, *supra* note 20, at 4.
90. *Id*.
91. NAT'L. HIGHWAY TRAFFIC SAFETY ADMIN., *supra* note 63.

fatalities from both non-automated and automated causes of vehicle accidents.[92] With substantive legislative policy, regulatory policy, and educational programs in place, the American public will move into the era of automation and, hopefully, dramatically reduce the current motor vehicle injury public health crisis.

92. *Id.* at 38.

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The Future of Cost-Free Contraception Under the Trump Administration

*Meredith Eng**

I. INTRODUCTION

On March 6, 2017, Republicans introduced the American Health Care Act, intending to repeal and replace the Affordable Care Act (ACA).[1] However, House Speaker Paul Ryan withdrew the bill before any votes were cast due to lack of support.[2] Regardless, the battle over health reform is not over. In order to gain more support amongst conservative Republicans, the next iteration of health reform may attempt to eliminate the ACA's "essential health benefits," which are ten categories of services that insurance plans must provide.[3] While the ACA's contraceptive mandate, which requires insurance plans to cover birth control without cost-sharing, is not one of the "essential health benefits,"[4] there is concern that it too will be eliminated.[5] The Senate's recent vote to allow states to determine whether to provide Title

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1. Jeff Overley, *Battle Lines Drawn as ACA Repeal Bill Unveiled*, LAW 360 (Mar. 6, 2017), https://www.law360.com/articles/898877/battle-lines-drawn-as-aca-repeal-bill-unveiled.

2. Stephen Collinson et al., *House Republicans Pull Health Care Bill*, CNN (Mar. 25, 2017), http://www.cnn.com/2017/03/24/politics/house-health-care-vote.

3. Philip Klein & Robert King, *House Leadership Considers Ditching Obamacare Regulations to Woo Conservatives*, WASH. EXAMINER (Mar. 22, 2017), http://www.washingtonexaminer.com/article/2618178.

4. CTRS. FOR MEDICARE & MEDICAID SERVS., *What Marketplace Plans* Cover, https://www.healthcare.gov/coverage/what-marketplace-plans-cover (last visited Apr. 8, 2017).

5. Emily Crockett, *The Republican Health Plan Wouldn't Touch Free Birth Control—But That Doesn't Mean Its Future Is Safe*, VOX (Mar. 8, 2017), http://www.vox.com/identities/2017/3/8/14843636/birth-control-benefit-ahca-republican-obamacare-repeal-replace.

X funding, which covers contraception and women's preventive services, to health care centers that perform abortions[6] and key leaders' vocal opposition to the mandate[7] suggest that the future of the contraceptive mandate is insecure.

However, removal of the contraceptive mandate would have negative consequences for the American people because a woman's access to contraception is directly correlated to increased health, education, and economic power.[8] This article will describe the ACA's contraceptive mandate and its application, alternative methods for expanding access to cost-free contraception, and ultimately suggest that future health care reform not only should maintain the mandate for cost-free contraception but also include additional provisions such as permitting a woman to obtain twelve months of contraception at one time and eliminating cost-sharing for vasectomies in order to further expand access to cost-free contraceptives.

II. BACKGROUND

Prior to the ACA, coverage, scope, and cost-sharing for prescription contraceptives was inconsistent across health plans.[9] Medicaid covered contraception without cost-sharing, but did not necessarily cover all eighteen

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6. Jennifer Steinhauer, *Senate Lets States Defund Clinics That Perform Abortions*, N.Y. TIMES (Mar. 30, 2017), https://www.nytimes.com/2017/03/30/us/politics/pence-congress-family-planning-money.html?_r=0.

7. Scott Keyes & Travis Waldron, *House Republican Leader Price: 'There's Not One Woman' Who Doesn't Have Access to Birth Control*, THINKPROGRESS (Feb. 10, 2012), https://thinkprogress.org/house-republican-leader-price-theres-not-one-woman-who-doesn-t-have-access-to-birth-control-5a13b090799c#.7uxa6eor9.

8. Sarah Lipton-Lubet, *Promoting Equality: An Analysis of the Federal Contraceptive Coverage Rule*, AM. CIVIL LIBERTIES UNION 1 (Oct. 2012), https://www.aclu.org/files/assets/promoting_equality_-_an_analysis_of_the_federal_contraceptive_coverage_rule.pdf.

9. *See generally* Laurie Sobel et al., *The Future of Contraceptive Coverage*, THE HENRY J. KAISER FAMILY FOUND. 5 (Jan. 2017), http://files.kff.org/attachment/Issue-Brief-The-Future-of-Contraceptive-Coverage [hereinafter *The Future of Contraceptive Coverage*] ("The 2010 Kaiser/HRET survey of employers found that 85% of large firms covered prescription contraceptives in their largest health plans, although they may have used cost-sharing and were not required to cover the full scope of contraceptive care, the amount of which can vary greatly by employer and type of plan.").

Food and Drug Administration (FDA) approved methods.[10] However, the ACA established uniformity for contraceptive coverage and cost-sharing.[11] Beginning January 1, 2013, the ACA required all private health insurance policies, with few exceptions, to cover each of the eighteen contraceptive methods for women approved by the FDA as well as related counseling without any cost-sharing.[12]

However, the contraceptive mandate does not apply to all insurance plans. For example, grandfathered health plans, which are health plans that were created (or individual health insurance policies that were purchased) on or before March 23, 2010, are exempt.[13] Group health plans offered by religious employers such as churches and houses of worship are also exempt from the requirement.[14] Exemption means that these plans and organizations do not

10. Crockett, *supra* note 5; U.S. FOOD & DRUG ADMIN., *Birth Control Guide*, https://www.fda.gov/downloads/ForConsumers/ByAudience/ForWomen/FreePublications/UCM517406.pdf (last visited Apr. 9, 2017)(explaining that the contraceptive methods covered by the ACA are Sterilization Surgery for Women, Sterilization Implant for Women, IUD Copper, IUD with Progestin, Implantable Rod, Shot/Injection, Oral Contraceptives "The Pill" (Combined Pill and Extended/Continuous Use Combined Pill), Oral Contraceptives "The Mini Pill" (Progestin Only), Patch, Vaginal Contraceptive Ring, Diaphragm with Spermicide, Sponge with Spermicide, Cervical Cap with Spermicide, Female Condom, Spermicide Alone, and Emergency Contraception (Levonorgestrel and Ulipristal Acetate); John Kraemer, *The ACA's Contraception Coverage Mandate: Constitutional Limits on Exempting Employers*, HEALTH AFF. BLOG (Mar. 20, 2014), http://healthaffairs.org/blog/2014/03/20/the-acas-contraception-coverage-mandate-constitutional-limits-on-exempting-employers (explaining that the ACA does not cover vasectomies, male condoms, or abortifacients, though they are FDA-approved).

11. GUTTMACHER INST., *Insurance Coverage of Contraceptives*, https://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives (last visited Apr. 2, 2017) [hereinafter *Insurance Coverage of Contraceptives*].

12. *See* Rita Luthra, *Contraception Counselling and Compliance*, WORLD HEALTH ORG., http://www.who.int/bulletin/volumes/85/11/07-041335/en (describing contraceptive counseling as educating patients about the mechanisms, efficacy, and safety of each contraceptive method so that the patient can choose the correct method for her body and lifestyle); *Insurance Coverage of Contraceptives*, *supra* note 11.

13. CTRS. FOR MEDICARE & MEDICAID SERVS., *Grandfathered Health Plan*, https://www.healthcare.gov/glossary/grandfathered-health-plan (last visited Apr. 9, 2017); *The Future of Contraceptive Coverage*, *supra* note 9, at 5.

14. THE CTR. FOR CONSUMER INFO. & INS. OVERSIGHT, *Fact Sheet: Women's Preventive Services Coverage, Non-Profit Religious Organizations, and Closely-Held For-Profit Entities*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/womens-preven-02012013.html (last visited May 15, 2017) [hereinafter THE CTR. FOR CONSUMER INFO. & INS. OVERSIGHT].

have to provide coverage for contraception.[15] Non-profit religious organizations are not exempt but are eligible for an accommodation, which means that they do "not have to contract, arrange, pay, or refer a person for contraceptive services coverage."[16] Instead, contraception is paid for by the insurance plan's issuer or the third-party administrator, if it is a self-insured plan, without cost-sharing by the woman or the organization.[17] In 2014, the Supreme Court extended the accommodation to closely-held for-profit companies in *Burwell v. Hobby Lobby*.[18]

The contraceptive mandate has improved the lives of American women in a variety of ways. As a result of the mandate, over fifty-five million women have access to cost-free contraception.[19] Eliminating cost-sharing for contraceptives saved women an estimated $1.4 billion per year on the pill alone.[20] Additionally, when cost-sharing was eliminated, women in affected plans were more likely to use prescription contraceptives and to choose more effective, long-acting reversible contraception (LARC), such as the intrauterine device (IUD) and birth control implant, than women whose cost sharing was not eliminated.[21] Prior to the mandate, LARC often had high up-front costs, which made LARC less accessible.[22]

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15. *Id*.
16. *Id*.
17. *Id*.
18. Burwell v. Hobby Lobby, 134 S. Ct. 2751 (2014).
19. U.S. DEP'T OF HEALTH & HUMAN SERVS., Asst. Sec. for Planning and Evaluation, *The Affordable Care Act Is Improving Access to Preventive Services for Millions of Americans*, ASPE DATA POINT (May 14, 2015), https://aspe.hhs.gov/sites/default/files/pdf/139221/The%20Affordable%20Care%20Act%20is%20Improving%20Access%20to%20Preventive%20Services%20for%20Millions%20of%20Americans.pdf.
20. Nora Becker & Daniel Polsky, *Women Saw Large Decrease In Out-of-Pocket Spending For Contraceptives After ACA Mandate Removed Cost Sharing*, 34 HEALTH AFF. 1204, 1209 (2015).
21. Caroline S. Carlin et al., *Affordable Care Act's Mandate Eliminating Contraceptive Cost Sharing Influenced Choices of Women With Employer Coverage*, 35 HEALTH AFF. 1608, 1614 (2016); see also THE AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, *Long-Acting Reversible Contraceptives (LARC): IUD and Implant*, (May 2016), https://www.acog.org/-/media/For-Patients/faq184.pdf (describing types of LARC).
22. *The Future of Contraceptive Coverage*, *supra* note 9, at 4.

Furthermore, access to contraception has far-reaching implications beyond the immediate avoidance of an unwanted pregnancy.[23] Following the legalization of the contraceptive pill in the 1960s and 1970s, women experienced a lower likelihood of living in poverty, higher rates of participation in the workforce, higher rates of attendance at professional schools, and increased wages.[24] Additionally, their children were also more likely to graduate college and earn higher incomes.[25] These outcomes demonstrate the importance of access to contraception. As the Kaiser Family Foundation succinctly stated, "In short, contraception helps women take control of their lives; inconsistent access undermines that."[26]

III. DISCUSSION

A. Alternative Approaches

a. Employer-Based Action

Even if the contraceptive mandate is eliminated from future health reform, contraceptives may still be covered by many insurance plans. First, some employers may choose to offer plans that cover contraceptives without cost-sharing because it is a low cost-benefit and popular with employees.[27] Second, in 2000, the Employment Equal Opportunity Commission (EEOC) held that employer-based health insurance policies that provided coverage for preventive prescription drugs and services but did not provide coverage for prescription contraceptives violated the Civil Rights Act.[28] The EEOC

23. Martha J. Bailey, *Fifty Years of Family Planning: New Evidence on the Long-Run Effects of Increasing Access to Contraception*, BROOKINGS PAPERS ON ECON. ACTIVITY, 341, 359 (Spring 2013).

24. *Id*.

25. *Id*. at 385–86.

26. Lipton-Lubet, *supra* note 8, at 6.

27. Jilian Mincer, *U.S. States Mull Contraception Coverage as Obamacare Repeal Looms*, REUTERS (Jan. 12, 2017), http://www.reuters.com/article/us-usa-obamacare-contraception-idUSKBN14W1CD.

28. *The Future of Contraceptive Coverage*, *supra* note 9, at 5.

viewed "failure to cover prescription contraceptives as sex discrimination under Title VII and the Pregnancy Discrimination Act, which prohibits discrimination against women based on their ability to get pregnant."[29] However, while this ruling requires employer-based insurance policies to cover prescription contraceptives, its effect is limited because it did not address the scope of coverage, nor did it consider the issue of cost-sharing.[30]

b. Pharmacist-Prescribed Prescription Contraceptives

Dispensing prescription contraceptives without a physician prescription is another potential alternative method for increasing access to contraceptives. Requiring a physician prescription to obtain birth control can be a barrier for women who do not have insurance, cannot take time off of work to see a doctor, or have difficulty obtaining an appointment with a physician.[31] Several states have enacted laws allowing women to obtain contraceptives without a physician's prescription.[32] For example, beginning January 1, 2016, Oregon pharmacists can prescribe and dispense oral and transdermal contraceptives after the patient takes a twenty question risk assessment.[33] California has a similar, but more expansive law that permits pharmacists to dispense vaginal rings and provide hormonal birth control shots in addition to oral and transdermal contraceptives.[34] The intent behind these laws is to

29. *Id.*

30. *Id.*

31. Sarah Breitenbach, *States Start to Let Pharmacists Prescribe Birth Control Pills*, THE PEW CHARITABLE TRUSTS (Feb. 18, 2016), http://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2016/02/18/states-start-to-let-pharmacists-prescribe-birth-control-pills.

32. *Id.*

33. Allison Gilchrist, *How Oregon Pharmacists are Prescribing Birth Control*, PHARMACY TIMES (Jan. 4, 2016), http://www.pharmacytimes.com/resource-centers/womens-health/how-oregon-pharmacists-are-prescribing-birth-control; Nat'l Partnership for Women & Families, *Ore. Governor Signs Another Bill to Improve Contraceptive Access*, WOMEN'S HEALTH POL'Y REP. (Jul. 8, 2015), http://go.nationalpartnership.org/site/News2?abbr=daily2_&page=NewsArticle&id=48233&security=1201&news_iv_ctrl=-1.

34. Breitenbach, *supra* note 31.

make birth control more readily available.[35] As ninety-three percent of Americans live within five miles of a pharmacy,[36] the pharmacy is a logical service point for increasing access.

This method of dispensing contraceptives has been proven to be safe.[37] Several studies have shown that women are effectively able to screen themselves for contraindications—situations in which a medication should not be used because it would be harmful to the patient—through the use of questionnaires that ask women about their medical history in order to identify risks.[38] Additionally, there is evidence that pharmacists are also able to effectively screen women for contraindications.[39]

While this approach has the potential to positively influence access to short-term contraceptive methods, it is not a perfect replacement for the contraceptive mandate as it still contains barriers to access and fails to address cost concerns. First, this method only applies to short-term contraceptives. It does nothing to increase women's access to LARC, which are significantly more effective than oral contraceptives,[40] but require insertion by a licensed provider.[41] Second, pharmacists in many states may refuse to fill prescriptions for contraceptives on the basis of religious or moral

35. *Id.*

36. *Id.*

37. THE AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, COMMITTEE OPINION NUMBER 544: OVER-THE-COUNTER ACCESS TO ORAL CONTRACEPTIVES 2 (2012), https://www.acog.org/-/media/Committee-Opinions/Committee-on-Gynecologic-Practice/co544.pdf?dmc=1&ts=20170219T2205342182 [hereinafter OVER-THE-COUNTER ACCESS]

38. *Id.*; MEDLINEPLUS, *Contraindication*, https://medlineplus.gov/ency/article/002314.htm (last updated Sept. 16, 2016) (defining "contraindication").

39. OVER-THE-COUNTER ACCESS, *supra* note 37.

40. AM. SEXUAL HEALTH ASS'N, *Understanding LARC*, http://www.ashasexualhealth.org/understanding-larc/ (explaining that LARC are more effective at preventing pregnancy than other contraceptive methods because they do not require any action by the user).

41. Sneha Barot, *Moving Oral Contraceptives to Over-the-Counter Status: Policy Versus Politics*, 18 GUTTMACHER POL'Y REV., 85, 86 (2015).

beliefs without repercussions.[42] Only eight states have laws that explicitly require pharmacists to fill a patient's prescription.[43] Seven states' pharmacy boards permit pharmacists to refuse to fill medication for religious or moral reasons, but forbid the pharmacist from interfering with a patient's access to contraception.[44] Furthermore, six states have enacted laws or policies that permit pharmacists and/or pharmacies to refuse to dispense contraceptives for moral or religious reasons.[45] However, some refusal laws do not contain corresponding protections for patients, such as requirements to transfer the prescription or refer the patient to another pharmacist or pharmacy.[46]

c. Over-the-Counter Availability

Another proposed strategy to increase access to birth control is to eliminate prescriptions entirely and make contraceptives available "over-the-counter" (OTC). If contraceptives were sold OTC, women would be able to purchase them without a prescription from a pharmacist or physician, similar to pain relievers or decongestants. While this solution has its benefits, it is still insufficient for several reasons. First, only the FDA can decide to make a medication truly OTC.[47] In order to make contraceptives OTC, every contraceptive manufacturer would have to submit a request to the agency for each individual contraceptive.[48] This process is long, costly, and requires the manufacturer to do research, including studying label comprehension and

42. *See* NAT'L WOMEN'S LAW CTR., *Pharmacy Refusals 101* (Jul. 2015), http://nwlc.org/wp-content/uploads/2015/08/pharmacy_refusals_101.pdf ("The laws and regulations in most states do not specifically speak to the issue of pharmacy refusals based on personal beliefs.").

43. *Id.*

44. *Id.*

45. *Id.*

46. *Id.*

47. Soumya Karlamangla, *What You Need To Know About California's New Birth Control Law*, L.A. TIMES, (Feb. 18, 2017, 4:19 PM), http://www.latimes.com/local/lanow/la-me-ln-birth-control-law-20160408-story.html.

48. Barot, *supra* note 41.

consumer actual use, that is then reviewed by the FDA before approval.[49] In addition to time, expense, and effort, some manufacturers may be hesitant to petition for review on a product that can be controversial.[50] These obstacles may disincentivize a manufacturer from seeking FDA approval and therefore decrease the likelihood of contraceptives obtaining OTC status.

Furthermore, even if a contraceptive were to obtain FDA-approval for OTC sale, there is concern that it still would not be accessible.[51] Specifically, state insurance laws may not eliminate cost-sharing for OTC medication. As a result, access may decline because the contraceptive is now cost-prohibitive, despite being sold over the counter.[52]

IV. PROPOSAL

There are no feasible alternatives to the ACA's contraceptive mandate that would provide a similar level of access to cost-free contraception. Additionally, exemptions for grandfathered plans, religious organizations, and small employers leave millions of women without access to contraception without cost-sharing.[53] Therefore, not only should future health reform maintain the contraceptive mandate, but lawmakers should expand the mandate by including provisions that would allow a woman to obtain twelve months of birth control at once and eliminate cost-sharing for vasectomies.

Currently, twenty-eight states have laws that require private insurance plans to provide birth control benefits.[54] Unfortunately, these laws are

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49. *Id.*
50. *Id.*
51. *Id.* at 87.
52. *Id.*
53. Marcia Boumil & Gregory Curfman, *The Contraceptive Mandate: Public Health Versus Religious Freedom* (Dec. 27, 2013), HEALTH AFF. BLOG, http://healthaffairs.org/blog/2013/12/27/the-contraceptive-mandate-public-health-versus-religious-freedom.
54. Mincer, *supra* note 27.

limited because they do not apply to all insurance plans, nor do most of them require birth control to be covered without cost-sharing.[55] However, change is on the horizon.[56] Several states, including California, Maryland, Vermont, and Illinois have already passed laws that mirror and even expand upon the ACA's contraception mandate.[57] California became the first to act when it passed the California Contraceptive Equity Act (CCEA) in 2014.[58] The CCEA requires cost-free coverage of all prescribed FDA-approved contraceptives by private and Medicaid managed care plans.[59] The provisions of the Maryland, Vermont, and Illinois laws built upon the CCEA by allowing women to obtain prescriptions for at least six months of contraceptives at a time.[60] Other provisions include coverage for vasectomies without cost-sharing, coverage for over-the-counter contraceptive medications like emergency contraception and increased Medicaid reimbursement to providers for LARC.[61] New York, Minnesota, Colorado, and Massachusetts have all stated their intent to pass similar laws within the year as well.[62]

While these laws represent a great step forward, they are limited in their effectiveness because they only apply to state-regulated plans.[63] Self-funded

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55. *Id.*
56. *Id.*
57. *Id*.
58. *Id*.; *The Future of Contraceptive Coverage*, *supra* note 9, at 5.
59. *The Future of Contraceptive Coverage*, *supra* note 9, at 5.
60. *See* PLANNED PARENTHOOD, *Maryland Contraceptive Equality Act*, https://www.plannedparenthood.org/planned-parenthood-maryland/get-involved-locally/action-network/maryland-contraceptive-equity-act (last visited Apr. 4, 2017) (noting that the Maryland Contraceptive Equity Act covers vasectomies and over-the-counter contraceptive medications like emergency contraception without cost-sharing); NAT'L PARTNERSHIP FOR WOMEN & FAMILIES, *Vt. Gov. Signs Bill Facilitating Access to Contraception*, WOMEN'S HEALTH POL'Y REP., (May 25, 2016), http://www.womenshealthpolicyreport.org/articles/vt-gov-signs-bill-contraception.html?referrer=https://www.google.com/ (noting that H.620 covers vasectomies without cost-sharing and increases Medicaid reimbursement to providers for LARC); 215 ILL. COMP. STAT. 5/356z.4 (West 2017).
61. *Id.*
62. Mincer, *supra* note 27.
63. *The Future of Contraceptive Coverage*, *supra* note 9, at 5.

plans, through which sixty-one percent of the workforce is insured,[64] are regulated by federal law under the Employee Retirement Income Security Act (ERISA) and therefore are not required to comply with these state regulations.[65] Additionally, by allowing each state to decide for itself how—or whether—to require the provision of cost-free contraception, the likely outcome is a lack of uniformity that will result in unequal access to cost-free contraception dependent on a woman's state of residence.[66] Therefore, to maintain and expand access to cost-free contraception uniformly across the country, future insurance reform should build upon the ACA mandate by permitting women to obtain twelve months of birth control at once and eliminate cost-sharing for vasectomies.

Currently, the amount of contraception that may be dispensed per prescription is at the discretion of the insurer.[67] Typically, insurers only cover one or three month supplies of contraceptives.[68] However, time and costs required for return visits to the clinic for additional contraceptives can result in reduced continuation rates.[69] Conversely, when women have access to multiple months of contraception at a time, they are more likely to use the contraception continuously.[70] As a result, women who have access to a year's

64. KAISER FAMILY FOUND. & HEALTH RES. EDUC. TRUST, *2014 Employer Benefits Survey*, I, 174 (2014), http://files.kff.org/attachment/2014-employer-health-benefits-survey-full-report.

65. Laurie Sobel et al., *Private Insurance Coverage of Contraception*, THE HENRY J. KAISER FAMILY FOUND. (DEC. 2012), http://files.kff.org/attachment/issue-brief-private-insurance-coverage-of-contraception [hereinafter *Private Insurance Coverage of Contraception*].

66. GUTTMACHER INST., *An Overview of Abortion Laws*, https://www.guttmacher.org/state-policy/explore/overview-abortion-laws (last updated Mar. 1, 2017) [hereinafter *An Overview of Abortion Laws*].

67. KAISER FAMILY FOUND., *Oral Contraceptive Pills*, at 5, http://files.kff.org/attachment/fact-sheet-oral-contraceptive-pills [hereinafter *Oral Contraceptive Pills*].

68. Barot, *supra* note 41, at 88.

69. Dawn Chin-Quee et al., *One Versus Multiple Packs for Women Starting Oral Contraceptive Pills: A Comparison of Two Distribution Regimens*, 79 CONTRACEPTION 369, 370 (2009).

70. OVER-THE-COUNTER ACCESS, *supra* note 37, at 2–3.

worth of contraception at once are thirty percent less likely to have an unplanned pregnancy than women who receive a one to three month supply of contraceptives.[71] Additionally, where women are dispensed multiple months' worth of contraception, they use pregnancy tests less frequently, total cost of care to providers per woman decreases, and the incidence of abortion is reduced.[72] These effects are greatest for women who receive up to a year's worth of contraception.[73] Therefore, in order to maximize these effects, the contraceptive mandate should permit women to receive twelve months of contraceptives at one time.

Additionally, in order to capture the full benefit of available contraceptive methods, the contraceptive mandate should be expanded to eliminate cost-sharing for vasectomies. The ACA's contraceptive mandate only requires coverage for FDA-approved contraceptive methods for women.[74] As Nguyen, Shih, and Turok wrote, "The U.S. government has recognized the importance of family planning by approving the contraceptive mandate; however, its exclusion of vasectomy and provisions for prospective male contraceptives reflect the nation's current view of family planning as a 'women's issue.'"[75] Most family planning programs focus on women as the users of contraceptive services with men playing a supporting role rather than being contraceptive users themselves.[76] Therefore, until contraceptive

71. *Oral Contraceptive Pills*, *supra* note 67 (comparing unintended pregnancy rates of women who receive up to a year's worth of contraception at once to women who receive one to three months' worth of contraception at a time).

72. Maria W. Steenland et al., *How Does the Number of Oral Contraceptive Pill Packs Dispensed or Prescribed Affect Continuation and Other Measures of Consistent and Correct Use? A Systematic Review.* 87 CONTRACEPTION 605, 609 (2013) [hereinafter *A Systematic Review*].

73. Diane G. Foster et al., *Number of Oral Contraceptive Pill Packages Dispensed and Subsequent Unintended* Pregnancies, 117 OBSTETRICS & GYNECOLOGY 566, 570–71 (2011).

74. *Insurance Coverage of Contraceptives*, *supra* note 11.

75. Brian T. Nguyen et al., *Putting the Man In Contraceptive Mandate*, 89 CONTRACEPTION 3, 4 (2014).

76. Karen Hardee et al., *Are Men Well Served By Family Planning Programs?* 14 REPROD. HEALTH 1,1 (2017).

benefits are provided for men, there will not be gender equality in the responsibility for family planning.[77]

Vasectomy is more effective, less risky overall, and has less expensive complications than female sterilizations.[78] It is also less expensive than female sterilization methods.[79] The average cost of a vasectomy is approximately $708 whereas the average cost for a tubal ligation is $2,912.[80] Furthermore, vasectomy is not only one of the most cost-effective contraceptive methods available, but it is also the most cost-effective contraceptive method for men.[81] However, despite evidence of its efficacy, safety, and cost-effectiveness, only 500,000 vasectomies are performed annually in the United States.[82]

This relatively lower incidence of vasectomy should not be construed to assume that men do not have an interest in controlling their own reproductive health. Recently, a clinical testing of an injectable hormone contraceptive for men was shown to be ninety-six percent effective at preventing pregnancy.[83] However, the trial was discontinued by an independent committee that determined the contraceptive's side effects of mood swings, increased libido, and pain at the injection site to be greater than its benefits.[84] Surprisingly, eighty percent of trial participants stated that they wanted to

77. Nguyen et al., *supra* note 75, at 4 ("An amendment to the contraceptive mandate [for cost-free vasectomy] would help to establish family planning as a 'human issue,' for which the involvement of men will increase safety and overall savings, as well as ethically balance the weight of the reproductive burden.").

78. *Id.* at 3.

79. *Id.* at 4.

80. *Id.*

81. *See* James Trussel et al., *Cost Effectiveness of Contraceptives in the United States*, 79 CONTRACEPTION 5, 13 (2009) ("[E]arlier analyses by Tussel et al., which also included male contraceptives, found that vasectomy, the copper-T IUD and the contraceptive implant were the most effective.").

82. David Turok et al., Reversing the United States Sterilization Paradox by Increasing Vasectomy Utilization, 83 CONTRACEPTION 289, 289 (2011).

83. Julie Beck, *The Different Stakes of Male and Female Birth Control*, THE ATLANTIC, (Nov. 1, 2016), https://www.theatlantic.com/health/archive/2016/11/the-different-stakes-of-male-and-female-birth-control/506120.

84. *Id.*

continue to use the contraceptive regardless of the risk of the side effects, suggesting that there is an unmet demand for male contraception.[85]

This demand could be met by making vasectomy more accessible. Currently, twenty-five percent of insurance companies do not cover vasectomy.[86] Though vasectomy is less expensive than female sterilization, without insurance coverage, it is still cost-prohibitive.[87] Therefore, in order to increase gender parity for reproductive services and access to this beneficial procedure, future efforts at health reform should include eliminating cost-sharing requirements for vasectomy.

V. COUNTERARGUMENTS

Fiscal conservatives will object to an expanded mandate because they do not want to pay for additional services. However, access to cost-free contraceptives is a money-saving proposition.[88] Currently, forty-nine percent of pregnancies in the United States are unplanned.[89] Unintended pregnancies are expensive; government expenditures on unintended pregnancies totaled $11.1 billion in 2006.[90] Further, for every dollar spent on publicly funded contraceptive services, the U.S. health care system saves nearly six dollars.[91] In particular, sterilization procedures, which are effective for decades, are significantly less expensive even for healthy pregnancies and births.[92]

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85. *Id.*

86. Nguyen et al., *supra* note 75, at 4.

87. *Cf. id.* (without insurance coverage, vasectomy would have the same out-of-pocket cost as LARC, which have been proven to be cost-prohibitive).

88. OFFICE OF THE ASSISTANT SEC'Y FOR PLANNING & EVALUATION, *The Cost of Covering Contraceptives Through Health Insurance*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (Feb. 10, 2012), https://aspe.hhs.gov/basic-report/cost-covering-contraceptives-through-health-insurance.

89. Lawrence B. Finer & Mia R. Zolna, *Unintended Pregnancy in the United States: Incidence and Disparities, 2006*, 84 CONTRACEPTION 478, 480 (2011).

90. Adam Sonfield et al., *The Public Costs of Births Resulting from Unintended Pregnancies: National and State-Level Estimates*, 43 PERSPS. ON SEXUAL & REPROD. HEALTH 94, 98 (Jun. 2011).

91. OFFICE OF THE ASSISTANT SEC'Y FOR PLANNING & EVALUATION, *supra* note 88.

92. Susan Scutti, *Obamacare in Jeopardy, States Protect No-Cost Contraception, Including Vasectomy*, CNN (Jan. 21, 2017, 11:26 PM),

In addition to saving money, access to contraception reduces the need for abortion.[93] Public funding for contraception results in 810,000 fewer abortions per year.[94] This should be attractive to religious groups who oppose abortion and consider it to be a sin.[95] Even for religious groups that oppose both contraception and abortion, contraception is sometimes seen as a lesser sin.[96]

Lastly, critics of multi-month access to contraception argue that the method will increase waste of contraceptives.[97] While it is true that women who are dispensed greater amounts of contraception tend to waste a greater amount than women who receive smaller amounts of contraception, the total cost of care for women receiving greater amounts of contraception was significantly less.[98] Therefore, despite the increase in waste, provision of a greater amount of contraception is still a cost-saving measure.

VI. CONCLUSION

The future of cost-free contraception for American women is unclear under the current administration. However, cost-free contraception is critical to the health and economic and educational success of American women, and consequently, the nation as a whole. Proffered solutions such as encouraging states to enact their own cost-free contraceptive mandates, making

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http://www.cnn.com/2017/01/20/health/states-protect-no-cost-contraception-and-vasectomy-aca.

93. GUTTMACHER INST., *1.94 Million Unintended Pregnancies and 810,000 Abortions Are Prevented Each Year By Publicly Funded Family Planning Services* (Feb. 24, 2009), https://www.guttmacher.org/news-release/2009/194-million-unintended-pregnancies-and-810000-abortions-are-prevented-each-year.

94. *Id.*

95. Gillian Mohney & Terry Moran, *Pope Francis Says Contraception May Be 'Lesser of Two Evils' During Zika Outbreak*, ABC NEWS (Feb. 18, 2017), http://abcnews.go.com/Health/pope-francis-contraception-lesser-evils-zika-virus-outbreak/story?id=37026017.

96. *Id.*

97. Dawn Chin-Quee et al., *supra* note 69, at 369.

98. Steenland et al., *supra* note 72, at 609 ("Despite the increased OCP wastage in the 13 cycle group. . .cost of care was $44 more for patients receiving one cycle and $99 dollars more for patients receiving three cycles than for patients who received 13 cycles.").

contraceptives available over-the-counter, or permitting pharmacists to dispense prescription contraceptives without a prescription by a physician, though in the spirit of increasing access to cost-free contraception, are insufficient to ensure equal access. True access to cost-free contraception requires a mandate at the federal level. Therefore, future health reform should contain an expanded contraceptive mandate to facilitate equal access to this critical benefit.

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Why Planned Parenthood® is Better than Un-Planned Parenthood: Why United States Sexual Education Should Remain Modernized

Lauren Batterham[*]

I. INTRODUCTION

Teen pregnancies are currently at an all-time low in the United States, but the rates are still much higher than in other developed countries[1] and result in negative health consequences for the women and children affected.[2] While abstinence-only sexual education is a form of sexual education that is commonly taught in American schools,[3] it is unclear whether abstinence-only curricula is the most effective form of sexual education.[4] In part due to our prevailing culture and norms, abstinence is no longer the most popular method of pregnancy prevention among teens.[5] Conversely, statistics show that comprehensive sexual education curricula decrease risk-taking behavior in teens and are shown to reduce teen pregnancies, in contrast to its abstinence-only counterpart.[6] Thus, the underutilization of comprehensive

[*] Loyola University Chicago School of Law Juris Doctor Candidate, 2018
[1] *About Teen Pregnancy: Teen Pregnancy in the United States*, CTRS. FOR DISEASE CONT. & PREVENTION, https://www.cdc.gov/teenpregnancy/about/ (last visited Mar. 31, 2017).
[2] *See infra* note 67 and accompanying text.
[3] Johannah Corblatt, *A Brief History of Sex Ed in America*, NEWSWEEK (Oct. 27, 2009, 8:00 PM), http://www.newsweek.com/brief-history-sex-ed-america-81001.
[4] Karen Perrin & Sharon Bernecki DeJoy, *Abstinence-Only Education: How We Got Here and Where We're Going*, 24 J. OF PUB. HEALTH POL'Y 445, 450–453 (2003); Henry Waxman, *Politics and Science: Reproductive Health*, 16 HEALTH MATRIX 5, 6 (2006).
[5] *Sexual Risk Behaviors: HIV, STD, & Teen Pregnancy Prevention*, CTRS. FOR DISEASE CONT. & PREVENTION (last visited Mar. 31, 2017), https://www.cdc.gov/healthyyouth/sexualbehaviors/.
[6] PLANNED PARENTHOOD, HISTORY OF SEX EDUCATION IN THE UNITED STATES 1, 4 (2012), https://www.plannedparenthood.org/files/3713/9611/7930/Sex_Ed_in_the_US.pdf.

sexual education programs in the primary school environment may be detrimental to teens without access to alternative forms of sexual education other than abstinence-only programs.

In the United States, teen pregnancy is a public health crisis that the federal government can solve through unified government action and the commonsense efforts of public health officials.[7] The Centers for Disease Control and Prevention ("CDC") lists teen pregnancy as one of its top seven priorities in public health and supports comprehensive, evidence-based sexual education programs for teens.[8] While the federal government has historically supported abstinence-only programs over comprehensive sexual education programs,[9] the Obama Administration began to shift federal funds from the former towards the latter due to comprehensive programs' ability to engender positive results for teens.[10] However, the individual states govern education curricula through their police powers; therefore, the federal government must ensure that other forms of sexual education remain available to teens when state governments fail to provide adequate education through their school systems.[11] Further, outside of school-administered programs, Planned Parenthood Federation of America, Inc. ("Planned Parenthood") is the largest provider of sexual education in the United States, and provides preventative services and sexual education to those in need.[12]

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[7] *See* Gabriel Scally, *Too Much Too Young? Teenage Pregnancy is a Public Health, Not a Clinical, Problem*, 31 INT'L J. OF EPIDEMIOLOGY 554, 554 (2002); *see, e.g.*, *Reproductive Health: Teen Pregnancy, Communitywide Initiatives*, CTRS. FOR DISEASE CONT. & PREVENTION, https://www.cdc.gov/teenpregnancy/projects-initiatives/communitywide.html (last updated Aug. 4, 2016).

[8] *About Teen Pregnancy: Teen Pregnancy in the United States*, *supra* note 1.

[9] John Santelli, *Abstinence-Only Education*, 73 SOC. RES. 835, 840 (2006); *see also* Perrin & DeJoy, *supra* note 2, 446–449.

[10] Kelly Percival & Emily Sharpe, *Sex Education in Schools*, 13 GEO. J. GENDER & THE L. 425, 425 (2012).

[11] *State Policies on Sex Education in Schools*, NAT'L CONF. OF STATE LEGISLATURES (Feb. 16, 2016), http://www.ncsl.org/research/health/state-policies-on-sex-education-in-schools.aspx; *Sex and HIV Education*, GUTTMACHER INST., https://www.guttmacher.org/state-policy/explore/sex-and-hiv-education (last updated Apr. 1, 2017).

[12] *See* PLANNED PARENTHOOD, *supra* note 6, at 10.

Since a comprehensive approach to sexual education is more realistic and efficient than rigid abstinence-only curricula, the federal government should continue to support and emphasize its efficacy in the prevention of teen pregnancy. This is because teen pregnancy can be solved by consistently providing practical and effective options through strong sexual education programs at the primary school level, supplemented by the availability of alternative programs outside of school. This supports the idea that health providers such as Planned Parenthood, youth services providers, and community-based organizations should remain available as resources to teens.

This article begins with Part I's discussion of sexual education in the United States, providing an overview of its history and discussing the origins of Planned Parenthood. Part II then contrasts abstinence-only and comprehensive sexual education curricula, explains why teen pregnancy is a public health issue, and examines current approaches to sexual education in the United States. Next, Part III discusses Planned Parenthood's success as a health care provider and educator, and the influence of the federal and state governments on sexual education. Finally, Part IV discusses the current obstacles Planned Parenthood faces as a health care provider and how it can continue to implement widespread sexual education programs for teens in the future.

I. BACKGROUND: SEXUAL EDUCATION IN THE UNITED STATES

A. General Overview

First generation sexual education programs in the United States were largely abstinence-only based, with an emphasis on religion rather than health.[13] However, the subsequent urbanization of the United States led to a

[13] JOHN D'EMILIO & ESTELLE FREEDMAN, INTIMATE MATERS: A HISTORY OF SEXUALITY IN AMERICA 68–69 (2012); SYLVESTER GRAHAM, A LECTURE TO YOUNG MEN ON CHASTITY: INTENDED ALSO FOR THE SERIOUS CONSIDERATION OF PARENTS AND GUARDIANS 66 (1837),

more public conversation about sexual education, albeit one that focused on the physical consequences of non-marital sex such as sexually transmitted diseases.[14] Alongside urbanization, the early twenty-first century brought the moral reform and social hygiene movement, which insisted that sexual problems arose from ignorance and emphasized the importance of educating the young.[15]

Despite this recognition, sexual education efforts were focused on married couples rather than teens.[16] In time, a disparity arose between what teens needed to learn regarding their reproductive health and what educators wanted to teach in the classroom; this was primarily a consequence of educators' desire to avoid "polluting" teen minds or interfering with parental rights to control their children's education.[17] As such, sexual education was largely omitted from American primary education.[18] The resistance to sexual education began to weaken in the early twentieth century with the first attempts to implement sexual education in public school systems.[19] The sexual revolution became more prominent later in the twenty-first century, paired with the Supreme Court holding for affirmative rights to contraception and abortion for women.[20]

Historically, the federal government has traditionally been conservative in its approach to sexual education, beginning with the 1981 passage of the

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https://collections.nlm.nih.gov/bookviewer?PID=nlm:nlmuid-7704062-bk; *see* Corblatt, *supra* note 3.

[14] *See* JAMES CIMENT, SOCIAL ISSUES IN AMERICA: AN ENCYCLOPEDIA (2015) (eBook); *see* Corblatt, *supra* note 3.

[15] Valerie Huber & Michael Firmin, *A History of Sex Education in the United States Since 1900*, 23 INT'L J. OF EDU. REFORM 25, 27 (2014).

[16] *See* CIMENT, *supra* note 14.

[17] *Id.*

[18] *Id.*; Jeffrey Moran, *"Modernism Gone Mad": Sex Education Comes to Chicago, 2013*, 83 J. AM. HIST. 481, 481 (1996).

[19] *See* Moran, *supra* note 18, at 482; Corblatt, *supra* note 3.

[20] *See* Griswold v. Connecticut, 381 U.S. 479, 485–86 (1965); Eisenstadt v. Baird, 405 U.S. 438, 446–47 (1972); *see also* Roe v. Wade, 410 U.S. 113, 164 (1973), Modified by Planned Parenthood of Southeastern Pennsylvania v. Casey, 505 U.S. 833 (1992).

Adolescent Family Life Act ("AFLA"), which set aside funds for abstinence-only sexual education.[21] AFLA created the Adolescent Family Life Program ("AFL Program"), which was specifically designed to address teen pregnancy via care and preventative services.[22] In addition, the AFL Program provided participating entities with the opportunity to apply for research grants if they remained within the program's mandates; this included promoting abstinence as the sole preventative service.[23] There was also a religious undercurrent to the legislation, which was an integral component of its program applications; entities applying for AFL Program funding were required to provide a description of how they would incorporate religious or charitable organizations into their efforts.[24] Further, no AFLA funding would be awarded to programs that provided abortion counseling or abortion procedures; resultantly, the AFL Program discouraged sexual education programs from teaching comprehensive sexual education programs by threatening their livelihood through the loss of necessary federal funding.[25]

The AFLA was later followed by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (the "1996 Welfare Reform"),[26] which also added provisions for abstinence-only sexual education that were later incorporated into the Community-Based Abstinence Education Program ("CBAE") in 2000.[27] Programs seeking funding were required to follow the

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21. *See* Percival & Sharpe, *supra* note 10, at 438.

22 ANONYMOUS, CONG. RES. SERVS., RS20873, REDUCING TEEN PREGNANCY: ADOLESCENT FAMILY LIFE AND ABSTINENCE EDUCATION PROGRAMS 1–2 (2010) [hereinafter CONG. RES. SERVS., RS20873].

23 CONG. RES. SERVS., RS20873, *supra* note 22, at 1–2.

24. INTRODUCTION TO ADOLESCENT FAMILY LIFE ACT—IMPORTANT AFLA CASES, 3 RELIGIOUS ORGANIZATIONS AND THE LAW § 13:28 [hereinafter INTRODUCTION TO AFLA].

25. INTRODUCTION TO AFLA, *supra* note 24, at § 13:28.

26. Personal Responsibility and Work Opportunity Reconciliation Act of 1996, Pub. L. No. 104-193, § 1 et seq., 110 Stat. 2105 (1996) [hereinafter "1996 Welfare Reform"].

27. 1996 Welfare Reform, § 912; *see* Corblatt, *supra* note 3 (discussing the 1996 Welfare Reform); *see also* 36 No. 8 Quinlan, School Law Bulletin art. 2. The 1996 Welfare Reform included the following 8-point definition of Abstinence Education for a Title V, Section 510 Program:

A. Have as its exclusive purpose teaching the social, psychological, and health gains

"8-point" definition of sexual education programs, or face the risk of forgoing federal funding.[28] From the legislative failures of this legislation, teens were deprived of a full understanding of their reproductive health and safe alternatives other than abstinence for those engaging in sexual intercourse.

Although the aforementioned abstinence-only provisions of the AFLA and the CBAE were eliminated in 2010, the Patient Protection and Affordable Care Act ("ACA") still allocated $250 million to abstinence-only programs.[29] However, additional federal funds were appropriated in the FY 2010 budget to target teen pregnancy prevention, and resulted in the creation of the Office of Adolescent Health ("OAH").[30] Also in 2010, the federal government implemented the Teen Pregnancy Prevention Initiative ("TPP")[31] and the Personal Responsibility Education Program ("PREP"),[32] which both incorporate abstinence-only and contraception-based programs into their evidence-based sexual education.[33] These groundbreaking programs revitalized the sexual education landscape, showing immediate success and

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> to be realized by abstaining from sexual activity; B. Teach abstinence from sexual activity outside marriage as the expected standard for all school-age children; C. Teach that abstinence from sexual activity is the only certain way to avoid out-of-wedlock pregnancy, sexually transmitted diseases, and other associated health problems; D. Teach that a mutually faithful, monogamous relationship in the context of marriage is the expected standard of sexual activity; E. Teach that sexual activity outside the context of marriage is likely to have harmful psychological and physical effects F. Teach that bearing children out of wedlock is likely to have harmful consequences for the child, the child's parents, and society G. Teach young people how to reject sexual advances and how alcohol and drug use increases vulnerability to sexual advances H. Teach the importance of attaining self-sufficiency before engaging in sexual activity.

1996 Welfare Reform, § 501(b)(2)(A–H).

28. *Id.*

29. *Id.*

30. Evelyn M. Kappeler & Amy Feldman, *Historical Context for the Creation of the Office of Adolescent Health and the Teen Pregnancy Prevention Program*, 54 J. OF ADOLESCENT HEALTH S3, S4 (2014).

31. 42 U.S.C. § 713(b)(2)(A).

32. *Id.*

33. Another program that evolved during this time was the Personal Responsibility Education Innovation Strategies ("PREIS"), whose mission is to explore innovative methods of preventing teen pregnancy in vulnerable populations. Kappeler & Feldman, *supra* note 30, at S4, S8; Percival & Sharpe, *supra* note 10, at 440.

reductions in teen pregnancy rates.[34] Previously, the federal government spent over $1.5 billion on abstinence-only education, but the preceding funding scheme shifted $180 million to comprehensive-based programs.[35] While the federal government has implemented major sexual education programs, the states inevitably play a larger hand in sexual education.

The federal government cannot directly control sexual education and can only assert influence at the state level through its funding decisions by virtue of the states' police powers.[36] While only twenty-four states statutorily mandate schools to teach sexual education,[37] over 95% of minors receive a formal sexual education before the age of eighteen at a school, church, community-based organization, or youth services program.[38] While some states allow or require sexual education and abstinence-plus programs in schools, other states prohibit discussion of contraceptive-use such as condoms, among other topics.[39]

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34. Brenda Wilson, *Proven Sex-Ed Programs Get a Boost from Obama*, NPR (June 6, 2010 12:26 PM), http://www.npr.org/templates/story/story.php?storyId=127514185.

35. Steven Ross Johnson, *Back to Abstinence-Only Education for Teens?*, MOD. HEALTHCARE (Dec. 10, 2016), http://www.modernhealthcare.com/article/20161210/MAGAZINE/312109982; *What the Research Says. . . Abstinence-Only-Until-Marriage Programs*, SIECUS, http://www.siecus.org/index.cfm?fuseaction=Page.ViewPage&PageID=1195 (last visited, Mar. 31, 2017).

36. The Supreme Court has held that the state police power includes the right of states to regulate education. Barbier v. Connolly, 113 U.S. 27, 31 (1884). *See also State Police Power*, BLACK'S LAW DICTIONARY (10th ed. 2014) (eBook) (defining police power); Perrin & DeJoy, *supra* note 4, at 446.

37. PLANNED PARENTHOOD, *supra* note 6, at 8; *Policies on Sex Education in Schools*, *supra* note 11; *see, e.g.*, *State Sex and HIV Education Policy*, KAISER FAM. FOUND., http://kff.org/hivaids/state-indicator/sexhiv-education-policy/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (last updated Mar. 1, 2017).

38. PLANNED PARENTHOOD, *supra* note 6, at 8; *Policies on Sex Education in Schools*, *supra* note 11; *see, e.g.*, *State Sex and HIV Education Policy*, *supra* note 37.

39. Certain conservative states often offer abstinence-only education in schools. For example, Mississippi only offers very vague school-sponsored sexual education, potentially only discussing it briefly during a health education class. Thus, students and their parents will pursue more effective forms of sexual education through community and youth outreach organizations. My Brother's Keeper, Inc. assists in facilitating such efforts among several community and youth organizations throughout the state. Telephone Interview with Antwan Nicholson, Training Program Manager, My Brother's Keeper, Inc. (Apr. 11, 2017) [hereinafter Telephone Interview with Antwan Nicholson]. *See also* Steve Siebold, *Mississippi's Horrific*

B. Planned Parenthood

In 1916, the precursor of what is now Planned Parenthood was founded in New York City with the opening of the first birth control clinic in the United States.[40] The organization's founder, Margaret Sanger, became inspired to learn and teach other women about contraceptives after experiencing the health and social costs of early or unintended pregnancies.[41] Although illegal at the time, Sanger's conviction and eventual appeal led to a ruling which eased existing state law and allowed doctors to disseminate contraceptive information to women.[42] This ruling ultimately enabled Sanger to open the Clinical Research Bureau ("CRB"), a legally run clinic in New York City.[43] Over time, Sanger's actions and promotion of female reproductive health led to New York doctors being permitted to prescribe birth control for general health reasons, rather than exclusively for venereal disease.[44] The CRB evolved into the Birth Control Clinical Research Bureau, which later collaborated with the American Birth Control League to form the

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Approach to Sex Education, HUFF. POST (Apr. 4, 2014), http://www.huffingtonpost.com/steve-siebold/mississippis-horrific-app_b_5125808.html (discussing sexual education in Mississippi schools). This is in contrast to states like California, which mandates that schools must provide comprehensive sexual education that includes STI prevention and sexual health education for seventh through twelfth grade. Jane Meredith Adams, *Sex Ed to Become Mandatory in Grades 7-12 in California*, EDSOURCE (Oct. 1, 2015), https://edsource.org/2015/sex-ed-to-become-mandatory-in-grades-7-12-in-california/88248. For more information on state mandated education, see *Sex and HIV Education*, *supra* note 10.

[40] *America's First Birth Control Clinic Opens*, PLANNED PARENTHOOD®, https://100years.plannedparenthood.org/?_ga=1.196450220.1674271943.1485638268#e1916-1936/1 (last visited Mar. 31, 2017); *The Margaret Sanger Papers Project: Biographical Sketch*, N.Y. UNIV., https://www.nyu.edu/projects/sanger/aboutms/index.php (last visited Apr. 7, 2017).

[41] *America's First Birth Control Clinic Opens*, *supra* note 40; *The Margaret Sanger Papers Project: Biographical Sketch*, *supra* note 40.

[42] *Id.*

[43] *Id.*; *The Margaret Sanger Papers Project: Birth Control Organizations: Birth Control Clinical Research Bureau*, N.Y. UNIV., https://www.nyu.edu/projects/sanger/aboutms/organization_bccrb.php (last visited Apr. 11, 2017) [hereinafter *Birth Control Organizations*].

[44] *Id.*; *About Sanger*, THE MARGARET SANGER PAPERS PROJECT, https://www.nyu.edu/projects/sanger/aboutms/organization_brownsville_clinic.php (last visited Mar. 31, 2017).

Birth Control Federation of America ("BCFA").[45] Finally, in 1942 the BCFA changed its name and became the Planned Parenthood that exists today.[46]

Women's rights continued to expand after the United States Supreme Court's decisions in *Griswold v. Connecticut*[47] and *Eisenstadt v. Baird*.[48] In the meantime, activists began to secretly educate, train, and provide access to safe abortions until abortions were legalized in *Roe v. Wade*.[49] Then, in 1989, Planned Parenthood established its national sexual education program, which provided teens with access to accurate medical information and health care services.[50] The Planned Parenthood Action Fund was also founded in 1989, with the goal of providing equal access to healthcare for all individuals.[51] Planned Parenthood continues to advocate to the federal government, with successes on access to emergency contraception and ensuring that women do not face an undue burden in seeking an abortion.[52]

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[45] *Birth Control Organizations*, *supra* note 43.
[46] *Id.*
[47] *Griswold*, 381 U.S. at 485–86.
[48] *Eisenstadt*, 405 U.S. at 446–47; *Birth Control is Legalized for Married People*, PLANNED PARENTHOOD®, https://100years.plannedparenthood.org/?_ga=1.196450220.1674271943.1485638268#e1956-1976/1 (last visited Mar. 31, 2017); *Birth Control is Legalized for Unmarried People*, PLANNED PARENTHOOD®, https://100years.plannedparenthood.org/?_ga=1.196450220.1674271943.1485638268#e1956-1976/5 (last visited Mar. 31, 2017).
[49] *Roe*, 410 U.S. at 163; *The Jane Collective in Chicago Creates an Underground Abortion Network*, PLANNED PARENTHOOD®, https://100years.plannedparenthood.org/?_ga=1.196450220.1674271943.1485638268#e1956-1976/4 (last visited Mar. 31, 2017).

[50] This program provides information and services to 1.5 million people since its inception. *Planned Parenthood Federation of America Launches National Sex Education Program*, PLANNED PARENTHOOD®, https://100years.plannedparenthood.org/?_ga=1.196450220.1674271943.1485638268#e1976-1996/2 (last visited Mar. 31, 2017).
[51] *Planned Parenthood Action Fund is Established*, PLANNED PARENTHOOD®, https://100years.plannedparenthood.org/?_ga=1.196450220.1674271943.1485638268#e1976-1996/5 (last visited Mar. 31, 2017).
[52] *The FDA Lifts the Age Restriction on Over-the-Counter Sales of Emergency Contraception*, PLANNED PARENTHOOD®, https://100years.plannedparenthood.org/?_ga=1.196450220.1674271943.1485638268#e1996-2016/6 (last visited Mar. 31, 2017); *The Supreme Court Protects Birth Control Access*, PLANNED PARENTHOOD®,

II. DISCUSSION

A. Abstinence-Only versus Comprehensive Programs

Abstinence-only and comprehensive sexual education programs not only differ in substance but also in their moral undertones.[53] Abstinence-only education tends to emphasize potentially harmful social, psychological, and physical consequences that may follow premarital sex, and often teaches only one acceptable set of values to teens.[54] Further, abstinence-only education often underscores the effectiveness of condoms, birth control, and other contraceptives.[55]

Federally sponsored abstinence-only education finds its origins in Title V of the Social Security Act, which focuses exclusively on abstinence as a solution to teen pregnancy.[56] Further, Title V selectively emphasizes how premarital sex results in lasting psychological and physical effects.[57] Title V then concludes that these harmful effects may only be avoided through monogamous marital relationships.[58]

In contrast, comprehensive sexual education programs emphasize that abstinence is the most effective form of pregnancy prevention while simultaneously providing information and education on contraception.[59] An ideal comprehensive sexual education program will cover the key areas of human development, interpersonal relationships, personal skills, sexual

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https://100years.plannedparenthood.org/?_ga=1.196450220.1674271943.1485638268#e1996-2016/7 (last visited Mar. 31, 2017).

53. *Sex Education Programs: Definitions and Point-by-Point Comparison*, ADVOCATES FOR YOUTH, http://www.advocatesforyouth.org/publications/publications-a-z/655-sex-education-programs-definitions-and-point-by-point-comparison (last visited Mar. 31, 2017) [hereinafter *Point-by-Point Comparison*].

54 *Id.*; PLANNED PARENTHOOD, *supra* note 6, at 6–7.

55. *Id.*

56 1996 Welfare Reform, § 501(b)(2)(A-H); CHRISTOPHER TRENHOLM ET AL., IMPACTS OF FOUR TITLE V, SECTION 510 ABSTINENCE EDUCATION PROGRAMS FINAL REPORT xiv (2007), http://files.eric.ed.gov/fulltext/ED496286.pdf.

57 1996 Welfare Reform, § 501(b)(2)(A-H); TRENHOLM ET AL., *supra* note 56, at xiv.

58. *Id.*

59. *Point-by-Point Comparison*, *supra* note 53.

behavior, sexual health, and reflect present-day society and culture.[60] The ultimate goal of comprehensive programs is to provide students with a holistic education that will enable them to make healthy and safe choices regarding their health and sexuality, in addition to teaching them skills and values to help exercise their reproductive rights.[61]

With a holistic and practical approach, comprehensive sexual education results in a greater impact as it reaches teens who are sexually active or do not believe in the moral benefits of abstinence, in addition to teens who choose to be abstinent as a method of pregnancy prevention.[62]

B. Teen Pregnancy as a Public Health Issue

Despite the availability of different forms of sexual education, teen pregnancy remains a public health issue in the United States.[63] In fact, the United States has the highest number of teen pregnancies among developed countries.[64] While teen pregnancy is currently at an historic low of 249,078 births in 2014,[65] it occurs in twenty-four out of 1,000 fifteen to nineteen year-

60. *Sexuality Education Q&A*, SIECUS, http://www.siecus.org/index.cfm?fuseaction=page.viewpage&pageid=521 (last visited Mar. 31, 2017); *see generally* INT'L WOMEN'S HEALTH COAL., COMPREHENSIVE SEXUALITY EDUCATION: WHAT WE KNOW (2015), https://iwhc.org/wp-content/uploads/2015/03/comprehensive-sexuality-education.pdf (discussing effective implementation of comprehensive sex education programs).

61. U.N. YOUTH, YOUTH & COMPREHENSIVE SEXUALITY EDUCATION 1 (2013), http://www.un.org/esa/socdev/documents/youth/fact-sheets/youth-sexuality-education.pdf; *HIV and AIDS: Sexuality Education*, UNESCO, http://www.unesco.org/new/en/hiv-and-aids/our-priorities-in-hiv/sexuality-education/ (last visited Apr. 11, 2017).

62. CHRIS COLLINS & PRIYA ALAGIRI ET AL., AIDS POL'Y RES. CTR. FOR AIDS PREVENTION STUD., ABSTINENCE-ONLY VS. COMPREHENSIVE SEX EDUCATION: WHAT ARE THE ARGUMENTS? WHAT IS THE EVIDENCE? 14–15 (2002), http://www.issuelab.org/resources/3100/3100.pdf; John Santelli & Mary A. Ott et al., *Abstinence and Abstinence-Only Education: A Review of U.S. Policies and Programs*, 38 J. OF ADOLESCENT HEALTH 72, 73 (2006).

63. *See* Donald Langille, *Teenage Pregnancy: Trends, Factors, and the Physician's Role*, 176 CAN. MED. ASS'N J. 1601, 1601–02 (2007), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1867841/ (pointing out factors that make teen pregnancy a public health issue).

64. Kathrin Stranger-Hall & David Hall, *Abstinence-Only Education and Teen Pregnancy Rates: Why We Need Comprehensive Sex Education in the U.S.*, 6 PLOS 1, 1 (2011).

65. This was a nine percent drop from 2013. *See About Teen Pregnancy: Teen Pregnancy*

olds, is easily preventable, and is associated with negative impacts on both teen mothers and their babies.[66] For example, infants born to teen mothers are at increased risks of infant mortality and hospitalization, and are more likely to be raised in an unstable home environment and becoming teen parents themselves.[67] In addition, teen mothers are at an increased risk of developing mental health illnesses, experiencing social isolation and poverty, and receiving fewer educational opportunities in comparison to other teens.[68]

While harming the welfare of the child, teen pregnancy also costs taxpayers $9.4 billion annually, mostly due to increased costs of care for mothers, foster care, and the incarceration of mothers, among other factors.[69] The Department of Health and Human Services' ("HHS") Healthy People 2020 lists teen pregnancy as one of its issues under adolescent health, and cites teen pregnancy prevention programs as an effective solution.[70] HHS lists teen pregnancy alongside public health issues such as cancer and tobacco use, and is an issue that can and should have additional resources devoted to it while using any means necessary to help ameliorate its effects.[71]

C. Current Sexual Education

As of 2015, approximately 41% of high school students reported that they were sexually active.[72] Despite this statistic, the federal government

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in the United States, *supra* note 1.

66. Langille, *supra* note 63, at 1601–02.

67. *Id.*; *State Policies on Sex Education in Schools*, *supra* note 11.

68. Langille, *supra* note 63, at 1601–02.

69. *Counting it Up: The Public Costs of Teen Childbearing*, THE NAT'L CAMPAIGN TO PREVENT TEEN AND UNPLANNED PREGNANCY, https://thenationalcampaign.org/why-it-matters/public-cost (last visited Feb. 17, 2017); *State Policies on Sex Education in Schools*, *supra* note 11.

70. *Adolescent Health*, HEALTHYPEOPLE.GOV, https://www.healthypeople.gov/2020/topics-objectives/topic/Adolescent-Health#Ref_08 (last visited Mar. 31, 2017).

71 *2010 Topics and Objectives – Objectives A-Z*, Healthypeople.gov, https://www.healthypeople.gov/2020/topics-objectives (last visited Jan. 29, 2018).

72. *Sexual Risk Behaviors: HIV, STD, & Teen Pregnancy Prevention*, CTRS. FOR DISEASE CONT. & PREVENTION (Aug. 4, 2017), https://www.cdc.gov/healthyyouth/sexualbehaviors/ (last visited Jan. 29, 2018).

references throughout the AFLA, CBAE, and Title V of the 1996 Welfare Reform that comprehensive approaches to sexual education may send mixed messages to teens and may actually promote sexual activity.[73] What is more, is that while the federal government recently set aside funds in 2010 for the evidence-based TPP initiative, it almost immediately renewed Title V abstinence-only funding.[74] Despite producing evidence through the federally funded TPP that evidence-based comprehensive sexual education programs reduce teen pregnancy rates, the federal government continues to fund rigid abstinence-only programs in their favor.[75]

Currently, twenty-four states and the District of Columbia require their public schools to teach sexual education to students, while thirty-three states and the District of Columbia require students to also receive education on HIV/AIDS.[76] However, only twenty states require that sexual education must be medically, factually, or technically accurate—the definition of which varies from state to state.[77] Of that number, thirty-eight states allow for parent involvement in their children's sexual education, ranging from parental consent to parental opt-outs.[78]

Opportunities for sexual education other than school-based programs include organizations such as Planned Parenthood, The National Campaign to Prevent Teen & Unplanned Pregnancy, and other health institutes nation-wide.[79] The OAH provides grants to agencies and organizations through the

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73. Stranger-Hall & Hall, *supra* note 64, at 1.

74. *Id.*

75 *Id.*

76. *State Policies on Sex Education in Schools*, *supra* note 11.

77. *Id.*; *see, e.g.*, Hawaii Rev. Stat. § 321-11.1(b) ("'Medically accurate' means verified or supported by research conducted in compliance with accepted scientific methods and recognized as accurate and objective by professional organizations and agencies with expertise in the relevant field [. . .].".); Me. Rev. Stat. Ann. tit. 22 § 1902 ("'[C]omprehensive family life education' [is] education from kindergarten to grade 12 regarding human development and sexuality, including education on family planning and sexually transmitted diseases, that is medically accurate and age appropriate.").

78. *State Policies on Sex Education in Schools*, *supra* note 11.

79. PLANNED PARENTHOOD, *supra* note 6, at 1; *Who Are the Current OAH Grantees?*,

TPP to help create and implement evidence-based sexual education programs for children.[80] The advent of TPP and its grant system during the Obama Administration led to a sharp decrease in teen pregnancies, which were already on a steady decline since 1991.[81] Programs are selected for federal grants through TPP after being subject to a rigorous standard to determine their effectiveness in preventing teen pregnancies, sexually transmitted diseases, and reducing risky sexual behaviors.[82] TPP grant applicants are asked to "choose from a range of systematically identified evidence-based models…. replicate them…. use performance data to ensure fidelity to those program models; and…. conduct rigorous evaluations" before being considered for an award.[83] This performance measures system employed by TPP ensures that an evidence-based approach is utilized, and will be effective and helpful to teens receiving the services.[84] TPP Grantees are divided into Tier 1 and Tier 2 programs.[85] Tier 1 programs receive the majority of federal funding because they have passed rigorous evaluations, while Tier 2 programs are promising or have innovative programs that are still in a developmental stage.[86] Planned Parenthood is a TPP-Tier 1A and 1B grantee,

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DEP'T OF HEALTH & HUM. SERVS.: OFF. OF ADOLESCENT HEALTH, https://www.hhs.gov/ash/oah/grants/current-grantees.html (last visited Mar. 31, 2017).

80. Johnson, *supra* note 35; *Teen Pregnancy Prevention*, DEP'T OF HEALTH & HUM. SERVS.: OFF. OF ADOLESCENT HEALTH, https://www.hhs.gov/ash/oah/oah-initiatives/tpp_program/about/ (last visited Mar. 31, 2017).

81. Johnson, *supra* note 35.

82. *TPP Resource Center: Evidence-Based Programs*, U.S. DEP'T OF HEALTH & HUM. SERVS.: OFF. OF ADOLESCENT HEALTH, https://www.hhs.gov/ash/oah/oah-initiatives/teen_pregnancy/db/index.html (last visited Feb. 18, 2017); *Teen Pregnancy Prevention Evidence Review*, TEEN PREGNANCY EVIDENCE REV., https://tppevidencereview.aspe.hhs.gov/ (Feb. 18, 2017); *see, e.g.*, U.S. DEP'T OF HEALTH & HUM. SERVS.: OFF. OF ADOLESCENT HEALTH, OAH GRANTEES BY STATE/PROGRAM (2010), https://www.hhs.gov/ash/oah/DEPRECATED/tpp/grantees/tpp-tier2.pdf.

83. Howard Koh, *The Teen Pregnancy Prevention Program: An Evidence-Based Public Health Program Model*, 54 J. ADOLESCENT HEALTH S1, S1 (2014).

84. *Id.*

85. Kappeler & Feldman, *supra* note 30, at S3; *Program Planning & Implementation*, U.S. DEP'T OF HEALTH & HUM. SERVS.: OFF. OF ADOLESCENT HEALTH, https://www.hhs.gov/ash/oah/resources-and-training/tpp-and-paf-resources/program-planning-and-implementation/index.html (last visited Apr. 11, 2017).

86. Kappeler & Feldman, *supra* note 30, at S3; *see Teen Pregnancy Prevention Program*

focusing on Capacity Building to Support Replication of Evidence-Based TPP Programs and Replicating Evidence-Based TPP Programs to Scale in Communities with the Greatest Need, and receives over $5 million in grants.[87]

TPP has various success stories,[88] and sponsors programs that focus specifically on capacity building, such as the REACH 2.0 CBA Project implemented by My Brother's Keeper, Inc. ("MBK") in Mississippi.[89] This project is flexible and replicates evidence-based TPP programs, reaching 1,500 youths per year and their parents at weekend-run workshops.[90] In addition, Planned Parenthood of the Greater Northwest is featured as another success story due to its administration of the Teen Outreach Program ("TOP"), which utilizes community service to promote student confidence and safety in schools.[91] TOP's evidence-based approach has assisted in decreasing teen pregnancies, suspensions, and high-school dropouts through these measures, and overall has assisted 2,000 teens.[92]

Despite the efficacy and the promise of TPP, there are several restrictions on grantees that prohibit them from advocating their services to individuals

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Performance Measures, U.S. DEP'T OF HEALTH & HUM. SERVS.: OFF. OF ADOLESCENT HEALTH, https://www.hhs.gov/ash/oah/grant-programs/teen-pregnancy-prevention-program-tpp/performance-measures/index.html (last visited Apr. 11, 2017).

87. *TPP Grantees by Tier*, U.S. DEP'T OF HEALTH & HUM SERVS.: OFF. OF ADOLESCENT HEALTH, https://www.hhs.gov/ash/oah/grants/grantees/tpp/index.html (last visited Mar. 18, 2017); *Who Are the Current OAH Grantees?*, *supra* note 79.

88. *Grantee Success Stories*, U.S. DEP'T OF HEALTH & HUM SERVS.: OFF. OF ADOLESCENT HEALTH, https://www.hhs.gov/ash/oah/oah-initiatives/teen_pregnancy/successes/ (last visited Mar. 18, 2017).

89. *Current Grantees: My Brother's Keeper, Inc.*, U.S. DEP'T OF HEALTH & HUM SERVS.: OFF. OF ADOLESCENT HEALTH, https://www.hhs.gov/ash/oah/grant-programs/teen-pregnancy-prevention-program-tpp/current-grantees/my-brothers-keeper-inc/index.html (last visited Apr. 11, 2017); Telephone Interview with Antwan Nicholson, *supra* note 39.

90. *See Current Grantees: My Brother's Keeper, Inc.*, *supra* note 89; Telephone Interview with Antwan Nicholson, *supra* note 39.

91. *See Success Story: Planned Parenthood of the Greater Northwest*, U.S. DEP'T OF HEALTH & HUM SERVS.: OFF. OF ADOLESCENT HEALTH, https://www.hhs.gov/ash/oah/oah-initiatives/teen_pregnancy/successes/tpp-plannedparenthoodgreaternw-successstory.html (last visited Mar. 18, 2017).

92. *Id.*

and entities that may benefit from their services.[93] The Consolidation Appropriations Act of 2012 prohibits any grassroots or direct lobbying by any grantees.[94] CDC also imposes Additional Requirement 12 ("AR-12") on all of their grantees, which bars even the appearance of influencing the public opinion or participating in lobbying activities.[95] Even if teens seek information on sexual education outside of school-sponsored programs, it may be difficult for TPP grantees to reach out without risking a loss of funding. This means that, any conversations about teen pregnancy and sexual education would before it even begins.

III. ANALYSIS

Although the rates of teen pregnancy have been declining since 1991, this could change if the federal government begins to move towards a pre-Obama Administration stance of abstinence-only over comprehensive sexual education. Additionally, it is not just that abstinence-only education fails to prevent intercourse and therefore fails to prevent teen pregnancy—studies have demonstrated that abstinence-only education may have no impact at all.[96] A 2007 study indicated that teens enrolled in Title V abstinence-only programs were no more likely to have *or* to not have sexual relations than other students.[97] Since abstinence-only curricula only offer an inflexible model against pre-marital sex, it is ineffective in preventing the negative

93. CTRS. FOR DISEASE CONT. & PREVENTION, ANTI-LOBBYING RESTRICTIONS FOR CDC GRANTEES 1 (2012), https://www.cdc.gov/grants/documents/anti-lobbying_restrictions_for_cdc_grantees_july_2012.pdf [hereinafter ANTI-LOBBYING RESTRICTIONS FOR CDC GRANTEES].

94. *Id.*; *see* Consolidated Appropriations Act of 2012, Pub. L. No. 112-74, § 503, 125 Stat. 110, 110 (2012).

95. ANTI-LOBBYING RESTRICTIONS FOR CDC GRANTEES, *supra* note 93, at 5–6.

96. TRENHOLM ET AL., *supra* note 56, at xvii; *Abstinence Only Until Marriage Problems*, SIECUS, http://www.siecus.org/index.cfm?fuseaction=Feature.showFeature&featureID=1041 (last visited Feb. 18, 2017).

97. TRENHOLM ET AL., *supra* note 56, at 17, 30.

consequences of teen pregnancy and fails to reshape risky sexual behaviors.[98] This failure results in a direct correlation between abstinence-only and increased teen pregnancy rates.[99] Further, states that emphasize abstinence-only policies tend to have higher rates of teen pregnancy than their comprehensive or abstinence-plus counterparts.[100] Abstinence-only programs also dispense misinformation,[101] which counter-intuitively promotes irresponsible teen behavior by limiting access to reproductive knowledge and failing to develop teens' rational decision-making skills relating to their sexual health.[102]

To narrow the gap, because the federal government cannot require states to issue mandates to their schools for comprehensive-sexual education reform, it is critical that other options remain available to teens when school programs fail to teach them other methods of pregnancy prevention.[103] In addition, teen pregnancy prevention can be well served by the public health model, which combines scientifically proven interventions and community engagement to improve its overall health,[104] and TPP is historically successful in its public health approach. Further, OAH offered a bridge in developing its relationships in the industries of health care, public health,

98. *National Data Shows Comprehensive Sex Education Better at Reducing Pregnancy than Abstinence-Only Programs*, SIECUS, http://www.siecus.org/index.cfm?fuseaction=Feature.showFeature&featureID=1041 (last visited Feb. 18, 2017).

99. Stranger-Hall & Hall, *supra* note 64, at 6.

100. *Id.*

101. Stranger-Hall & Hall, *supra* note 64, at 9; Waxman, *supra* note 4, at 8; Sue Alford, *Abstinence-Only-Until-Marriage Programs*, ADVOCATES FOR YOUTH (2007), http://www.advocatesforyouth.org/publications/publications-a-z/597-abstinence-only-until-marriage-programs-ineffective-unethical-and-poor-public-health.

102. Stranger-Hall & Hall, *supra* note 64, at 9; KELLEEN KAYE & KATHERINE SUELLENTROP ET AL., THE FOG ZONE: HOW MISPERCEPTIONS, MAGICAL THINKING, AND AMBIVALENCE PUT YOUNG ADULTS AT RISK FOR UNPLANNED PREGNANCY 21 (2009), www.thenationalcampaign.org/fogzone/pdf/fogzone.pdf.

103. *State Policies on Sex Education in Schools*, *supra* note 11.

104. CTRS. FOR DISEASE CONT. & PREVENTION, A PUBLIC HEALTH APPROACH FOR ADVANCING SEXUAL HEALTH IN THE UNITED STATES: RATIONALE AND OPTIONS FOR IMPLEMENTATION 10 (2011), https://www.cdc.gov/sexualhealth/docs/sexualhealthreport-2011-508s.pdf.

faith-based groups, and community after-school programs to reach those exposed to the risks of teen pregnancy before a pregnancy occurs.[105] While the Obama Administration protected Planned Parenthood and other organizations that provide preventative health services and family planning options from the loss of federal funding, it is unknown whether subsequent administrations will follow.[106]

Importantly, comprehensive sexual education recommends that the best method of pregnancy prevention is abstinence, but still incorporates other forms of preventative education on sexually transmitted diseases and contraceptives.[107] Despite opposition from religious groups who argue that comprehensive sexual education leads to promiscuity,[108] comprehensive education may actually result in *fewer* teen pregnancies in comparison to abstinence-only programs.[109]

IV. PROPOSAL

With several years of decreasing teen pregnancy, TPP established a working public health model, and organizations like Planned Parenthood rely on TPP to continue to operate and successfully prevent teen pregnancy.[110] Unfortunately, Planned Parenthood attracts negative attention due to its

105. Koh, *supra* note 83, at S1–S2.

106. Compliance with Title X Requirements by Project Recipients in Selecting Subrecipients, 81 Fed. Reg. 91,852 (Dec. 19, 2016) (to be codified at 42 C.F.R. pt. 59), https://www.gpo.gov/fdsys/pkg/FR-2016-12-19/pdf/2016-30276.pdf; Kimberly Leonard, *Obama Administration Moves to Protect Planned Parenthood*, U.S. NEWS (Dec. 14, 2016), http://www.usnews.com/news/articles/2016-12-14/obama-administration-blocks-states-from-defunding-planned-parenthood. In 2017, the Trump Administration withdrew funding from international Planned Parenthood. Bradford Richardson, *Trump Signs Executive Order Defunding International Planned Parenthood*, WASH. TIMES (Jan. 24, 2017), http://www.washingtontimes.com/news/2017/jan/24/donald-trump-signs-executive-order-defunding-inter/.

107. Stranger-Hall & Hall, *supra* note 64, at 6.

108 *Campaigns to Undermine Sexuality Education in the Public Schools*, ACLU, https://www.aclu.org/other/campaigns-undermine-sexuality-education-public-schools (last visited Jan. 29, 2018).

109. *Id.*

110. *See supra* notes 79–84 and accompanying text.

provision of abortions as a family planning device. While Planned Parenthood offers abortion services, in reality the organization is part of an interconnected system of health care and education providers and should be able to continue providing comprehensive, evidence-based sexual education to teens. To ensure ultimate protection, advocacy groups and organizations such as Planned Parenthood currently working with TPP should continue to advocate for the program and its comprehensive approach to sexual education. Further, Planned Parenthood outreach efforts should strive to mirror the values and account for the needs of the communities they serve.

On a federal level, while Planned Parenthood receives Tier 1 grants from TPP, federal legislation surfaced during the Trump Administration that may detrimentally affect Planned Parenthood's effectiveness.[111] This includes the "Global Gag Rule," which prevents foreign organizations from receiving American international family funds for advocacy or information on pregnancy prevention, and the Defund Planned Parenthood Act of 2017 which would revoke all of its funding if it continues to provide abortions.[112] If this legislation were passed, it would deprive many teens of the necessary educational and health services that Planned Parenthood provides to its patients.[113]

All hope is not lost for Planned Parenthood, even in the face of injurious legislation. For instance, the Planned Parenthood Access Fund may be utilized successfully combat the legislation's potentially negative impact on

111. *See infra* note 112 (discussing the Global Gag Rule).

112. Aram Schvey, *Trump's Global Gag Rule Hurts the World's Most Vulnerable Women*, THE HILL (Jan. 30, 2017 4:40 PM), http://thehill.com/blogs/pundits-blog/the-administration/316930-trumps-global-gag-rule-on-abortion-hurts-the-worlds; *H.R.354 - Defund Planned Parenthood Act of 2017*, CONGRESS.GOV, https://www.congress.gov/bill/115th-congress/house-bill/354?q=%7B%22search%22%3A%5B%22planned+parenthood%22%5D%7D&r=1 (last visited Mar. 18, 2017).

113 *See Planned Parenthood Action Fund is Established*, PLANNED PARENTHOOD®, https://100years.plannedparenthood.org/?_ga=1.196450220.1674271943.1485638268#e1976-1996/5 (last visited Mar. 31, 2017).

teen pregnancy through national and local advocacy efforts.[114] In order to preserve the essential mission of Planned Parenthood of providing comprehensive reproductive health and educational services, another solution may be to separate Planned Parenthood's abortion services from the remaining services to mitigate political divisiveness and remove stigma. Teen pregnancy should be viewed as a bipartisan issue, and educational programs tend to have strong bipartisan support. Further, the Trump Administration's targeting of Planned Parenthood indicates that other family planning and sexual education providers' funding may be at risk in the future. The hypothetical elimination of these invaluable education services run the risk of destroying the progress made in lowering the rates of teen pregnancy.

Notwithstanding these potential legislative consequences, Planned Parenthood must continue to implement widespread education to reach teens who do not seek help voluntarily. While its TOP program has been lauded as a TPP success story, in the face of a less supportive administration and Congress, Planned Parenthood should attempt to partner with smaller community-based organizations to ensure that teens are receiving the help and education they need to live safely and healthfully. These organizations tend to target a specific group of individuals and may find it easier to implement similar TPP strategies to Planned Parenthood.[115] While aggressively pursuing the protection of reproductive rights, Planned Parenthood must act carefully through advocacy and realize the issues in partnering or sharing funds with an organization, based on the legal restrictions in place at the federal funding level for CDC grantees pursuant to AR-12, in addition to barriers at the state levels that may be prohibitive to these collaborative efforts.[116] Finally, collaborative efforts are the most

114. *See id.*

115. *See, e.g.*, *About Us*, MY BROTHER'S KEEPER, INC., http://mbkinc.org/?page_id=8 (last visited Mar. 18, 2017).

116. *See generally* ANTI-LOBBYING RESTRICTIONS FOR CDC GRANTEES, *supra* note 93

efficacious when they come together organically and truly connect to the targeted community,[117] which Planned Parenthood should recognize and consider in the future.[118]

V. CONCLUSION

Comprehensive sexual education is an evidence-based and effective model that should remain part of sexual education in the modern United States. During the tumult of a new Administration, the federal government should continue to support TPP and other public health initiatives it currently has in place to combat teen pregnancy, due to its evidence-based programs proven efficacy among targeted teen populations. Overall, it is essential for organizations like Planned Parenthood to continue to receive federal funding due to their established nature and ability to reach teens who can benefit from TPP programs, in addition to serving as a vestibule for new research and projects to help solve the teen pregnancy public health crisis in the United States.

(listing restrictions put into place for the appropriation of funds for CDC grantees); Rebecca Klein, *These Maps Show Where Kids in America Get Terrifying Sex Ed*, HUFF. POST (Apr. 8, 2014 5:11 PM), http://www.huffingtonpost.com/2014/04/08/sex-education-requirement-maps_n_5111835.html.

117. Telephone Interview with Antwan Nicholson, *supra* note 39.

118. *See, e.g.*, *Planned Parenthood's Adult Role Models Program: Connecting to Community*, CHOICE VOICE (Planned Parenthood® of N.Y. City), July 2006, at 1.

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An Unfulfilled Promise: Ineffective Enforcement of Mental Health Parity

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The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Act of 2008 ("MHPAEA")[1] was designed to improve access to mental health and substance use disorder benefits for millions of Americans. However, almost ten years later, genuine mental health parity—i.e., coverage for mental health and substance use conditions comparable to medical/surgical conditions—largely remains an unfulfilled promise.[2] Enforcement of the MHPAEA has been divided among numerous state and federal agencies, many of which have not taken substantial steps to ensure implementation of the federal parity law.[3] As a result of minimal enforcement, consumers, unsure of either how to identify a parity violation

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1. Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008, 26 U.S.C. § 9812 (2017); 29 U.S.C. § 1185a (2017); Public Health Service Act, 42 U.S.C. §§ 201, 300gg-5 (2017).

2. California is a rare example of a state enforcing mental health parity laws. Kathleen G. Noonan & Stephen J. Boraske, *Enforcing Mental Health Parity Through the Affordable Care Act's Essential Health Benefit Mandate*, 24 ANNALS HEALTH L. 252, 253, 273 (2015). New York is also another rare example of "aggressive" enforcement of mental health parity. *A.G. Schneiderman Offers Assistance For Individuals And Families Seeking Substance Abuse and Mental Health Treatment,* N.Y. OFF. OF THE ATT'Y GEN. (May 11, 2016), https://ag.ny.gov/press-release/ag-schneiderman-offers-assistance-individuals-and-families-seeking-substance-abuse-and.

3. State regulators have primary enforcement authority over individual and group plans, including Medicaid (HHS has secondary authority if it determines states have failed to substantially enforce MHPAEA), DOL and IRS have enforcement authority over employer-based plans (generally, these are subject to ERISA), and HHS has primary authority over non-federal government plans which have not opted-out of complying with MHPAEA. *See* Noonan & Boraske, *supra* note 2, at 264. *See also* Sarah Goodell, *Enforcing Mental Health Parity*, HEALTH AFFAIRS 4 (Nov. 9, 2015), http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=147.

or what coverage they are entitled to by law, are tasked with reporting parity violations through a confusing appeals process.[4] In many states, very few potential violations have been reported, giving state regulators an illusory justification for inaction. In addition, enforcing the MHPAEA through litigation has delivered limited success, leaving many consumers without the protections of the federal parity law.[5] Mental health advocates and stakeholders have repeatedly voiced their concerns about lax implementation and enforcement of mental health parity, but the promise of parity has been—and remains—empty for many. This article seeks to identify the causes for ineffective enforcement of the MHPAEA, assessing the flawed or limited means of enforcing mental health parity that have sprung up in the absence of a strong regulatory framework (i.e., consumer complaints, internal appeals, and parity litigation). In addition, the article offers recommendations to improve enforcement of mental health parity by utilizing audits of health plans for compliance with the MHPAEA. However, until adequate resources and funding are allocated to the enforcement of parity, none of these approaches will succeed and many insured individuals will continue to face barriers in accessing mental healthcare.

I. THE PROMISE OF PARITY: BACKGROUND ON THE MHPAEA

Prior to the introduction of federal parity laws, health insurance issuers and employer-sponsored plans rarely offered coverage for mental health

4. *See* THE KENNEDY FORUM, NAVIGATING THE NEW FRONTIER OF MENTAL HEALTH AND ADDICTION: A GUIDE FOR THE 115TH CONGRESS 9, https://thekennedyforum-dot-org.s3.amazonaws.com/documents/9/attachments/The_New_Frontier_CongressGuide.pdf?1485267841.

5. ERISA, which codifies the requirements of MHPAEA, provides for a private right of enforcement. Gerald DeLoss et al., *Mental Health Parity and Addiction Equity Act Final Rules: Limited Enforcement Options Don't Overcome Unequal Treatment*, 7 J. HEALTH & LIFE SCI. L. 73, 98 (June 2014). Parity Litigation has been effective for MHPAEA violations involving residential treatment limitations. *See, e.g.*, N.F. v. Sinclair Serv. Co., 158 F.Supp.3d 1239, 1261-62 (D. Utah 2016), Craft v. Health Care Serv. Corp., 84 F. Supp. 3d 748, 753 (N.D. Ill. 2015), S.S. v. Microsoft Corp. Welfare Plan, 2015 WL 11251744 (W.D. Wash. 2015).

conditions that was equal or comparable to other medical conditions.[6] More restrictive financial limitations and treatment limitations to mental health benefits compared to medical or surgical benefits were common.[7] In addition, states' legislative responses to this disparity in coverage were largely inconsistent and inadequate.[8] The MHPAEA was designed to ensure that if a health plan or issuer offered mental health coverage, any financial requirements or treatment limitations would not be applied in a more restrictive manner to mental health benefits than compared to other medical benefits.[9] Group health plans or health insurance issuers are not required to offer mental health coverage; however, if plans or issuers provide such coverage, it must be in parity with medical and surgical coverage.[10] The ACA further expanded the parity protections of the MHPAEA by including mental health among one of ten "essential health benefits" that must be included in any individual or small group plan.[11]

The MHPAEA itself offered only a rough framework for determining whether mental health coverage was in parity with medical or surgical benefits; further regulation was required to articulate and implement genuine

6. Goodell, *supra* note 3, at 1.

7. Financial limitations include, for example, restrictions on the number of inpatient and outpatient days or annual and lifetime limits whereas treatment limitations could consist of separate prior authorization requirements. *Id.* at 2.

8. John V. Jacobi, *Mental Illness: Access and Freedom,* 16 HOUS. J. HEALTH L. & POL'Y 37, 54 (2016) ("The uneven nature of states' responses to inequity in coverage, as well the limits on state power to affect the growing self-insured market, led to federal parity protection.").

9. MHPAEA prohibits aggregate lifetime and annual limits on mental health benefits if the plan or coverage does not include such limit on substantially all medical and surgical benefits. Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008, 42 U.S.C. § 300gg-26(a)(1)-(2) (2017). In addition, a group health plan or health insurance issuer may not apply separate financial requirements or treatment limitations on mental health benefits unless such restrictions are no more restrictive than the predominant requirements applied to substantially all medical and surgical benefits. 42 U.S.C. § 300gg-26(a)(3)(A).

10. 42 U.S.C. § 300gg-26(a)(1)-(3).

11. 42 U.S.C. § 18022; Jacobi, *supra* note 8, at 55-56 ("[in combination,] MHPAEA and the ACA extend parity protections to most large group plans, self-funded or insured, that choose to offer behavioral health coverage. . . as well as all individual and small group plans.").

parity.[12] Recognizing that plans and issuers have not provided as expansive mental health coverage as medical or surgical coverage for decades is clear; however, defining parity in such a way as to comprehensively prevent discrimination in mental health coverage continues to be difficult.[13] Although the MHPAEA clearly requires that mental health and other medical benefits must be comparably covered, exactly how to perform this analysis for services unique to behavioral healthcare remained unclear.[14] In November 2013, the Departments of Health and Human Services ("HHS"), Labor ("DOL"), and Treasury ("Treasury") jointly released a final rule clarifying how to conduct parity analysis and determine whether plans or issuers are in compliance.[15] Under the final rule, comparison between mental health benefits and medical or surgical benefits must be made with reference to one of six classifications of benefits: inpatient, in-network; inpatient, out-of-network; outpatient, in-network; outpatient out-of-network; emergency care; and prescription drugs.[16]

Additionally, the final rule established a two-branched analysis for comparing mental health benefits to medical or surgical benefits if a plan or issuer offers mental health benefits. First, a plan or issuer may not apply any

12. DeLoss et al., *supra* note 5, at 77 ("The general framework of MHPAEA itself includes some discussion of advancing parity and equity, but does not offer a practical, straightforward methodology for comparing MH/SUD with medical/surgical benefits.").

13. Nathaniel Counts et al., *What's Confusing Us About Mental Health Parity*, HEALTH AFFAIRS BLOG (Dec. 22, 2016), http://healthaffairs.org/blog/2016/12/22/whats-confusing-us-about-mental-health-parity/.

14. Michael Ollove, *Enforcement of Mental Health Care Coverage Lacking*, PEW TRUSTS STATELINE (Jun. 3, 2016), http://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2016/06/03/enforcement-of-mental-health-care-coverage-lacking ("How, for example, can you compare the treatment of chronic mental illnesses, such as schizophrenia or bipolar disorder, with physical disease such as diabetes or high blood pressure?").

15. Final Rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008, 78 Fed. Reg. 68240-01 (Nov. 13, 2013).

16. If a plan offers mental health benefits in any one of these classifications, mental health benefits must also be provided in the remaining classifications as long as medical/surgical benefits are provided in those classifications. 45 C.F.R. § 146.136(c)(2)(ii)(A) (2014).

financial requirements, or *quantitative* treatment limitations ("QTLs"),[17] to a classification of mental health benefits if that limitation is more restrictive than the predominant (more than one-half) financial requirements or QTLs applied to substantially all (at least two-thirds) medical or surgical benefits in the same classification.[18] Second, a plan or issuer may not apply *non-quantitative* treatment limitations ("NQTLs")[19] unless the deciding factors for the limitation "are comparable to, and are applied no more stringently than, the processes, evidentiary standards, or other factors used in applying the limitation with respect to medical/surgical benefits in the classification."[20] Although disparate financial requirements and QTLs have largely been reduced, if not completely eliminated,[21] NQTLs continue to be a major hurdle for implementing and enforcing parity.[22]

II. BREAKING THE PROMISE: CAUSES OF INEFFECTIVE ENFORCEMENT OF THE MHPAEA

Despite the MHPAEA and subsequent regulation, the blackletter

17. "Financial requirements" include any deductibles, copayments, coinsurance, or out-of-pocket maximums but do not include either aggregate lifetime or annual dollar limits. "Quantitative treatment limitations" refer to any limitations on treatment expressed numerically. 45 C.F.R. § 146.136(a).

18. 45 C.F.R. § 146.136(c)(2)(i); 45 C.F.R. § 146.136(c)(3)(i)(A) (defining "substantially all" as at least two-thirds); 45 C.F.R. § 146.136(c)(3)(i)(B) (defining "predominant" is defined as more than one-half).

19. NQTLs refer to all treatment limitations which cannot be expressed numerically and "otherwise limit the scope or duration of benefits." 45 C.F.R § 146.136(a). Examples include medical necessity criteria; formulary design for prescription drugs; network tier design; standards for including providers in networks (including reimbursement rates); methods for determining usual, customary, and reasonable charges; fail-first policies (refusing to pay for more expensive therapies until a cheaper therapy is shown to be ineffective); exclusions for failing to complete a course of treatment; and geographic restrictions. 45 C.F.R. § 146.136(c)(4)(ii).

20. 45 C.F.R. § 146.136(c)(4)(i).

21. LUKE BUTLER ET AL., STATE OF PARITY REPORT 2 (Feb. 23, 2016), http://scattergoodfoundation.org/sites/default/files/State%20of%20Parity%20Report%20FINAL.pdf.

22. For example, in FY 2016, the majority (54.55%) of the 44 MHPAEA violations identified by DOL investigations of 191 plans involved NQTL violations. EMPLOYEE BENEFITS SECURITY ADMINISTRATION, FACT SHEET: FY 2016 MHPAEA ENFORCEMENT, https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/fact-sheets/mhpaea-enforcement-2016.pdf (last visited Apr. 27, 2017).

requirements of mental health parity have been largely unrealized for many Americans, who continue to experience more restrictive coverage for mental health conditions.[23] The framework of enforcement authority for the MHPAEA has allowed for inconsistent enforcement, with several agencies tasked with ensuring compliance for various types of plans or coverage.[24] As such, enforcement has been inconsistent at best and nonexistent at worst.[25] Although both federal and state regulators have roles in enforcing the MHPAEA, enforcement for the MHPAEA is largely left to state insurance commissioners, state Medicaid directors, and attorneys general; many of whom have not actively pursued efforts to inform consumers or hold plans and issuers accountable for compliance.[26] The DOL recently increased efforts to audit plans over which it has enforcement authority,[27] but the number and impact of these investigations have been minimal.[28] While HHS has the authority to enforce the requirements of MHPAEA for individual and

23. *See* THE KENNEDY FORUM, NAVIGATING THE NEW FRONTIER OF MENTAL HEALTH AND ADDICTION: A GUIDE FOR THE 115TH CONGRESS 9, https://thekennedyforum-dot-org.s3.amazonaws.com/documents/9/attachments/The_New_Frontier_CongressGuide.pdf?1485267841 (last visited Apr. 27, 2017) ("The Federal Parity Law has been in place for nearly a decade, yet insurance coverage for mental health and substance use disorder care is still more restrictive than coverage for other medical care. Health plans and issuers have simply shifted the way they suppress costs so that disparity is no longer in plain view.").

24. *See* Goodell, *supra* note 3.

25. For example, state regulators in Alabama, Oklahoma, Missouri, Texas, and Wyoming do not think they have the authority under state law to enforce MHPAEA. *Id.*

26. Kenneth L. Davis, *Mental Health Parity Is a Serious Issue*, FORBES (Oct. 7, 2016, 8:00 AM), http://www.forbes.com/sites/kennethdavis/2016/10/07/the-need-for-mental-health-parity/#79211f791a04.

27. Sarah Roe Sise, *Mental Health Parity – Can a Plan Exclude Residential Treatment Facility Benefits? Federal District Court Says No*, THE NAT'L L. REV. (Mar. 6, 2016), http://www.natlawreview.com/article/mental-health-parity-can-plan-exclude-residential-treatment-facility-benefits; s*ee also* David A. Slaughter, *DOL Highlights Growth in MHPAEA Enforcement*, HR DAILY ADVISOR (Jan. 31, 2017), http://hrdailyadvisor.blr.com/2017/01/31/dol-highlights-growth-mhpaea-enforcement/.

28. Despite having authority over 2.3 million health plans, EBSA conducted 191 MHPAEA audits in FY 2016 and identified only 44 violations. EBSA, EBSA RESTORES OVER $777.5 MILLION TO EMPLOYEE BENEFIT PLANS, PARTICIPANTS AND BENEFICIARIES, https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/fact-sheets/ebsa-monetary-results.pdf (last visited Apr. 27, 2017); *See* EBSA, *supra* note 22 (noting that EBSA benefit advisors answered 112 public inquiries regarding MHPAEA compliance).

group plans if it determines a state has not substantially enforced parity, HHS has only stepped in for four states.[29] Therefore, overall enforcement has been limited.

Since most state and federal agencies have not aggressively enforced the MHPAEA, the burden for identifying violations and encouraging compliance has fallen on consumers. Requiring consumers to identify parity violations is unrealistic when consumers lack clarity regarding how to file an internal appeal with their insurer, which state or federal agency with which to file a complaint in the event an internal appeal is unsuccessful, and in obtaining mental health medical necessity standards and medical and surgical standards to conduct parity analysis. Many state regulators then perceive the low number of complaints as confirmation that there is little need to pursue aggressive enforcement of state or federal parity requirements.

III. FLAWED AND LIMITED ROUTES TO ENFORCING THE MHPAEA

Since state and federal agencies have not substantially enforced the federal parity law, consumers and advocates have tried other routes for pursuing compliance, with limited success. A consumer-driven model of enforcement is problematic for a host of reasons. This model requires extensive consumer education about identifying parity violations in order to be effective.[30] Additionally, consumers have to determine where to file a complaint with one of several state and federal agencies in order to hold plans and issuers accountable for a parity violation.[31] Furthermore, if state regulators do not

29. HHS is currently enforcing MHPAEA in Missouri, Oklahoma, Texas, and Wyoming. THE MENTAL HEALTH & SUBSTANCE USE DISORDER PARITY TASK FORCE, FINAL REPORT 15 (Oct. 2016), https://www.hhs.gov/sites/default/files/mental-health-substance-use-disorder-parity-task-force-final-report.pdf [hereinafter TASK FORCE REPORT].

30. *See* SUBSTANCE ABUSE & MENTAL HEALTH SERVICES ADMIN., APPROACHES IN IMPLEMENTING THE MENTAL HEALTH PARITY AND ADDICTION EQUITY ACT: BEST PRACTICES FROM THE STATES 9, HHS Publication No. SMA-16-4983 (2016), http://store.samhsa.gov/shin/content/SMA16-4983/SMA16-4983.pdf ("Consumer education . . . is essential in ensuring that consumers receive the benefits of the law.").

31. *See* Laura Goodman, *Guidance for Advocates: Identifying Parity Violations & Taking*

take action, under this model the only remedy available is litigation – but only if the consumer has a plan subject to the Employee Retirement Income Security Act of 1974 ("ERISA").[32] However, these limited means of enforcement share a common flaw – they all place the primary burden on the consumer, instead of regulators or insurers, to guarantee compliance with the requirements of the MHPAEA. Enforcing the requirements of the MHPAEA through either internal appeals, complaints filed with regulators, or litigation has largely failed to achieve parity. Shifting the responsibility for and cost of enforcement onto consumers fails to ensure true mental health parity and must be replaced with regulator-driven enforcement to achieve true parity.

A. Consumer Complaints and Internal Appeals

The vacuum created by minimal state and federal enforcement of the MHPAEA has resulted in shifting the primary responsibility for identifying parity violations onto consumers.[33] However, expecting consumers to effectively identify and report violations is unrealistic for many individuals with serious mental illnesses, and can be just as impractical even for

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Action, HEALTH L. ADVOCATES, http://www.healthlawadvocates.org/tools/publications/files/0021.pdf (last visited April 27, 2017). The 21st Century Cures Act addresses this issue by allowing consumers to file complaints on the HHS website. *See* MENTAL HEALTH AND ADDICTION INSURANCE HELP, https://www.hhs.gov/mental-health-and-addiction-insurance-help (last visited Feb. 17, 2017).

32. Joseph Friedman et al., *A Crystal Ball: Managed Care Litigation in Light of the Patient Protection and Affordable Care Act*, 27 HEALTH L. 1, 7 (Dec. 2014) ("Importantly, although litigation cannot arise specifically under the parity acts or PPACA provisions affecting mental health, mental health parity has been held by courts to be enforceable by ERISA and thus may be enforced by remedies provided under ERISA."). For example, Joseph and Gail F. submitted three internal appeals with their employer-sponsored group health plan prior to filing suit under ERISA for denial of residential treatment for their daughter's mental health condition. Joseph & Gail F. v. Sinclair Services Co., 125 F.Supp.3d 1238, 1245–46 (D. Utah 2016).

33. GUIDE FOR THE 115TH CONGRESS, *supra* note 23, at 9 ("Right now, far too much of the burden [of] determining compliance falls upon consumers and their family members."). *See also* TASK FORCE REPORT, *supra* note 29, at 13 ("We are keenly aware that parity is only meaningful if health plans properly implement its requirements. It's only meaningful if consumers and providers understand how it works. And it's only meaningful if there is appropriate oversight by both federal and state agencies.").

sophisticated consumers.[34]

Multiple barriers prevent consumers from even filing a complaint with the correct office or agency. For example, many consumers are unaware that certain denials of mental health benefits are a violation of federal parity law.[35] Despite more than twenty years of advocacy, legislation, and consumer education efforts, most individuals have not heard of such protections, could not define "parity," and almost certainly would not know how to identify a potential violation.[36] Several consumer education campaigns, by state agencies[37] and advocacy groups[38] have tried to repackage mental health parity for consumers, but with limited success.[39] Additionally, identifying how to file an internal appeal with a plan or issuer is not always clear.[40] Furthermore, if a plan or issuer does not reverse its decision after an internal review, consumers face difficulty navigating which state or federal agency to file a complaint with depending on their plan or coverage.[41] Lastly,

34. Jenny Gold, *Federal Panel Calls for Stricter Enforcement of Mental Health Care Parity Law*, NPR SHOTS (Oct. 31, 2016, 10:52 AM), http://www.npr.org/sections/health-shots/2016/10/31/500056803/federal-panel-calls-for-stricter-enforcement-of-mental-health-care-parity-law.

35. In a January 2011 survey, seven percent of Americans had heard of the term "mental health parity" and even fewer had heard of MHPAEA. *Your Mental Health: A Survey of Americans' Understanding of the Mental Health Parity Law*, AM. PSYCH. ASS'N (Jan. 2011), https://www.apa.org/news/press/releases/parity-law.pdf.

36. *Id.*

37. For example, the Connecticut Insurance Department has created a consumer toolkit to assist individuals in navigating insurance coverage for behavioral healthcare. CONN. INS. DEP'T, CONSUMER TOOLKIT FOR NAVIGATING BEHAVIORAL HEALTH AND SUBSTANCE ABUSE CARE THROUGH YOUR HEALTH INSURANCE PLAN (Nov. 2013), http://www.ct.gov/cid/lib/cid/Behavioral_Health_Consumer_Tool_Kit.pdf.

38. *See* THE KENNEDY FORUM, PARITY RESOURCE GUIDE FOR ADDICTION & MENTAL HEALTH CONSUMERS, PROVIDERS AND ADVOCATES (2015), https://parityispersonal.org/media/documents/KennedyForum-ResourceGuide_FINAL_1.pdf.

39. The presidential task force specifically recommended improving consumer education indicating this continues to be an area with room for improvement. THE WHITE HOUSE, FACT SHEET, FEDERAL PARITY TASK FORCE TAKES STEPS TO STRENGTHEN INSURANCE COVERAGE FOR MENTAL HEALTH AND SUBSTANCE USE DISORDERS 1 (Oct. 27, 2016), https://obamawhitehouse.archives.gov/the-press-office/2016/10/27/fact-sheet-mental-health-and-substance-use-disorder-parity-task-force.

40. *See* PARITY RESOURCE GUIDE, *supra* note 38.

41. Gold, *supra* note 34.

consumers might be tossed between state and federal agencies as they delay or decline to process the consumer complaint.

Even when a consumer can identify a violation and navigate the complaint process, there is no guarantee she will get access to the necessary information regarding the how a plan determines what is and is not considered medically necessary. Group health plans and health issuers have often considered medical necessity criteria to be proprietary information and declined to disclose such information necessary for parity analysis.[42] In addition, benefit denials often fail to provide enough information for consumers to appeal the determination, which also result in evidentiary hurdles for any subsequent litigation.[43]

When considering the substantial barriers consumers face to resolving parity violations through the complaint process, it is not surprising that many state regulators report they have not received many parity-related complaints.[44] Efforts have been taken by stakeholders[45] and, more recently, by legislators to create a one-stop-shop where all consumers—regardless of plan or issuer—can report potential parity violations.[46] Advocates in many

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42. Counts et al., *supra* note 13.

43. Despite guidance from the DOL regarding what must be included in denial letters, detailed information is not always provided. *See* U.S. DEP'T OF LABOR, FAQS ABOUT AFFORDABLE CARE ACT IMPLEMENTATION PART 31, MENTAL HEALTH PARITY IMPLEMENTATION, AND WOMEN'S HEALTH AND CANCER RIGHTS ACT IMPLEMENTATION 11 (April 20, 2016), https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-31.pdf. The DOL has expressly stated that issuers and plans may not decline to disclose medical necessity criteria because it has been characterized as proprietary or commercially valuable information. *Id.* at 5.

44. Alex Ruoff, *Mental Health Groups Taking Parity Fight to States*, BLOOMBERG BNA (Oct. 31, 2016), https://www.bna.com/mental-health-groups-n57982082089/.

45. The Kennedy Forum, a mental health and substance use disorder advocacy organization, recently released a website where consumers can register complaints and find resources about how to file complaints with the appropriate state or federal agency. THE KENNEDY FORUM, PARITY REGISTRY, http://parityregistry.org/ (last visited Feb. 17, 2017). For a description of this tool see, Patrick J. Kennedy Appearances, *Patrick Kennedy Mental Health Parity Rights Video*, YOUTUBE (Oct. 20, 2016), https://www.youtube.com/watch?v=8zkmmQAGnk0.

46. The 21st Century Cures Act, on the recommendation of the Presidential Task Force, provided for a new website available through HHS where any consumer may file complaints or appeals for potential parity violations. *See* MENTAL HEALTH AND ADDICTION INSURANCE

states have adopted this approach to place pressure on state regulators and attorneys general to enforce the requirements of state and federal parity laws by providing data for improper benefit denials.[47] However, such an approach is a work-around solution, designed to make up for inadequate state and federal enforcement. Ultimately, requiring consumers to be primarily responsible for holding plans and issuers accountable is not a sustainable or equitable means of implementing the MHPAEA.[48]

B. Parity Litigation

If a consumer has exhausted all internal appeals without success,[49] they may file an action against the plan or administrator for violating the MHPAEA—so long as the group health plan is subject to the ERISA.[50] The MHPAEA itself does not create a private right of action; however its protections are codified at Section 712 of ERISA,[51] which gives beneficiaries and participants of ERISA plans a private right of action.[52] As a result,

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HELP, https://www.hhs.gov/mental-health-and-addiction-insurance-help (last visited Feb. 17, 2017).

47. Ruoff, *supra* note 44.

48. This concern was specifically voiced in a listening session held by the Mental Health and Substance Use Disorder Parity Task Force. MENTAL HEALTH & SUBSTANCE USE DISORDER PARITY TASK FORCE, SUMMARY OF SECOND STAKEHOLDER MEETING 2 (May 17, 2016), https://www.hhs.gov/sites/default/files/PTF%20May%20listening%20session%20notes_Remediated.pdf ("Enforcement cannot rely on a complaint-driven and appeals process given the consumer/provider-insurance provider information gap.").

49. Generally, beneficiaries are required to avail themselves of a plan's internal review prior to filing a cause of action under ERISA. There is an exception to this exhaustion requirement if internal review procedures do not adequately allow for meaningful review and the beneficiary can demonstrate futility. A.F. v. Providence Health Plan, 157 F. Supp. 3d 899, 909 (D. Oregon 2016).

50. Plan participants and beneficiaries of ERISA plans may bring actions to recover benefits for alleged parity violations under § 502(a) of ERISA. 29 U.S.C. § 1185a(a)(1)(B) (2009). The plaintiff may challenge the basis for a denial of benefits or challenge the design of the plan itself. *See* Michael C. Barnes & Stacey L. Worthy, *Achieving Real Parity: Increasing Access to Treatment for Substance Use Disorders Under the Patient Protection and Affordable Care Act and the Mental Health and Addiction Equity Act*, 36 U. ARK. LITTLE ROCK L. REV. 555, 593 (2014).

51. 29 U.S.C. § 1185a.

52. *See* DeLoss et al., *supra* note 5, at 98.

litigation has been largely limited to beneficiaries of ERISA plans.[53] It is unclear whether beneficiaries and participants of non-ERISA plan are also entitled to a private right of enforcement,[54] but state parity laws may provide a private right of action where the MHPAEA does not.[55] In addition, the success of litigating towards enforcement of the MHPAEA has been limited, since many cases have not survived motions to dismiss or summary judgment.[56] Furthermore, standing to bring such actions has been limited.[57]

Beyond limitations in who may properly bring private actions for violations of the MHPAEA, this route of enforcement leads to uneven results with regard to parity. Since group health plans are subject to both state and federal parity laws, judicial interpretation could create entirely different standards of compliance for each type of health plan, resulting in disparate coverage for mental health services.[58] In addition, limiting enforcement of

53. *See* PARITY TRACK, https://www.paritytrack.org/reports/federal-report/litigation (last visited Feb. 19, 2017).

54. DeLoss et al., *supra* note 5, at 98 ("Because ERISA, and not MHPAEA, provides for private enforcement of the MHPAEA, beneficiaries and participants of non-ERISA plans may not be entitled to this same private right of enforcement.").

55. *See* Rea v. Blue Shield of California, 172 Cal. Rptr. 3d 823, 826 (Ct. App. 2014) (alleging violations under the California Mental Health Parity Act). *See also* O.S.T. ex rel. G.T. v. BlueShield, 335 P.3d 416, 418 (Wash. 2014) (alleging violations under the Washington parity law). Both state laws included mandated coverage for mental health treatment, which MHPAEA does not specifically require.

56. Barnes & Worthy, *supra* note 50, at 594 ("To date [in summer 2014], no federal parity case appears to have made it past summary judgment."). This statement continues to be accurate. *See*, N.Y. Psych. Ass'n, Inc. v. UnitedHealth Group, 798 F.3d 125 (2d Cir. 2015) (appealing a motion to dismiss); Am. Psych. Ass'n v. Anthem Health Plans, Inc., 821 F.3d 352 (2d Cir. 2016) (appealing a motion to dismiss).

57. *See* New York State Psychiatric Ass'n, Inc. v. UnitedHealth Group, 798 F.3d 125 (2d Cir. 2015), *cert. denied*, 136 S.Ct. 506 (2015). *But see* American Psychiatric Ass'n v. Anthem Health Plans, Inc., 821 F.3d 352 (2d Cir. 2016). For a discussion of standing as a barrier to parity enforcement, see Jeremy Ard, *Unfavorable Opinion from the Second Circuit Holding Psychiatrists, Associations Lack Standing in Parity Case*, THE KENNEDY FORUM ILLINOIS (May 25, 2016), http://thekennedyforumillinois.org/unfavorable-opinion-from-the-second-circuit-holding-psychiatrists-associations-lack-standing-in-parity-case/.

58. For example, the Ninth Circuit held that the California Mental Health Parity Act required coverage of residential treatment for eating disorders; however, a subsequent California state appellate decision held that residential care was not covered under the same parity law. Paul Garcia, Note, *The Problem with Parity: An Analysis of the Confusion Surrounding the California Mental Health Parity Act*, 87 S. CAL. L. REV. POSTSCRIPT 38, 38 (2014).

parity to litigation forces consumers to shoulder the costs of enforcement.[59] Moreover, many of the same barriers consumers face with filing complaints and internal appeals also limit the initiation of parity litigation.[60] Further, parity litigation only offers a remedy when there has been a denial of benefits; if a treatment option is not offered in the first place, parity litigation offers no solution.[61] In this way, litigation cannot effectively remedy issues with workforce shortages, network adequacy, and unfavorable reimbursement rates, all of which have a substantial impact of the availability of behavioral healthcare services.[62]

IV. FULFILLING THE PROMISE: RECOMMENDATIONS FOR IMPROVED ENFORCEMENT

Congress recently enacted the 21st Century Cures Act ("Act"),[63] which includes the Helping Families in Mental Crisis Reform Act of 2016 and appears to expand enforcement of the MHPAEA by increasing federal regulators' authority and means to require compliance. The Act increased Medicaid reimbursement by eliminating a prohibition against billing for mental health and primary care services on the same day.[64] Additionally, it gave clear statutory authority for the Secretaries of HHS, DOL, and Treasury to audit health plans to determine their compliance with mental health parity

59. DeLoss et al., *supra* note 5, at 105.

60. *See supra* Part III. A.

61. Counts et al., *supra* note 13 ("Most of the litigation around parity compliance centers [on] benefit denials. Because no one is being offered collaborative care, no one is being denied."). In addition, when provider reimbursement is uncertain for innovative models of care, such as collaborative care models which integrate primary and behavioral care, there is little incentive for providers to adopt these newer models when MHPAEA is not effectively enforced. *Id.*

62. TASK FORCE REPORT, *supra* note 29, at 18, 20, 27.

63. 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat 1033 (Dec. 13, 2016).

64. 21st Century Cures Act § 12000, Pub. L. No. 114-255, 130 Stat 1033 (Dec. 13, 2016). *See* Jason B. Caron et al., *Tackling the Growing Problem of Mental Health and Substance Use Disorders*, MCDERMOTT WILL & EMERY, 21ST CENTURY CURES: A CLOSER LOOK (Jan. 2017), https://www.mwe.com/en/thought-leadership/publications/2016/12/21st-century-cures-tackling-mental-health.

laws.[65] Further, the Act requires HHS to develop an action plan for improved coordination in enforcement efforts among state and federal agencies, including a timeline for when certain strategic objectives will be met.[66] The Act also requires additional guidance clarifying disclosure requirements and providing illustrative, de-identified examples of compliance and noncompliance with special emphasis on NQTLs.[67] However, in practice, the Act is unlikely alter the landscape of mental health parity because no additional funding was allocated to finance this increased federal enforcement.[68]

The 21st Century Cures Act may result in increased enforcement, but it remains to be seen if federal agencies will more rigorously enforce the MHPAEA, or whether state regulators will take advantage of federal grants to bolster enforcement of state and federal parity laws. In addition, further guidance is needed to clarify disclosure requirements and NQTLs, to ensure NQTLs are not impermissibly used as a means of disproportionately denying coverage for medically necessary behavioral healthcare. Further, since the Act will be implemented under a new administration with an uncertain mental health policy, it is unclear how robustly the MHPAEA will be enforced in the coming years.[69]

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65. 21st Century Cures Act § 13001, 42 U.S.C. § 300gg-26(d)(1) ("In the case that . . . a group plan or health insurance issuer . . . has violated, at least 5 times, [the requirements of MHPAEA] . . . the appropriate Secretary shall audit plan documents for such health plan or issuer in the plan year following the Secretary's determination in order to help improve compliance with such section.").

66. 21st Century Cures Act § 13002(c)(4).

67. 21st Century Cures Act § 13001, 42 U.S.C. § 300gg-26(a)(6)(B)(i)(I), (a)(7)(A).

68. Richard Frank, *What the 21st Century Cures Act Means for Behavioral Health*, HARVARD HEALTH BLOG (Jan. 19, 2017, 9:30 AM), http://www.health.harvard.edu/blog/21st-century-cures-act-means-behavioral-health-2017011910982/print/.

69. Some concern has been voiced about the fate of mental health reform under the Trump administration, given that mental health has become a bipartisan issue in recent years. Michelle Chen, *Trump's Obamacare Repeal Could Lead to a Mental-Health Crisis*, THE NATION (Jan. 18, 2017)
https://www.thenation.com/article/trumps-obamacare-repeal-could-lead-to-a-mental-health-crisis/. In particular, the repeal and replacement of the Affordable Care Act, including its essential health benefit provisions, could seriously weaken the enforcement of parity by no

The Act adopted recommendations of the Substance Abuse & Mental Health Services Administration ("SAMHSA") and a presidential task force in granting the secretaries of the HHS, DOL, and Treasury the authority to audit health plans—both routinely and at random—for compliance with the MHPAEA.[70] Audits are a powerful tool under a regulator-driven model of parity enforcement in which plans are reviewed by regulators for compliance with federal parity law and further action may be taken in the event of a violation.[71] Although limited by inadequate funding, state and federal audits—also referred to as market conduct examinations—have uncovered significant violations of the MHPAEA and corresponding state parity laws.[72] The failure to sufficiently allocate funds for routine and targeted audits limits the DOL's capacity to ensure compliance with the MHPAEA and deprives regulators of one of their most effective tools for enforcing parity.[73] When audits are not properly funded, state and federal regulators will only take action to conduct audits after enough consumer complaints have amassed, requiring more than inertia from these agencies.[74] Until audits are used proactively, not as an enforcement tool of last resort, it is likely that parity enforcement will continue to be consumer-driven and thus ineffective.

V. CONCLUSION

The language of the MHPAEA suggests that disparity in coverage for mental and physical health conditions has largely been eliminated, especially when combined with the essential health benefits requirements of the ACA.

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longer requiring the inclusion of mental health services in health plans. Alex Ruoff, *Obamacare Repeal Likely a Setback for Mental Health, Opioid Crisis*, BLOOMBERG BNA (Mar. 7, 2017), https://www.bna.com/obamacare-repeal-likely-n57982084849/.

70. Caron et al., *supra* note 64, at 4. *See* BEST PRACTICES FROM THE STATES, *supra* note 30, at 1,10. *See also* FEDERAL PARITY TASK FORCE, *supra* note 39.

71. Gold, *supra* note 34.

72. GUIDE FOR THE 115TH CONGRESS, *supra* note 23, at 9.

73. PARITY TASK FORCE, *supra* note 39.

74. *Id.* ("Given current resources, Federal parity enforcement efforts to date have generally focused on investigating consumer, provider and other parity complaints.")

However, in practice, many disparities persist as a result of minimal enforcement by state and federal agencies specifically tasked with implementing the MHPAEA. Inaction by underfunded or ambivalent agencies has resulted in a vacuum where consumers, not regulators, must lead the charge in securing their right to parity under the MHPAEA. Yet consumers are more likely encounter confusion, difficulty, and external barriers when they seek to remedy parity violations either by internal appeals, complaints filed with regulators, or litigation. The 21st Century Cures Act, on its face appearing to fill in gaps in guidance and expand federal enforcement, may not be the answer when no additional funding has been allocated to that purpose. In order to achieve parity, the primary responsibility for enforcement must shift back to state and federal regulators, who should take a proactive role in the enforcement of the MHPAEA. Auditing plans for compliance and publicly disclosing non-confidential results of enforcement action are powerful tools for enforcement which should be pursued; however, the capacity for this enforcement tool is limited by funding and requires a political will to address disparities in mental health coverage.

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Pain Management & Opioid Abuse in America: Causes, Solutions, and a Policy Prescription Worth Writing

*Andrew White**

I. INTRODUCTION

Opioid abuse has been a pressing public health issue in the United States since the end of the 20th century.[1] Between 2001 and the present, opioid related deaths have increased six-fold.[2] The opioid problem is unique from many other public health issues because it almost equally affects urban, suburban and rural communities.[3] It affects both men and women, and it is increasing across both low and high income communities.[4] This rapid increase in opioid-related deaths has several causes.[5] This article focuses its analysis of the epidemic of prescription opioids, and offers some potential solutions to the issue. This article will address the causes of the current opioid epidemic and assert that pharmaceutical companies must research and develop alternatives, while being held accountable for the practices that led to the overuse of opioids. It will further argue that lawmakers should continue funding short-term opioid abuse treatment initiatives, make antidote drugs more affordable and readily available, and advocate for the increased

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1. E.W., *Efforts Grow to Tackle America's Heroin Crisis*, ECONOMIST (Mar. 31, 2016), http://www.economist.com/blogs/democracyinamerica/2016/03/addiction-and-legislation-0.
2. Kano & Thiruvananthapuram, *The Problem of Pain*, ECONOMIST (May 28, 2016), http://www.economist.com/news/international/21699363-americans-are-increasingly-addicted-opioids-meanwhile-people-poor-countries-die.
3. E.W., *supra* note 1; Kano & Thiruvananthapuram, *supra* note 2.
4. E.W., *supra* note 1; Kano & Thiruvananthapuram, *supra* note 2.
5. E.W., *supra* note 1; Kano & Thiruvananthapuram, *supra* note 2.

use of opioid alternatives by providers.[6]

First, this article will discuss how flawed studies suggested that extended administration of opioids for chronic pain is safe, that opioid producers relied on these studies to promote opioid prescription, and that physicians acquiesced because it provided a quick solution to otherwise difficult problems.[7] Then, it will analyze how the government's long-term deterrent programs—including state-run Prescription Drug Monitoring Programs and increased drug enforcement—prevent patients dependent on opioids from acquiring prescription opioids, leading some to pursue illegal forms, without confronting the drug and its addictive properties.[8] It will also address how short-term treatment and therapy and research and development for alternatives are underfunded.[9] This article will conclude that lawmakers should continue funding short-term opioid abuse treatment initiatives and make antidote drugs more affordable and readily available.[10] It will advocate for increased use and insurance coverage for non-prescription based alternatives.[11] Furthermore, it will advocate incentivizing pharmaceutical companies to research and develop safer alternatives, while also condemning the practices that led to the misconception that opioids were safe for long-term use.[12] To slow and reverse what is the worst drug epidemic in United

6. NAT'L SAFETY COUNCIL, *infra* note 10.

7. Kano & Thiruvananthapuram, *supra* note 2; Sydney Lupkin, *5 Reasons Prescription Drug Prices Are So High in the U.S.*, MONEY (Aug. 23, 2016), http://time.com/money/4462919/prescription-drug-prices-too-high/; German Lopez, *The Real Causes of the Worst Drug Crisis in US History*, VOX (Mar. 2, 2017, 2:00 PM), https://www.vox.com/science-and-health/2017/3/2/14781304/anna-lembke-opioid-epidemic.

8. Judy Illes & Julie M. Robillard, *Fixing Fentanyl with Naloxone Alone Won't Work*, CBC NEWS (Jan. 29, 2017, 8:00 AM), http://www.cbc.ca/news/canada/british-columbia/fixing-fentanyl-with-naloxone-alone-wont-work-1.3956308.

9. U.S. GOV'T ACCOUNTABILITY OFF., GAO-04-110, PRESCRIPTION DRUGS: OXYCONTIN ABUSE AND DIVERSION AND EFFORTS TO ADDRESS THE PROBLEM (2003).

10. NAT'L SAFETY COUNCIL, NSAIDS ARE STRONGER PAIN MEDICATIONS THAN OPIOIDS, http://www.nsc.org/RxDrugOverdoseDocuments/evidence-summary-NSAIDs-are-stronger-pain-medications-than-opioids-with-IFP.pdf (last visited Feb. 19, 2017); E.W., *supra* note 1; Kano & Thiruvananthapuram, *supra* note 2.

11. Lopez, *supra* note 7.

12. *Id.*

States history, state and federal lawmakers should allocate time and funds not only to initiatives that treat the fallout of opioid abuse, but also on treating the root causes of the epidemic.[13]

II. BACKGROUND

Traditionally, opioids were prescribed with reservation.[14] Opioids have long been known for their powerful pain-numbing and highly addictive effects.[15] They stimulate receptors in the brain that numb pain, lessen anxiety and depression, and create a feeling of euphoria, making opioids highly addictive.[16] Even short-term uses of prescribed opioids can cause addiction and withdrawal symptoms.[17] Due to these realities, opioids were used only to treat acute pain and for palliative care for most of the twentieth century.[18]

In the 1980s, a series of American publications were released, suggesting opioids could be used safely for longer periods of time.[19] The first was a letter to the editor in the *New England Journal of Medicine* in 1980, which concluded that less than one percent of patients at the Boston University Medical Center who received opioids while admitted in the hospital became addicted.[20] The second was a study in *Pain* in 1986, concluding that opioids could be used for extended periods with little risk of addiction or other

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13. *Id.*

14. E.W., *supra* note 1; *see also* Kano & Thiruvananthapuram, *supra* note 2.

15. Sonia Moghe, *Opioid History: From 'Wonder Drug' to Abuse Epidemic*, CNN (Oct. 14, 2016, 6:41 AM), http://www.cnn.com/2016/05/12/health/opioid-addiction-history/; Kano & Thiruvananthapuram, *supra* note 2.

16. *Opioid Addiction 2016 Facts and Figures*, ASAM, 2016, http://www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf [hereinafter *Opioid Addiction 2016 Facts and Figures*]; Kano & Thiruvananthapuram, *supra* note 2.

17. E.W., *supra* note 1.

18. E.W., *supra* note 1.

19. Celine Gounder, *Who Is Responsible for the Pain-Pill Epidemic?*, NEW YORKER (Nov. 8, 2013), http://www.newyorker.com/business/currency/who-is-responsible-for-the-pain-pill-epidemic.

20. *See generally* H. Jick & J. Porter, *Addiction Rare in Patients Treated With Narcotics*, 302 N. ENGL. J. MED. 123 (1980); Gounder, *supra* note 19; Moghe, *supra* note 15; E.W., *supra* note 1; Kano & Thiruvananthapuram, *supra* note 2.

maladaptive effects.[21] The publications made assertions that were supported by slight evidence and both publications called for long-term studies to solidify their findings.[22] These two publications were the only major publications used to spur the movement toward increased opioid prescription.[23]

These publications gave opioid producers support to increase patient use of opioids.[24] Shortly after their publication, opioid producers—like OxyContin's producer, Purdue Pharmaceuticals—began using formidable marketing campaigns that supported opioid use for extended, chronic pain.[25] These campaigns included regular advertisements in highly regarded medical publications.[26] Also, manufacturers created organizations like the American Pain Society, which published guidelines advocating for the expanded use of prescription opioids to relieve chronic pain.[27] Further, pharmaceutical companies incentivized doctors to prescribe opioids by offering perks to

21. Gounder, *supra* note 19; Foley & Portenoy, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases*, 25 PAIN 171–76 (1986); ABOUT US, PAIN, http://journals.lww.com/pain/Pages/aboutthejournal.aspx (last visited Mar. 17, 2017) ("This journal is the official publication of the International Association for the Study of Pain and publishes original research on the nature, mechanisms and treatment of pain. The journal provides a forum for the dissemination of research in the basic and clinical sciences of multidisciplinary interest.").

22. Gounder, *supra* note 19; Jick & J. Porter, *supra note* 20; Foley & Portenoy, *supra* note 21; SCHOLARLY LITERATURE TYPES: PEER REVIEW, CORNELL UNIVERSITY LIBRARY, http://guides.library.cornell.edu/c.php?g=293669&p=2004554 (last visited Apr. 9, 2017) (Journal articles in peer-reviewed academic journals typically undergo vigorous review from colleagues in their discipline, either synthesize existing research or conduct a study to gain new knowledge through observation and research, and are organized in a way that can be replicated and critically analyzed by peers. Just because a journal is peer reviewed, however, does not mean that all its articles are peer-reviewed. Letters to the editor and news reports in peer-reviewed scientific journals are not peer-reviewed.).

23. Kano & Thiruvananthapuram, *supra* note 2.

24. *Id*.

25. Gounder, *supra* note 19; Moghe, *supra* note 15; E.W., *supra* note 1; Kano & Thiruvananthapuram, *supra* note 2.

26. Gounder, *supra* note 19; Moghe, *supra* note 15; E.W., *supra* note 1; Kano & Thiruvananthapuram, *supra* note 2.

27. Gounder, *supra* note 19; Moghe, *supra* note 15; E.W., *supra* note 1; Kano & Thiruvananthapuram, *supra* note 2.

physicians and lucrative speaking engagements.[28]

American doctors began prescribing opioids for chronic pain, abandoning the previous view that opioids were reserved for acute and terminal pain.[29] Pharmaceutical companies also increased direct advertising for opioids to patients.[30] Patients grew familiar with the brands of prescription opioids and welcomed opioids' potency as a cure for pain; the strength of the drugs in conjunction with their exposure trumped prior treatment options.[31] For many patients, the idea of a "quick fix" and an aversion to accepting the limits of one's body made opioids very appealing.[32] It was easy for doctors to make the shift because patients wanted opioids.[33] In fact, opioids appealed the same, if not more, to doctors than they did to patients.[34] The increased number of large, integrated healthcare systems forced physicians to try to treat as many patients as quickly as possible, so their institutions could increase their profits.[35] The fee-for-service payment model in large healthcare systems encouraged physicians to prescribe opioids to patients.[36] In a fee-for-service payment system physicians are paid for each service performed, incentivizing physicians to maximize the number treatments per office visit and keep patients returning for future visits.[37] If a patient is

28. *See* Moghe, *supra* note 15 (discussing the lucrative events associated with opioid engagements).

29. *Id*.

30. *See Id.* (analyzing an opioid advertisement from the period).

31. *Id.*; Nora Volkow, *America's Addiction to Opioids: Heroin and Prescription Drug Abuse*, SEN. CAUCUS ON INT'L NARCOTICS CONTROL (May 14, 2014), https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse.

32. Lopez, *supra* note 7 (discussing how a culture where people expect to have the same mobility and health they had at one time contributes to the opioid epidemic).

33. *Id*.

34. *Id*.

35. *Id.* (discussing the "Toyotazation" of healthcare in which doctors in large healthcare systems are incentivized to treat more patients in a small period of time, almost as if they were on a production line).

36. Gounder, *supra* note 19; E.W., *supra* note 1; Kano & Thiruvananthapuram, *supra* note 2.

37. *Fee for Service Definition*, HEALTHCARE.GOV, https://www.healthcare.gov/glossary/fee-for-service/ (last visited Apr. 9, 2017); Rushika

seeking a prescription for opioids and the physician denies the request, the patient will go elsewhere.[38]

Between 1994 and 2006 the number of adults being prescribed opioids increased from approximately three percent to seven percent.[39] In the same period, 165,000 Americans died from prescription-opioid overdoses.[40] By 2012, there were 282 million prescriptions written for opioids, enough to supply every adult in the United States with a prescription.[41] Drug overdose is the leading cause of accidental death in the United States, with 52,404 lethal drug overdoses in 2015. Opioid addiction is driving this epidemic, with 20,101 overdose deaths related to prescription pain relievers, and 12,990 overdose deaths related to heroin in 2015.[42] The rapid increase in deaths from opioid overdose is the result of both the growing number of opioid prescriptions and the effect opioids have on the human body.[43] Opioids stimulate receptors in the brain that numb pain, but opioids also slow the respiratory system.[44] If too many opioids are taken or mixed with alcohol or a sleep aid, they can slow the respiratory system causing the user to stop breathing.[45] This is amplified by the reality that the difference between an effective and lethal dose is both small and unpredictable.[46]

In response to increasing overdoses and deaths, the Centers for Disease

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Fernandopulle, *Breaking The Fee-For-Service Addiction: Let's Move To A Comprehensive Primary Care Payment Model*, HEALTH AFF. BLOG (Aug. 17, 2015), http://healthaffairs.org/blog/2015/08/17/breaking-the-fee-for-service-addiction-lets-move-to-a-comprehensive-primary-care-payment-model/.

38. Fernandopulle, *supra* note 37; Lopez, *supra* note 7.

39. INJURY PREVENTION & CONTROL: OPIOID OVERDOSE, CDC (Feb. 19, 2017), https://www.cdc.gov/drugoverdose/epidemic/; *Opioid Addiction 2016 Facts and Figures*, *supra* note 16.

40. E.W., *supra* note 1; Kano & Thiruvananthapuram, *supra* note 2.

41. Gounder, *supra* note 19; Moghe, *supra* note 15.

42. *Opioid Addiction 2016 Facts and Figures*, *supra* note 16.

43. E.W., *supra* note 1; Kano & Thiruvananthapuram, *supra* note 2.

44. Gounder, *supra* note 19; Moghe, *supra* note 15; E.W., *supra* note 1; Kano & Thiruvananthapuram, *supra* note 2; Volkow, *supra* note 31.

45. Kano & Thiruvananthapuram, *supra* note 2.

46. Gounder, *supra* note 19; Moghe, *supra* note 15; E.W., *supra* note 1; Kano & Thiruvananthapuram, *supra* note 2; Volkow, *supra* note 31.

Control (CDC) initiated Prescription Drug Monitoring Programs (PDMPs).[47] PDMPs are state-run databases that track patient opioid prescriptions through information entered by pharmacists into databases.[48] In theory, PDMPs prevent fake prescriptions and over-prescription of opioids to patients.[49] This gives physicians and pharmacists an opportunity to identify individuals at high risk of forming a dependency and assists in early intervention for those who abuse prescription pain relievers.[50]

The Drug Enforcement Administration (DEA) has also cracked down on "pill mill" doctor offices, which prescribe opioids and other prescription drugs without a medical justification.[51] Pill mills flood the black market with prescription opioids.[52] Pill mills are a significant avenue in which opioids get into people's hands in such large quantities.[53] Communities with opioid problems often have small pain clinics that will give opioid prescriptions for cash.[54] Then, these patients take these prescriptions to small, "mom and pop" pharmacies that fill them.[55] That is how small towns, like those in Mingo County, West Virginia, see enormous shipments of opioids come in to small

47. Gounder, *supra* note 19; Moghe, *supra* note 15; *see also* E.W., *supra* note 1; *see also* Kano & Thiruvananthapuram, *supra* note 2; *see also* Volkow, *supra* note 31.

48. Gounder, *supra* note 19; Moghe, *supra* note 15; *see also* E.W., *supra* note 1; *see also* Kano & Thiruvananthapuram, *supra* note 2; *see also* Volkow, *supra* note 31.

49. CDC, *supra* note 39 ("Prescription Drug Monitoring Programs (PDMPs) are state-run electronic databases used to track the prescribing and dispensing of controlled prescription drugs to patients. They are designed to monitor this information for suspected abuse or diversion (i.e., channeling drugs into illegal use), and can give a prescriber or pharmacist critical information regarding a patient's controlled substance prescription history. This information can help prescribers and pharmacists identify patients at high-risk who would benefit from early interventions.").

50. *Id.*

51. Kano & Thiruvananthapuram, *supra* note 2; Brian Krans, *More 'Pill Mill' Doctors Prosecuted Amid Opioid Epidemic*, HEALTHLINE (May 19, 2016), http://www.healthline.com/health-news/pill-mill-doctors-prosecuted-amid-opioid-epidemic.

52. Krans, *supra* note 51.

53. Interview by Rachel Martin with Eric Eyre of the Charleston Gazette-Mail, NPR.ORG (Dec. 22, 2016), http://www.npr.org/2016/12/22/506550248/drug-firms-make-millions-by-sending-opioid-pills-to-w-va-report-says.

54. *Id.*

55. *Id.*

pharmacies.[56]

Doctors have grown uneasy about increased DEA and PDMP scrutiny, fearing liability or professional discipline.[57] As a result, physicians who previously may have liberally prescribed opioids, now avoid prescribing opioids to patients, even those who are unable to find comparable, timely, and effective treatment for pain management.[58] Often, physicians will stop prescribing opioids to a patient once they are flagged in the PDMP as high risk for dependency or misuse.[59] When physicians stop prescribing to patients suffering from chronic pain, these patients sometimes turn to heroin, pill mills, or other illegal options to purchase opioids.[60]

The CDC and the Obama Administration took steps to attempt to reverse this crisis.[61] The CDC urged new guidelines for when to prescribe opioids to non-cancer patients, recommending physicians prescribe pain-relievers like ibuprofen prior to prescribing opioids and reduce the supply of opioids to only a few days in any given prescription.[62] President Obama authorized the

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56. *Id.*

57. *Id.*; Gounder, *supra* note 19; Nolan & Amico, *supra* note 16.

58. Prescription Drug Abuse and Diversion: The Role of Prescription Drug Monitoring Programs: Hearing of the Comm. on Health, Educ., Lab., & Pensions, 108th Cong. 2 (2004) (Sen. Sessions discusses the difficult position of physicians in his opening statement).

59. Pradip K. Muhuri et al., *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*, CTR. FOR BEHAV. HEALTH STAT. & QUALITY REV. (Aug. 2013), https://www.samhsa.gov/data/sites/default/files/DR006/DR006/nonmedical-pain-reliever-use-2013.htm; *but see* Mir M. Ali et al., *Prescription Drug Monitoring Programs, Nonmedical Use of Prescription Drugs, and Heroin Use: Evidence From the National Survey of Drug Use and Health*, 69 ADDICTIVE BEHAVIORS 65, 71 (2017) (concluding that of all opioid users, only approximately 4% are heroin users, and while PDMPs have not drastically effected the percentage of opioid users use heroin, they have increased the number of days per year heroin users use heroin), *available at* http://ac.els-cdn.com/S030646031730014X/1-s2.0-S030646031730014X-main.pdf?_tid=b4819856-0ce5-11e7-8e5f-00000aab0f26&acdnat=1489956817_6f58529ac94446a60e01b9ca3c8e35f9.

60. E.W., *supra* note 1.

61. Joanne E. Brady et al., *Prescription Drug Monitoring and Dispensing of Prescription Opioids*, 129 PUB. HEALTH REP. 2, 139 (2014); E.W., *supra* note 1; Kano & Thiruvananthapuram, *supra* note 2.

62. Kano & Thiruvananthapuram, *supra* note 2; These new guidelines received some criticism because it may create unfair hurdles for patients with pain that requires the strength of opioids. Sabrina Tavernise, *C.D.C. Painkiller Guidelines Aim to Reduce Addiction Risk*, N.Y. TIMES (Mar. 15, 2016), https://www.nytimes.com/2016/03/16/health/cdc-opioid-guidelines.html.

use of over one billion dollars for opioid-addiction treatment for Fiscal Year 2017.[63] President Obama also signed a measure to curtail DEA enforcement, so that that pharmacies and physicians would not be paralyzed from practicing.[64] The measures taken can help, however, much of the spending that was authorized was not actually apportioned to opioid reduction initiatives, and many of these problems have not reduced the number of opioids on the market or increased the availability of realistic alternatives.[65]

IV. ANALYSIS

There are several avenues available to help resolve this public health crisis. It is important that those who were responsible for misleading the medical community be held accountable.[66] It is imperative that doctors both understand the addictive nature of opioids and significantly dial back prescribing opioids for chronic pain, and instead, turn both to prescription drug and non-drug treatment alternatives. In addition, there must be programs available to assist people struggling with addiction to opioids.[67] Drugs like naloxone, which acts as an antidote to opioid overdose, should be readily available both to first responders and anyone likely to encounter an opioid overdose.[68] These possibilities would reduce the severity of the

63. Moghe, *supra* note 15; E.W., *supra* note 1; Kano & Thiruvananthapuram, *supra* note 2.

64. This measure also received some criticism, as many addiction advocates and legislatures thought it provided too much leeway for wholesalers and pharmaceutical companies that are profiting off the epidemic. Gardiner Harris & Emmarie Huetteman, *Action by Congress on Opioids Haven't Included Limiting Them*, N.Y. TIMES (May 18, 2016), https://www.nytimes.com/2016/05/19/us/politics/opioid-dea-addiction.html?_r=0.

65. Kano & Thiruvananthapuram, *supra* note 2; Harris & Huetteman, *supra* note 64.

66. Gounder, *supra* note 19; Moghe, *supra* note 15; Lupkin, *supra* note 7.

67. *See generally* M. Douglas Anglin & Yih-Ing Hser, *Treatment of Drug Abuse*, 13 CRIME & JUST. 393 (1990) (discussing in more detail the potential regulations and grants that would be effective deterrents to drug abuse).

68. Gounder, *supra* note 19; Moghe, *supra* note 15; E.W., *supra* note 1; MD DEP'T OF HEALTH & MENTAL HYGIENE, NALOXONE SAVES LIVES (2016), *available at* http://bha.dhmh.maryland.gov/NALOXONE/Pages/Naloxone.aspx (discussing that doctors can prescribe naloxone to anyone either at risk of having or at risk of witnessing an opioid overdose).

epidemic, but physicians must still find a way to appropriately respond to patients' pain needs.[69] Thus, it is equally as important that policymakers encourage and incentivize pharmaceutical manufacturers to move away from opioids toward safe, effective alternatives, like Ibuprofen hybrids, and encourage providers and insurers to prescribe non-prescription based pain therapy.[70] This can be achieved through both regulation and grant funding for research and development, and a more inclusive health insurance system.[71]

A. New Research and Litigation

Recent studies have refuted the limited studies that pharmaceutical companies marketing opioids relied on in the 1980s and 1990s.[72] Some of the physicians responsible for early studies advocating opioid use for chronic pain have spoken out against such use.[73] Dr. Portenoy, one of the doctors responsible for the *Pain* publication used by pharmaceutical companies, recently came out criticizing his role in the opioid epidemic.[74]

In 2007, three Purdue Pharmaceuticals executives pled guilty to criminal charges that they had misled the Food and Drug Administration, clinicians, and patients about the addiction risks of their patented opioid, OxyContin, by aggressively marketing the drug to providers and patients as a safe alternative to treat chronic pain long-term.[75] Holding these individuals responsible will likely deter similar actions by other pharmaceutical entities in the future and

69. E.W., *supra* note 1.

70. Kano & Thiruvananthapuram, *supra* note 2; Volkow, *supra* note 31; Lopez, *supra* note 7.

71. Brady, *supra* note 61.

72. Moghe, *supra* note 15; *Opioid Addiction 2016 Facts and Figures*, *supra* note 16.

73. Moghe, *supra* note 15 (interviewing Dr. Portenoy and discussing the tactics used by large pharmaceutical companies, and his actions on their behalf, to market in favor of the increased use of prescription opioids for chronic pain treatment).

74. *Id.*

75. Gounder, *supra* note 19 (discussing the criminal charges against three Purdue executives because of the tactics used to increase sales and of OxyContin).

will raise awareness in the medical and lay communities.[76]

B. Provider Avenues

Recent research, physician anti-opioid advocacy, and litigation against opioid-producing pharmaceutical companies have increased physicians' awareness.[77] PDMPs and the increased DEA scrutiny have further discouraged physicians from over-prescribing opioids.[78] The recent CDC regulations have required care providers to look to alternatives like ibuprofen prior to prescribing opioids, and limit how many opioids they can prescribe in a given time.[79] Limiting how many opioids physicians can and are willing to prescribe to patients, however, leaves physicians in a difficult position where they may not be able to adequately address patients' long-term pain.[80] The lack of alternatives makes it difficult for physicians to do more to reduce the opioid epidemic other than limit how much they prescribe.[81]

The transition out of a fee-for-service healthcare system would take some pressure off physicians to prescribe opioids.[82] When physicians are paid a fee per visit instead of based on health outcomes of the patient, they are incentivized to keep the patient satisfied by prescribing what the patient requests and keep the patient returning for future visits.[83] It encourages physicians to prescribe a drug, like an opioid, rather than implementing long-term treatment plans like physical therapy, or addressing deeper problems in a patient, such as the psychological impact that a condition has had on the patient.[84]

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76. *Id.*
77. *Id.*
78. Gounder, *supra* note 19; Moghe, *supra* note 15; E.W., *supra* note 1; Kano & Thiruvananthapuram, *supra* note 2; Volkow, *supra* note 31.
79. Tavernise, *supra* note 62.
80. *Id.*
81. *Id.*
82. *Fee for Service Definition*, *supra* note 37; Fernandopulle, *supra* note 37.
83. Fernandopulle, *supra* note 37.
84. Lopez, *supra* note 7 (discussing how opioids are often treated as a catchall to relieve

Alternative payment systems, like comprehensive care payment systems, could help providers in the fight against opioids.[85] A comprehensive care payment system would allow a group of people with certain health concerns to pay a single price for all their healthcare services for a specified period of time.[86] This system, rather than a fee-for-service system, would allow for physicians to focus less on ensuring regular visits and more on improving health.[87] This would allow physicians to use multiple healthcare providers and other avenues to remedy the patients' problems.[88] This would permit physicians to utilize more resources to provide care to the patient before making the leap to prescription opioids.[89] Increased healthcare coverage would also help providers by allowing them to prescribe more unconventional, non-drug alternatives that are often excluded from health insurance plans.[90]

C. Congressional Action

There has been a significant amount of congressional activity focusing on opioid abuse.[91] Congress passed almost twenty opioid related bills in 2016.[92]

"pain" when much of the patients' pain may involve difficulty in coping with their weakened condition rather than physical pain).

85. Fernandopulle, *supra* note 37.

86. *Id.*; CTR. FOR HEALTHCARE QUALITY & PAYMENT REFORM, TRANSITIONING TO COMPREHENSIVE CARE PAYMENT, http://www.chqpr.org/downloads/transitioningtocomprehensivecarepayment.pdf (last visited Apr. 9, 2017).

87. Fernandopulle, *supra* note 37.

88. CTR. FOR HEALTHCARE QUALITY & PAYMENT REFORM, *supra* note 86.

89. *Id.*

90. Lopez, *supra* note 7 (interviewing an opioid abuse expert who concluded that treatments like physical therapy or psychological counseling may be necessary to help reduce the number of opioid users); Alternative treatments, such as medical marijuana, are often excluded from health insurance plans, making them difficult to prescribe to patients. Alexandra Sifferlin, *Can Medical Marijuana Help End the Opioid Epidemic?*, TIME (Jul. 28, 2016), http://time.com/4419003/can-medical-marijuana-help-end-the-opioid-epidemic/ (discussing that medical marijuana could be a viable and effective alternative to opioids).

91. Gounder, *supra* note 19; Moghe, *supra* note 15; E.W., *supra* note 1; Kano & Thiruvananthapuram, *supra* note 2 (outlining the measures being taken in the federal government to remedy the issue in 2016 alone); Volkow, *supra* note 31.

92. Gounder, *supra* note 19; Moghe, *supra* note 15; E.W., *supra* note 1.

The most recent and noteworthy of these include the Comprehensive Addiction and Recovery Act of 2016 ("CARA") and the Protecting Our Infants Act.[93]

CARA is a bill designed to expand addiction treatment programs and increase availability of overdose reversal medications, like naloxone.[94] CARA was intended to attack drug addiction in eight different ways: increasing funding, innovating treatment, increasing prevention, assisting in addiction recovery, increasing availability of overdose reversal drugs, increasing access to addiction treatment, increasing law enforcement training on how to handle drug addiction and overdose, and criminal justice reform to prevent the misplacement of addicted individuals in prison systems.[95] CARA allocates federal funding to the Secretary of Health and Human Services to fund programs that provide education for clinicians, providers, and other first responders on how to monitor for signs of opioid abuse and how to address addiction.[96] CARA also increases the Department of Health and Human Services' (HHS) funding for addiction treatment for pregnant and postpartum mothers and funding and subsidies for municipalities to purchase opioid overdose reversal medication.[97]

The Protecting Our Infants Act of 2015 charges HHS with monitoring and reporting on opioid abuse's effect on pre-and-neonatal infants.[98] It also requires HHS to look for gaps in care and addiction treatment that can

93. *See generally* Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-198 (2016); Jason Simcakoski Memorial Opioid Safety Act; Protecting our Infants Act of 2015, Pub. L. No. 114-91 (2015).

94. Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-198, §§106, 110, 301, 303 (2016).

95. Press Release from Sen. Rob Portman Re: CARA, (Jul. 15, 2016), http://www.portman.senate.gov/public/index.cfm/2016/7/the-comprehensive-addiction-recovery-act-cara.

96. *Id*.

97. Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-198, §§303, 501, 601 (2016).

98. Protecting our Infants Act of 2015, Pub. L. No. 114-91 (2015).

negatively affect infants exposed to opioids.[99] Initial reports to Congress on the effectiveness of the Protecting Our Infants Act suggest success on a broad range of efforts, including data collection, research, grant programs, and training.[100] Reports also address concerns of screening-related challenges, including limited availability of screening instruments and a lack of knowledge among providers and researchers about how to correctly identify and manage neonatal opioid withdrawal.[101] Furthermore, reports have identified that while efforts ensuring that women and infants have access to effective pain management and treatment are critical, they are underfunded.[102] Limited knowledge and resources among providers hinders their ability to provide timely, evidence-based treatment.[103] Initial reports have also called for more grant funding, treatment programs, training, and technical assistance.[104]

Both CARA and the Protecting Our Infants Act lack the appropriate funding to proceed with solutions to identified problems.[105] These bills are some of many congressional actions taken to ignite action in response to opioid abuse in the United States.[106] As admirable as they sound, however, many are significantly stunted due to congressional disagreements over federal spending.[107] Congress has denied over $600 million in measures to fund treatment programs, arguing it is best addressed at the state level.[108] State programs vary widely and in states like Illinois and Missouri,

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99. *Id.*

100. SUBCOMM. ON PRESCRIPTION DRUG ABUSE, PROTECTING OUR INFANTS ACT: REPORT TO CONGRESS 33 (2016).

101. *Id.*

102. *Id.*

103. *Id.*

104. *Id.*

105. Kano & Thiruvananthapuram, *supra* note 2; SUBCOMM. ON PRESCRIPTION DRUG ABUSE *supra* note 100.

106. Comprehensive Addiction and Recovery Act of 2016; Jason Simcakoski Memorial Opioid Safety Act; Protecting our Infants Act of 2015.

107. E.W., *supra* note 1; Kano & Thiruvananthapuram, *supra* note 2.

108. E.W., *supra* note 1; Kano & Thiruvananthapuram, *supra* note 2.

financially strapped budgets prevent state-based opioid abuse programs from taking off.[109]

D. Relief, Alternatives, and Costs

Solving the opioid problem is costly from administrative costs to medical costs to human costs. One such cost is connected to naloxone—the drug used to reverse an opioid overdose—because it has become more difficult to afford and, thus, more difficult for municipalities and individuals to obtain.[110] Naloxone producers have increased the price of naloxone from $15 to $2000 in the last decade.[111] One of the reasons for the price increase was the advent of a nasal spray delivery system, which made the product much more effective.[112] These delivery systems have very short shelf lives of about eighteen months, requiring regular replacements.[113] Another reason is the producers of the naloxone nasal injector have a patent on the technology,

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109. Community Behavioral Healthcare Association of Illinois, *The Prescription Drug and Heroin Epidemic in Southern Illinois A Call for Community Health Solutions*, 2016, http://www.cbha.net/resources/Documents/SI%20Prescription%20Drug%20and%20Heroin%20Epidemic%20DRAFT%20-%20June%202016.pdf; Jesse Bogan, *A Mass Killer: St. Louis Heroin Deaths Hit New High*, ST. LOUIS POST (Feb. 19, 2017), http://www.stltoday.com/news/local/metro/a-mass-killer-st-louis-heroin-deaths-hit-new-high/article_2fd6130c-3c35-524a-891e-e51eff2e40b4.html. Some states have taken matters in their own hands in the absence of adequate state and federal funding and attempted to negotiate directly with naloxone producers. *See* Press Release, Attorney General Mara Healey, AG Healey Announces $325K Agreement with Naloxone Manufacturer, Dedicates Funds to Help First Responders Statewide Access Life-Saving Drug (Aug. 31, 2015), *available at* http://www.mass.gov/ago/news-and-updates/press-releases/2015/2015-08-31-amphastar-agreement.html.

110. Gounder, *supra* note 19; Moghe, *supra* note 15; E.W., *supra* note 1; Kano & Thiruvananthapuram, *supra* note 2.

111. Illes & Robillard, supra note 8.

112. Harrison Jacobs, *The Price of the 'Antidote' to the Overdose Crisis is Skyrocketing*, BUS. INSIDER (Aug. 1, 2016), http://www.businessinsider.com/price-of-naloxone-narcan-skyrocketing-2016-7; Gounder, *supra* note 19; Moghe, *supra* note 15; E.W., *supra* note 1; *see also* Kano & Thiruvananthapuram, *supra* note 2 (discussing the rapid increase in the cost of naloxone).

113. Christopher Moraff, *Narcan Prices Are Skyrocketing and Cities Are Begging for Help to Buy It*, DAILYBEAST.COM (Sep. 8, 2016), http://www.thedailybeast.com/articles/2016/09/08/narcan-prices-are-skyrocketing-and-cities-are-begging-for-help-to-buy-it.

giving them control of the price of the drug.[114] Without loosening our patent law system to allow competitors into the market, or a government intervention to artificially reduce the price, federal funding is necessary to supply state municipalities with naloxone.[115] If both state and federal governmental bodies are able to increase addiction treatment and fund these treatment programs, overdose trends will reverse and the opioid problem will be reduced.[116]

Federal acts and short term treatment methods decrease the abuse of opioids and the number of deaths caused by overdose, but it is still necessary to provide viable alternatives for patients in need of pain relief.[117] Increased DEA and CDC scrutiny have helped incentivize physicians to look to alternatives.[118] Combinations of other drugs such as paracetamol and ibuprofen, acetaminophen and ibuprofen, or naproxen combinations can provide equal if not better levels of pain relief as opioids without being addictive.[119] The government should attempt to increase funding and granting for research into opioid alternatives.[120] This is a difficult task to ask of a Congress currently seeking to reduce federal spending.[121] This would only succeed with either a temporary increase in spending on alternative

114. Kano & Thiruvananthapuram, *supra* note 2; Lupkin, *supra* note 7.

115. Kano & Thiruvananthapuram, *supra* note 2; Lupkin, *supra* note 7.; Community Behavioral Healthcare Association of Illinois, *The Prescription Drug and Heroin Epidemic in Southern Illinois A Call for Community Health Solutions*, 2016, http://www.cbha.net/resources/Documents/SI%20Prescription%20Drug%20and%20Heroin%20Epidemic%20DRAFT%20-%20June%202016.pdf; Bogan, supra note 109.

116. Kano & Thiruvananthapuram, *supra* note 2.

117. Gounder, *supra* note 19; Moghe, *supra* note 15; E.W., *supra* note 1; Kano & Thiruvananthapuram, *supra* note 2; Volkow, *supra* note 31; Harrison Jacobs, *Drug Overdoses Won't Stop Rising — and That's not Even the Worst Part*, BUS. INSIDER (Jan. 20, 2016), http://www.businessinsider.com/drug-overdoses-wont-stop-rising-and-thats-not-even-the-worst-part-2016-1.

118. NAT'L SAFETY COUNCIL, *supra* note 10; E.W., *supra* note 1; Kano & Thiruvananthapuram, *supra* note 2.

119. NAT'L SAFETY COUNCIL, EFFICACY OF PAIN MEDICATIONS (Feb. 19, 2017), http://www.nsc.org/RxDrugOverdoseDocuments/Evidence-Efficacy-Pain-Medications.pdf.

120. Kano & Thiruvananthapuram, *supra* note 2.

121. *Id.*

treatment methods, or through reductions in spending in other areas of the budget.[122]

Providers and governmental entities must also champion alternative treatments that already exist.[123] Some states, like Minnesota and Massachusetts, are investing in opioid treatment resources, and are also looking into the use of medical marijuana as a short-term, cost-effective alternative treatment for those either with chronic pain or with opioid addictions.[124] Simultaneously, these states are calling on organizations like the CDC to invest more time into the development of alternatives for pain treatment.[125] Vermont has changed its criminal justice system to allow drug convicts to enroll in treatment and avoid a criminal record, in addition to increasing treatment funding and attempting to address what drugs are actually being prescribed to patients.[126] Minnesota, Michigan, and Vermont may be on the right track, but a meaningful solution will only be reached if the federal and state governments work together to ensure that funding is used to provide states with treatment and overdose reversal resources, and successful alternatives for patients struggling with chronic, severe pain are championed and made more accessible to those with limited resources or insurance plans.[127]

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122. *Id.*; Moghe, *supra* note 15.

123. Sifferlin, *supra* note 90.

124. *Id.*

125. *Id.*

126. *4 Steps for Fighting Opioid "Crisis" at the State Level*, THE PEW CHARITABLE TRUSTS (Feb. 23, 2016), http://www.pewtrusts.org/en/research-and-analysis/analysis/2016/02/23/4-steps-for-fighting-opioid-crisis-at-the-state-level; Pew, *Opioid and Heroin Addiction: Confronting an Epidemic*, YOUTUBE (Feb. 19, 2016), https://www.youtube.com/watch?v=D71YoOPxRQQ.

127. Kano & Thiruvananthapuram, *supra* note 2; Some alternatives already exist, such as therapy, counseling, and medical marijuana, but for patients relying on health insurance these treatment options are usually not fully covered. To truly help reduce the opioid epidemic, we must also address the issue of health insurance coverage in the U.S. and insure that the safe alternatives that already exist are readily accessible. Lopez, *supra* note 7; Sifferlin, *supra* note 90.

V. CONCLUSION

Opioid abuse has become a huge problem in the United States in the past twenty-five years.[128] This began through changes in what was thought to be the appropriate time to prescribe opioids to patients.[129] Many Americans have been prescribed opioids to manage chronic pain, and became addicted due to its properties.[130] Solving the epidemic requires governmental support to stem the problem, but also requires changes to the incentives and inclinations of providers and patients to break the cycle of prescription and addiction.[131] It is important that legislators apportion funds to acts that will supply states with the resources they need to provide treatment to individuals, as well as to the development of non-opioid drugs that relieve pain without addiction and the accessibility of non-drug alternatives that are already available.[132]

128. Kano & Thiruvananthapuram, *supra* note 2; Lopez, *supra* note 7; Sifferlin, *supra* note 90.
129. Kano & Thiruvananthapuram, *supra* note 2; Lopez, *supra* note 7; Sifferlin, *supra* note 90.
130. Kano & Thiruvananthapuram, *supra* note 2; Lopez, *supra* note 7; Sifferlin, *supra* note 90.
131. Kano & Thiruvananthapuram, *supra* note 2; Lopez, *supra* note 7; Sifferlin, *supra* note 90.
132. Kano & Thiruvananthapuram, *supra* note 2; Lopez, *supra* note 7; Sifferlin, *supra* note 90.

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The Pornography Public Health Crisis: Using a Holistic Approach to Protect Citizens' Welfare

Collin Rosenbaum[*]

I. INTRODUCTION

The adult film industry has witnessed tremendous expansion in the past two decades.[1] In 1996, pornography generated $8 billion in annual sales.[2] By 2005, that number exceeded $12 billion.[3] More than 13,000 adult videos were produced in the United States in 2006, a number 60% higher than recorded ten years earlier.[4] In contrast, 507 major Hollywood films were released in 2005, resulting in an annual revenue of $8.8 billion.[5] Aggression, degradation, and misogyny, themes typically associated with adult film controversies, are prevalent in an industry that dwarfs Hollywood.[6] Research has shown that viewing aggressive adult films is "likely to have a negative influence on the thoughts, attitudes, or behavior of audience members."[7] Evidence suggests that degrading adult films "increase dominating and harassing behavior toward women" and cause "harsher evaluations of real-life partners" and "loss of compassion for female rape victims."[8]

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1. *See* Ana J. Bridges et al., *Aggression and Sexual Behavior in Best-Selling Pornography Videos: A Content Analysis Update*, 16 VIOLENCE AGAINST WOMEN 1065, 1065 (2010), http://journals.sagepub.com/doi/pdf/10.1177/1077801210382866.
2. *Id.*
3. *Id.*
4. *Id.*
5. *Id.* at 1065-66.
6. *See id.* at 1065 (stating that approximately 88% of adult films depict some form of physical aggression).
7. *Id.* at 1066.
8. *Id.*

The current state of pornography is arguably a public health "crisis," which is vaguely defined by the World Health Organization as a "situation that is perceived as difficult" and a "time of danger."[9] However, even for those who disagree, certain explicit content likely poses more harm than good for citizens. Based on anti-pornography actions taken by the Republican Party, as well as states such as Utah and South Dakota, there is a growing attitude that the current law and its corresponding enforcement is not sufficient enough to combat the modern pornography industry.[10] This article proposes that in order for anti-pornography advocates to attain meaningful success, they must undertake a holistic approach that encompasses both state and federal enforcement mechanisms, improves sex education, and encourages private action in the home. This article will first summarize the delicate constitutionality of pornography under existing Supreme Court decisions. It will then discuss the current state of anti-pornography opposition. Lastly, it will detail how a holistic approach provides anti-pornography advocates with the best chance for success in their fight against the adult film industry.

II. THE CONSTITUTIONALITY OF PORNOGRAPHY

The First Amendment protects an individual's freedom of speech or expression.[11] Pornography, considered a form of expression, is thus constitutional: It is legal for "adults [to] own it, look at it, and even make or

9. World Health Org., *Definitions: Emergencies*, HUMANITARIAN HEALTH ACTION, http://www.who.int/hac/about/definitions/en/ (last visited Feb. 19, 2017).

10. *See generally* Tal Kopan, *GOP Platform Draft Declares Pornography "Public Health Crisis,"* CNN POLITICS (July 11, 2016), http://www.cnn.com/2016/07/11/politics/gop-platform-republican-convention-internet-pornography/; *see generally* UTAH STATE LEGISLATURE, CONCURRENT RESOLUTION ON THE PUBLIC HEALTH CRISIS, https://le.utah.gov/~2016/bills/static/SCR009.html (last visited Feb. 19, 2017); *see generally* Scott Waltman, *South Dakota Senate: Porn a Public Health Crisis*, ABERDEEN NEWS (Jan. 25, 2017), http://www.aberdeennews.com/news/politics/south-dakota-senate-porn-a-public-health-crisis/article_756d4ce8-e1b0-5d2c-b8a4-c82677602e85.html.

11. U.S. CONST. amend. I (stating that Congress shall make no law [. . .] abridging the freedom of speech).

publish it."[12] However, the First Amendment is not absolute: it does not protect material deemed "obscene."[13] Every state has legislated laws governing obscenity, with the possibility of civil or criminal penalties depending on the offense.[14]

The Supreme Court has long evaluated this dilemma, which arises from a person's First Amendment right to read or watch material of his or her choosing, while respecting that an implicit obscenity exception to the free speech clause exists.[15] The first landmark case in this area, *Jacobellis v. Ohio*, involved nudity and sexual contact portrayed in a movie.[16] In *Jacobellis*, the state of Ohio categorized the art film *Les Amants* as obscene, notwithstanding that it was not intended to serve as pornography.[17] In his memorable concurrence in favor of the film, Justice Stewart wrote that only the most hard-core pornography would be deemed unconstitutional.[18] Furthermore, rather than proposing a bright-line test by which to identify obscene content (and recognizing the difficulty in doing so intelligibly), the Justice merely stated that he would "know it when he saw it."[19]

The Supreme Court analyzed private possession of adult materials in *Stanley v. Georgia*.[20] Effectively legalizing the private possession of pornography, Justice Marshall held that the First Amendment protects an

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12. *Pornography, Obscenity and the Law*, LAWYERS.COM, http://civil-rights.lawyers.com/pornography-obscenity-and-the-law.html (last visited Mar. 15, 2017).

13. *Id.* ("Pornography loses its First Amendment protections, however, when it becomes obscene or it involves children.").

14. *See State Laws on Obscenity, Child Pornography and Harassment*, LORENAVEDON.COM, http://www.lorenavedon.com/laws.htm (last visited Mar. 17, 2017) ("Anyone violating these laws may be fined, sent to jail or both.").

15. *See, e.g.*, Jacobellis v. Ohio, 378 U.S. 184 (1964); *see, e.g.*, Stanley v. Georgia, 394 U.S. 557 (1969); *see, e.g.*, Miller v. California, 413 U.S. 15 (1973).

16. *See* Jacobellis v. Ohio, 378 U.S. 184 (1964).

17. *See id.* at 196 ("There is an explicit love scene in the last reel of the film, and the State's objections are based almost entirely upon that scene.").

18. *Id.* at 197 ("Criminal laws in this area are constitutionally limited to hard-core pornography.").

19. *See id.* ("I shall not today attempt to further define the kinds of material I understand to be embraced within that shorthand description [. . .] But I know it when I see it.").

20. *See* Stanley v. Georgia, 394 U.S. 557 (1969).

individual's decision to read or watch material of his or her own choosing in the privacy of the home.[21] However, the definition of "obscene," and consequently what was within a state's power to regulate, still remained an obscure concept.

In *Miller v. California*, Chief Justice Burger created a three-part test that is used to evaluate whether content qualifies as obscene:[22]

The basic guidelines for the trier of fact must be: (a) whether 'the average person, applying contemporary community standards,' would find that the work, taken as a whole, appeals to the prurient interest; (b) whether the work depicts or describes, in a

patently offensive way, sexual conduct specifically defined by the applicable state law; and (c) whether the work, taken as a whole, lacks serious literary, artistic, political, or scientific value.

While this test certainly provides more guidance than Justice Stewart's ambiguous "I know it when I see it" language, one is still tasked with defining "contemporary community standards," "patently offensive," as well as "prurient interest" under the *Miller* analysis.[23]

Ultimately, the question of whether certain pornographic content falls under a state's authority to regulate because it is not protected by the First Amendment remains an unsettled area of law. In his dissent of *Miller*, Justice Douglas cited the majority test as well-intentioned, but lacking in clarity.[24] He wrote that "obscenity" is a subjective concept; what causes one person to "boil up in rage" may give another "sustenance."[25] Since "obscenity" may

21. *See id.* at 565 ("If the First Amendment means anything, it means that a State has no business telling a man, sitting alone in his own house, what books he may read or what films he may watch.").

22. Miller v. California, 413 U.S. 15, 24 (1973) (acknowledging the constitutional dangers of regulating expression and that regulatory state statutes must be "carefully limited").

23. *Id.*

24. *See id.* at 40 (stating that despite the Court's good intentions, it is inherently difficult to define "obscenity" because it does not exist in the Constitution or the Bill of Rights and is a subjective matter).

25. *Id.* at 41.

be defined in a multitude of different ways and is not mentioned in the Constitution, it is through the democratic process, and not by a handful of individuals on the Supreme Court, that a legal definition should be established.[26] The Justice further described the *Miller* test as a trap because a potential violator is unlikely to know whether he or she has broken the law.[27] In conclusion, he declared that "no more vivid illustration of vague and uncertain laws could be designed than those we have fashioned."[28]

III. THE CURRENT STATE OF PORNOGRAPHY OPPOSITION

With the Supreme Court essentially ruling that only the most harmful and exploitative pornographic acts would likely meet the vague obscenity test established in *Miller*, many anti-pornography advocates have turned away from the First Amendment, and have instead focused their arguments on the detrimental effects that certain adult content imposes on the public's well-being.

Utah, at the forefront of this movement, was the first state to declare pornography a public health crisis.[29] The state passed a resolution describing adult content as degrading, addictive, harmful, and an epidemic that is "harming the citizens of Utah and the nation."[30] It lists eighteen unique harms that stem from pornography and serves to "recognize the need for education, prevention, research, and policy change at the community and societal level."[31] However, the resolution's immediate legal impact is minimal, as it

26. *See id.* ("We deal here with a regime of censorship which, if adopted, should be done by constitutional amendment after full debate by the people.").

27. *See id.* ("Under the present regime—whether the old standards or the new ones are used—the criminal law becomes a trap.").

28. *Id.*

29. *See* UTAH STATE LEGISLATURE, *supra* note 10 ("This concurrent resolution [. . .] recognizes that pornography is a public health hazard leading to a broad spectrum of individual and public health impacts and societal harms."); *see also* Lucy Westcott, *Utah Becomes First State to Declare Pornography a Public Health Hazard*, NEWSWEEK (Apr. 20, 2016), http://www.newsweek.com/utah-porn-public-health-hazard-450223.

30. UTAH STATE LEGISLATURE, *supra* note 10.

31. Tyler Ahlstrom, *What Are the Legal Ramifications of Utah's Resolution Against*

does not change any laws or earmark funds to combat pornography.[32]

Nevertheless, Utah's resolution arguably serves as a symbolic rejection of the country's laissez-faire attitude associated with pornography and has the potential to influence further action.[33] Along with the resolution, Utah's governor also signed bill H.B. 155, which states that computer engineers who find child pornography during the course of their work must report it or risk being charged with a class B misdemeanor.[34] In July 2016, the Republican Party amended its platform to declare pornography a public health crisis.[35] Then, in December 2016, a Virginia lawmaker filed a bill, currently awaiting consideration, that would declare pornography a public health hazard.[36] Most recently, in January 2017, South Dakota's Senate unanimously passed a resolution that similarly declared pornography a public health crisis.[37] While the legal effects stemming from the GOP platform amendment and various resolutions are minimal, they increase awareness to what is becoming an ever more salient public health issue in the United States.[38] The public, being more informed of pornography's impact on society, can pressure legislators to take more direct legal action, such as Utah's H.B. 155.[39]

Thus, anti-pornography advocates seem to be gaining momentum on the public health front. The overarching question, however, is what affirmative actions private actors, as well as the state and federal governments, can take

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Pornography? 29 UTAH B.J. 38, 38 (2016); *see also* UTAH STATE LEGISLATURE, *supra* note 10 (stating that pornography "perpetuates a sexually toxic environment," causes "low self-esteem and body image disorders," shapes sexual templates, treats women as objects, and normalizes violence, among other harms).

32. Ahlstrom, *supra* note 31.

33. *See id.* ("[. . .] [S]upporters declared the resolution a symbolic victory. They found it has the potential to influence further actions and laws.").

34. Westcott, *supra* note 29.

35. Kopan, *supra* note 10.

36. Vernon Freeman Jr., *Virginia Lawmaker Proposes Bill to Declare Porn a "Public Health Hazard,"* CBS NEWS (Dec. 29, 2016), http://www.cbsnews.com/news/virginia-lawmaker-wants-porn-declared-a-public-health-hazard/.

37. Waltman, *supra* note 10.

38. *See* Ahlstrom, *supra* note 31, at 38.

39. *See, e.g.*, Westcott, *supra* note 29.

without straying outside the confines of current jurisprudence. Del. Robert G. Marshall, author of the proposed Virginia bill, compared the current stage of anti-pornography activism to that of smoking: "Before smoking was identified as a problem, at least the recognition that it led to certain pathologies was a starting point to put restrictions on it…. If you recognize it as a problem, then you're going to try to find ways to solve it within the framework of the statutes we can pass and the institutions we have."[40]

IV. ADVOCATING A HOLISTIC APPROACH TO COMBAT THE PORNOGRAPHY PUBLIC HEALTH CRISIS

While Marshall is correct to note that some change can stem from within the current statutory framework, as discussed above, the Supreme Court has held pornography consumption constitutional and has also rejected state regulatory control. Therefore, for meaningful substantive change to the status quo, a holistic, all-hands-on-deck approach is required. Specifically, this approach must encompass not only state and federal legal action, but also a revision of sex education and encouragement of private actors to take on a bigger role in raising the nation's youth with respect to pornography awareness.

A. Obscenity Laws

The first - and most obvious - approach to regulating certain explicit content is through the enforcement of obscenity laws, which already exist and serve to prohibit the production and distribution of obscene content that is not protected by the First Amendment.[41] Utah's obscenity laws are

40. Freeman Jr., *supra* note 36.

41. *See Pornography, Obscenity and the Law*, *supra* note 12 (discussing how federal and state laws make it illegal to make, sell, own and even look at some of these materials); *see also State Laws on Obscenity, Child Pornography and Harassment*, *supra* note 14 ("Generally, these statutes prohibit the sale, lending, renting, giving, publication, exhibition or other dissemination of materials, with general knowledge of their obscene character and content.").

particularly forceful – even defining obscenity as "pornographic material."[42] The distribution of pornographic material in Utah is also considered a third-degree felony.[43]

Despite its tough stance on obscenity, Utah is still required to apply the three-prong *Miller* test.[44] Therefore, vague and burdensome terms such as "contemporary community standards" and "prurient interest" must still be satisfied for a successful prosecution. For example, in 2013, out of 174,403 recorded crimes, only 233 were pornography/obscene material offenses (approximately 0.1%).[45] In comparison, California, which has a more relaxed view of obscenity, reported 123 obscenity offenses out of 835,370 total misdemeanors in 2015 (approximately 0.01%).[46] Thus, while Utah is prosecuting ten times the amount of obscenity cases as California, it remains a very low percentage of total offenses.

Another hindrance to obscenity law enforcement is the current status quo. Even though obscene materials are prohibited, they remain prevalent despite many people agreeing that certain content should be removed.[47] This inconsistency exists because obscenity laws have often been ignored by both federal and state prosecutors."[48] Lackadaisical enforcement is derived from society's general acceptance of explicit content in addition to an ignorance of the fact that obscene material is a violation of the law.[49]

Nonetheless, despite the obstacles associated with enforcing obscenity laws, they remain the most direct legal route that is already available for

42. Ahlstrom, *supra* note 31, at 40.
43. UTAH CODE ANN. § 76-10-1204(4)(a) (West 2016).
44. *See* UTAH CODE ANN. § 76-10-1203 (West 2016).
45. CRIME IN UTAH REPORT, UTAH DEP'T PUB. SAFETY 1, 87 (2013).
46. CRIME IN CALIFORNIA, CA DEP'T OF JUSTICE 1, 46 (2015).
47. *See* Ahlstrom, *supra* note 31, at 40 ("[D]espite the laws prohibiting obscenity, items and images that many people would deem obscene are prevalent today.").
48. *Id.* at 40.
49. *See id.* (stating that there is "widespread community acceptance of sexually explicit content" and that it is not reported because "[people] do not know that they can report it").

restraining obscene pornographic content.[50] Utah's resolution, along with actions taken by other states and the Republican Party, may bring heightened attention to the current lack of enforcement. In turn, prosecutors may be more inclined to pursue obscenity law cases.[51] The public, being more aware of the definition of obscenity as well as the duty to report it, may pressure prosecutors to take obscenity enforcement more seriously.[52] Lastly, these actions may serve as evidence that certain communities are opposed to obscenity under the "contemporary community standards" prong of the *Miller* test.[53] Consequently, what is currently a very burdensome standard of review may gain leniency, enabling states to more effectively legislate (and consequently prosecute) their obscenity laws in the pornography arena.

B. Broadcast Laws

Another medium through which anti-pornography activists can make an impact is via the Federal Communications Commission (FCC). The FCC is responsible for providing oversight to telephone, radio, and television industries in the United States and is charged with the duty to maintain "decency" standards designed to protect the public well-being.[54] The FCC has the power to revoke a station's license, impose financial sanctions, and issue warnings to entities broadcasting indecent or obscene content.[55] While the FCC's regulatory authority extends beyond the confines of public health, it could make a significant impact on the pornography front by tightening its control over adult late night television broadcasts and/or particularly explicit

50. *Id.* at 39.
51. *Id.* at 40.
52. *Id.*
53. *Id.*
54. *Federal Communications Commission (FCC)*, ALLGOV, http://www.allgov.com/departments/independent-agencies/federal-communications-commission-fcc?agencyid=7325 (last visited Feb. 19, 2017).
55. *See* Fed. Commc'ns Comm'n v. Pacifica Found., 438 U.S. 726, 737 (1978); *see also* Ahlstrom, *supra* note 31, at 40.

pay-per-view programs. The public can encourage FCC action by joining groups like the Parents Television Council, which serves to monitor television broadcasts and alert the FCC to programs it determines cross an unacceptable explicit threshold.[56]

However, similarly to obscenity laws, enforcing broadcast laws poses First Amendment challenges.[57] The FCC is also prohibited from censoring content before it airs pursuant to the doctrine of "prior restraint."[58] Notwithstanding these obstacles, the FCC's power to regulate merely "indecent" material provides anti-pornography advocates perhaps an easier burden to meet when compared to the *Miller* obscenity test. Growing opposition to the current state of pornography may put increased pressure on the FCC to regulate indecent content, providing anti-pornography activists with another legal weapon in their fight against the industry.

C. Sexual Education

Turning away from public legal enforcement, it is critical to examine possible solutions under the principle of subsidiarity. Subsidiarity holds that decisions are best made at the least centralized, local level because that is where "they will have their effect."[59] In other words, local communities are best equipped to handle problems within their respective areas because they are more knowledgeable of their issues than a centralized authority that dictates from a great distance away.[60]

In the context of pornography, improved sexual education at the

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56. *See* Ahlstrom, s*upra* note 31, at 40 ("Groups like the Parents Television Council monitor television shows and send out emails to participants encouraging them to file a complaint with show sponsors and the FCC when they see something they feel violates the obscenity, indecency, or profanity definitions.").

57. *Id.* (stating that FCC regulation "has been a continuous source of contention and litigation because it brushes up against the First Amendment").

58. *See* 47 U.S.C.A. § 326.

59. *Subsidiarity*, CAMBRIDGE DICTIONARY, http://dictionary.cambridge.org /us/dictionary/english/subsidiarity (last visited Mar. 19, 2017).

60. *See id.*

adolescent level is critical during a time when individuals are exposed to easily accessible explicit content at such a young age.[61] Particularly concerning are the possible effects of watching adult content prior to becoming sexually active: Will viewers be able to appreciate the sheer unrealism being presented? Are there detrimental self-esteem and body image implications when witnessing "pneumatic female stars" and "ever-ready, freakishly endowed males" perform?[62] Meg Kaplan, a psychologist at Columbia University who treats individuals convicted of sexual offenses, finds it "likely" that certain sexual preferences are developed during puberty.[63] Accordingly, exposure to the "wrong" material during this sensitive time period can have life-long consequences.[64]

In response, local communities should encourage their school districts to discuss pornography in the classroom. Even in the unlikely event of sweeping anti-pornography success nationwide, access to the most hardcore explicit content will remain relatively easy, at least for a time, due to the substantial volume of adult content present on the web.[65] By confronting pornography, teenagers are better equipped to decipher the differences between adult entertainment and the reality of sexual relationships."[66]

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61. *See Hardcore, Abundant and Free: What is Online Pornography Doing to Sexual Tastes – and Youngsters' Minds?*, THE ECONOMIST (Sept. 26, 2015), http://www.economist.com/news/international/21666113-hardcore-abundant-and-free-what-online-pornography-doing-sexual-tastesand ("Portable devices make it easy to view porn in the privacy of a bedroom – or in the workplace or playground. Tech-minded teenagers can easily bypass content filters with the help of a VPN.").

62. *Id.*

63. *Id.*

64. *See id.* ("[I]ll-timed exposure to unpleasant or bizarre material could cause a lifelong problem.").

65. *See* Julie Ruvolo, *How Much of the Internet is Actually for Porn*, FORBES (Sept. 7, 2011), https://www.forbes.com/sites/julieruvolo/2011/09/07/how-much-of-the-internet-is-actually-for-porn/#51e613a55d16 ("In 2010, out of the million most popular (most trafficked) websites in the world, 42,337 were sex-related sites. That's about 4% of sites.").

66. *See* Helen Russell, *Porn Belongs in the Classroom, says Danish Professor*, THE GUARDIAN (Mar. 15, 2015), https://www.theguardian.com/culture/2015/mar/16/pornography-belongs-classroom-professor-denmark (stating that classroom discussion of pornography helps teenagers become "conscientious and critical consumers" who can "tell the difference between pornography and the reality of sexual relationships").

On a global level, Denmark has made sexual education mandatory since 1970 – with pornography implemented into the curriculums of numerous Danish schools.[67] Christian Graugaard, a leading sexologist and professor at Aalborg University in Denmark, argues that because a great majority of adolescents have viewed pornographic content even before reaching puberty, it is a matter of strengthening "their ability to distinguish between the media's depictions of the body and sex and the everyday life of an average teenager."[68]

Those opposed to expanding sexual education to include pornography discussion may insist that its negatives outweigh any potential benefits. For example, the American College of Pediatricians states that because pornography is so damaging to young individuals, it "must never be used as a tool to teach children human sexuality."[69] Such a mentality, combined with the democratic barrier posed by local school board approval, may prove a formidable obstacle in expanding sexual education – especially in conservative districts which are more likely to view pornography as having no place in the classroom.

In sum, localities are best situated to effectuate immediate change on the anti-pornography front. While improving sexual education will not censor existing content, it will provide teenagers with open-minded, constructive dialogue concerning the difference between what they view on the internet and what a real sexual relationship entails.[70] In addition to alleviating concerns associated with teenage self-esteem, improved sexual education may also deter the acquisition of unhealthy sexual preferences, such as those

67. *Id.*
68. *Id.*
69. L. David Perry, *The Impact of Pornography on Children*, AM. C. PEDIATRICIANS (Oct. 2015), https://www.acpeds.org/the-college-speaks/position-statements/the-impact-of-pornography-on-children (last updated June, 2016).
70. *See* Russell, *supra* note 66 ("[. . .] [A]n open-minded, constructive dialogue is the best way to make sure that they [kids] are able to make meaningful decisions for themselves.").

that Kaplan treated during her time with convicted sexual offenders.

Sexual education should be extended into the private home as well. While subsidiarity is traditionally associated with varying levels of formal governance structures, parents are in a critical position to understand their children's personalities and to educate accordingly.[71] The American Academy of Pediatrics recommends that parents refrain from installing televisions in their children's bedrooms and co-view television and movies in order to offer perspective.[72] The American College of Pediatricians similarly encourages parents to place computers in public spaces and install internet filtering and monitoring software to mitigate exposure.[73] At the very least, these actions are immediately implementable and will facilitate constructive discussion between parent and child, hopefully curbing the potential negative consequences of viewing adult films and helping children discern the differences between the internet and reality.

V. CONCLUSION

The adult film industry continues to witness significant annual growth. Anti-pornography activism is also seeing expansion, as states such as Utah, South Dakota, and Virginia, as well as the Republican Party, have taken steps to declare it a public health crisis prevalent throughout America in recent years. While the evidence is conflicting, and in many cases speculative, concerning pornography's effect on the human psyche, it is undeniable that certain explicit content has little to offer besides the potential for significant negative consequences.

The Supreme Court, in an effort to protect First Amendment rights, has

71. *See* Perry, *supra* note 69 (recommending that pediatricians and other pediatric healthcare providers be equipped to discuss with parents the dangers that pornography poses to both children and the family).

72. James Hamblin, *Inside the Movement to Declare Pornography a "Health Crisis,"* THE ATLANTIC (Apr. 14, 2016), https://www.theatlantic.com/health/archive/2016/04/a-crisis-of-education/478206/.

73. Perry, *supra* note 69.

made it difficult to censor pornography. Thus, a holistic approach is needed to effectively combat the status quo. Anti-pornography advocates should continue lobbying their respective states to pass resolutions that serve as a symbolic rejection of the current law and its mild enforcement. These actions will increase the salience of anti-pornography efforts, pressuring prosecutors to treat pornography more seriously and possibly making the *Miller* test easier on plaintiffs. Additionally, localities should initiate reform in school sexual education, as well as in the home, for two primary reasons: first, these actions are easier to implement than convincing the Supreme Court to adopt a clearer obscenity test. Second, local communities are much more cognizant of their particular needs and, accordingly, are better suited to deliver appropriate solutions than a more centralized authority. Actions taken under this holistic approach, coupled with patience, provides anti-pornography advocates with the best opportunity for effectuating significant change in their area of endeavor.

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Supervised Injection Facilities: Fighting the Prescription Overdose Epidemic

Christine Bulgozdi[*]

I. INTRODUCTION

There is little debate that the United States is in the middle of a prescription drug overdose epidemic.[1] The overall usage and deaths from opioids, both prescription and recreational, dramatically increased over the last decade with more than 33,000 individuals dying from opioid overdoses in 2015 alone.[2] Lawmakers in many states attempted to address this epidemic through various regulations and programs.[3] Although programs have been implemented to aid individuals with addiction,[4] especially opioid and prescription drug addictions,[5] more can be done to assist these individuals more directly.[6]

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1. KRISTEN FINKLEA, LISA N. SACCO, & ERIN BAGALMAN, CONG. RESEARCH SERV., R42593, PRESCRIPTION DRUG MONITORING PROGRAMS 1 (2014) (commenting that the CDC describes prescription drug abuse as an epidemic in the United States); *Fifty State Survey of Prescription Drug Overdose Laws*, MEDICAL L. PERSP. SCALPEL WKLY. NEWS (Apr. 21, 2014), http://medicallawperspectives.com/Content_Weekly/Fifty-State-Survey-of-Prescription-Drug-Overdose-Laws.aspx ("More than 38,000 people died of drug overdoses in 2010False Three-quarters of prescription drug overdose deaths in 2010 (16,651) involved a prescription opioid pain reliever.. . .").

2. 2015 S*ymposium: on New Legal Strategies to Prevent Drug Overdoses*, 12 RUTGERS J. L. & PUB. POL'Y 588, 590 (2015) ("[D]rug overdose death rates have tripled since 1990."); *Injury Prevention & Control: Opioid Overdose*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/drugoverdose/ (last updated Feb. 9, 2017).

3. FINKLEA, SACCO & BAGALMAN, *supra* note 1, at 3 (describing Prescription Drug Monitoring Programs); CTRS. FOR DISEASE CONTROL & PREVENTION PUB. HEALTH LAW PROGRAM, MENU OF STATE LAWS RELATED TO PRESCRIPTION DRUG OVERDOSE EMERGENCIES 2–3 (2012) https://www.cdc.gov/phlp/docs/menu-pdoe.pdf (looking at state immunity and mitigation statutes) [hereinafter *MENU OF STATE LAWS*].

4. Illinois Controlled Substances Act, 720 ILL. COMP. STAT. ANN. 570/316 (LexisNexis 2015); *How to Find a State-Funded Rehab Center*, AM. ADDICTION CTR., http://americanaddictioncenters.org/rehab-guide/state-funded/ (last visited Apr. 30, 2017).

5. KAREN BLUMENSCHEIN ET AL., UNIV. OF KY. INST. FOR PHARM. OUTCOMES & POL'Y, REVIEW OF PRESCRIPTION DRUG MONITORING PROGRAMS IN THE UNITED STATES, 2–3 (2010), http://chfs.ky.gov/NR/rdonlyres/85989824-1030-4AA6-91E1-7F9E3EF68827/0/KASPEREvaluationPDMPStatusFinalReport6242010.pdf.

6. *See generally* Nora D. Volkow, *What is the Federal Government Doing to Combat the*

Intervention sites that provide safe injection spaces, such as supervised injection facilities, are not a novel concept.[7] However, the United States has primarily addressed the opioid epidemic and root causes of prescription drug overdoses through state-run Prescription Drug Monitoring Programs and state immunity and mitigation statutes.[8] Although the general American population would likely oppose new program proposals that allocate tax dollars to harm-reduction programs,[9] empirical research shows that supervised injection facilities operating in international countries yield positive results, such as a decrease in the number of deaths by overdose and an increase in requests for drug treatment.[10] Therefore, the concept of global supervised injection facilities should be maintained globally and implemented in the United States. When properly implemented, and with the help of current United States Prescription Drug Monitoring Programs, state or locally-funded supervised injection facilities geared toward opioid use "best practices" could track opioid and prescription drug users and allow them to have safe haven facilities. Ultimately, the overall goal of implementing supervised injection facilities in the United States is three-fold: decrease death rates from overdoses, encourage safe usage, and encourage voluntary cessation or treatment of drug addiction and usage.

This article will first review current prescription drug laws in the United States, specifically looking at immunity and mitigation laws and state Prescription Drug Monitoring Programs. Next, this article will discuss

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Opioid Abuse Epidemic?, NAT'L INST. ON DRUG ABUSE (May 1, 2015), https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/what-federal-government-doing-to-combat-opioid-abuse-epidemic (stating that prevention and treatment strategies are currently underutilized and increased usage of these options may help address growing concerns about the opioid epidemic).

7. *Supervised Injection Facilities: Fact Sheet*, DRUG POL'Y ALLIANCE 1, 1 (Feb. 2016), http://www.drugpolicy.org/sites/default/files/DPA%20Fact%20Sheet_Supervised%20Injection%20Facilities%20(Feb.%202016).pdf (acknowledging that safe injection facilities operate in countries such as Switzerland, Germany, Australia, Spain and Canada).

8. FINKLEA, SACCO & BAGALMAN, *supra* note 1, at 3–4; MENU OF STATE LAWS, *supra* note 3, at 2–4.

9. Katie Zezima, *Awash in overdoses, Seattle Creates Safe Sites for Addicts to Inject Illegal Drugs*, THE WASH. POST, (Jan. 27, 2017), https://www.washingtonpost.com/politics/awash-in-overdoses-seattle-creates-safe-sites-for-addicts-to-inject-illegal-drugs/2017/01/27/ddc58842-e415-11e6-ba11-63c4b4fb5a63_story.html?utm_term=.26a52e671d94 (stating that opponents of supervised injection facilities claim that it is a way to tolerate, instead of eliminate, heroin and controlled substance abuse).

10. Leo Beletsky et al., *The Law (and Politics) of Safe Injection Facilities in the United States*, 98 AM. J. OF PUB. HEALTH 231, 232 (2008); Kate Dolan et al., *Drug Consumption Facilities in Europe and the Establishment of Supervised Injecting Centres in Australia*, 19 DRUG & ALCOHOL REV. 337, 340-41 (2000); Evan Wood, et al., *Summary of Findings from the Evaluation of a Pilot Medically Supervised Safer Injection Facility*, 175 CANADIAN MED. ASS'N. J. 1399, 1400–03 (2006).

supervised injection facilities that have been implemented internationally, ending with a discussion of the current question of opening a supervised injection facility in the United States. Finally, it will analyze the proposal of combining efforts between state prescription drug monitoring programs and supervised injection facilities and how this combination can address the current opioid epidemic in the United States.

II. CURRENT PRESCRIPTION DRUG LAWS IN THE UNITED STATES

In the United States, states are responsible for implementing, regulating, and enforcing prescription drug laws.[11] Although state drug laws vary,[12] immunity and mitigation statutes and prescription drug monitoring programs help states target the opioid epidemic.[13]

A. Immunity and Mitigation Statutes

Many states implemented prescription drug immunity and mitigation statutes in response to the growing opioid epidemic.[14] These laws are intended to provide immunity and mitigation circumstances to individuals who dial 911 in emergency drug overdose situations.[15] Immunity statutes offer individuals immunity from prosecution when an individual seeks medical attention to help either himself or another during an overdose.[16] Currently, thirty-seven states, including the District of Columbia, have adopted some form of an immunity law.[17] Many states only offer immunity from prosecution for drug possession charges; however, some states offer additional immunity from other criminal charges.[18]

On the other hand, mitigation statutes provide that seeking help or assisting another in an emergency overdose situation can mitigate the severity

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11. *MENU OF STATE LAWS*, *supra* note 3, at 1.

12. *Prescription Drug State Database: 2015-2017 State Legislation on Prescription Drugs*, NAT'L CONF. OF STATE LEGIS. (Apr. 10, 2017), http://www.ncsl.org/research/health/prescription-drug-statenet-database.aspx.

13. BLUMENSCHEIN ET AL., *supra* note 5, at 2; *MENU OF STATE LAWS*, *supra* note 3, at 1.

14. *MENU OF STATE LAWS*, *supra* note 3, at 2–4.

15. *Id.* at 1.

16. *Id.* at 2.

17. *Id.* at 2–3; Corey Davis et al., *Legal Interventions to Reduce Overdose Mortality: Naloxone Access and Overdose Good Samaritan Laws*, NETWORK FOR PUB. HEALTH L., 1, 2 (June 2016).

18. Davis et al., *supra* note 17, at 2; *Good Samaritan Overdose Prevention Statutes*, NAT'L ALLIANCE FOR MODEL ST. DRUG LS. 1, 3–16 (2015) (showing that certain states with immunity statutes allow for immunity from other criminal charges other than simple possession including underage drinking, underage use of controlled substances, possession of counterfeit controlled substances, possession of paraphernalia and contribution to the delinquency of a minor); *MENU OF STATE LAWS*, *supra* note 3, at 2–3.

of criminal charges and sentencing.[19] Only twelve states and the District of Columbia have both immunity and mitigation statutes to help an individual during prosecution and sentencing.[20] Although immunity and mitigation laws provide benefits for individuals, many individuals still hesitate to seek assistance because of the potential criminal charges that may come as a result of seeking assistance.[21]

B. Prescription Drug Monitoring Programs

Prescription drug monitoring programs (PDMPs) are electronic, state-run databases that track federal controlled substance prescriptions within a state.[22] Each database monitors the prescribing and dispensing habits of patients and detects patients suspected of abuse, misuse, or diversion.[23] This information allows pharmacists and prescribers to review a patient's prescription drug history and identify high-risk patients who may need an alternative treatment or who may be "doctor shopping."[24] Law enforcement officials also have access to PDMPs.[25] The database information can assist law enforcement officials by collecting data for drug-related investigations to identify patients who may be seeking prescriptions drugs for illegal distribution, diversion, or other misuse.[26]

Currently, forty-nine states authorize PDMPs through state legislation.[27] For example, Illinois authorized a PDMP through the Illinois Controlled Substances Act[28] and California's Health and Safety Code authorized a PDMP through the CURES Act.[29] Yet, only forty of authorized PDMPs are

19. *MENU OF STATE LAWS*, *supra* note 3, at 3–4.

20. *Id.*; *Good Samaritan Overdose Prevention Statutes*, *supra* note 18, at 3–16.

21. *MENU OF STATE LAWS*, *supra* note 3, at 2.

22. BLUMENSCHEIN ET AL., *supra* note 5, at 2; *Prescription Drug Monitoring Programs (PDMPs)*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/drugoverdose/pdmp/index.html (last updated Mar. 23, 2016); *What States Need to Know about PDMPs*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/drugoverdose/pdmp/states.html (last updated Mar. 23, 2016).

23. BLUMENSCHEIN ET AL., *supra* note 5, at 2; *Prescription Drug Monitoring Programs (PDMPs)*, *supra* note 22.

24. BLUMENSCHEIN ET AL., *supra* note 5, at 2 (explaining that PDMPs can help detect patients who are faking illness and seeing multiple physicians to obtain prescription drugs for misuse); *Prescription Drug Monitoring Programs (PDMPs)*, *supra* note 22.

25. BLUMENSCHEIN ET AL., *supra* note 5, at 2; Richard M. Reisman et al., *Prescription Opioid Usage and Abuse Relationships: An Evaluation of State Prescription Drug Monitoring Program Efficacy*, 3 SUBSTANCE ABUSE: RES. & TREATMENT 41, 42 (2009).

26. BLUMENSCHEIN ET AL., *supra* note 5, at 2.

27. Hallam Gugelmann, Jeanmarie Perrone & Lewis Nelson, *Windmills and Pill Mills: Can PDMPs Tilt the Prescription Drug Epidemic*, 8 J. MED. TOXICOLOGY 378, 378 (2012).

28. Illinois Controlled Substances Act, 720 ILL. COMP. STAT. ANN. 570/316 (LexisNexis 2015).

29. CAL. HEALTH & SAFETY CODE § 11165 (West 2017).

operational.[30] Furthermore, not every state authorized a PDMP through legislation partly because each state is responsible for implementing its own program.[31] This meant that each state would also determine how that PDMP program will be individually operated.[32] To help standardize state PDMPs, the National Alliance for Model State Drug Laws ("NAMSDL") outlined a model program.[33] States are not required to follow the NAMSDL model and are still free to implement PDMPs as they see fit.[34] Nevertheless, state-funding shortages created issues in implementing these programs.[35] Although states may receive federal funding for PDMPs,[36] states are ultimately responsible for the entire process from conception to execution.[37]

Overall, evidence shows that PDMPs are rather effective in reducing diversion and improving prescribing practices, among other things.[38] State surveys of medical prescribers demonstrate that since states implemented PDMPs, prescribers have become more informed of their personal prescribing habits.[39] In turn, a large percentage of prescribers in multiple states opine that this method of prescribing controlled substances greatly reduces "doctor shopping" among patients.[40] Furthermore, studies illustrate

30. Gugelmann, Perrone & Nelson, *supra* note 27, at 378.

31. FINKLEA, SACCO & BAGALMAN, *supra* note 1, at ii ("Each state determines which agency houses the PDMP; which controlled substances must be reported; which type of dispensers are required to submit data (e.g., pharmacies); how often data are collected; who may access information in the PDMP database (e.g., prescribers, dispensers, or law enforcement); the circumstances under which the information may (or must) be accessed; and what enforcement mechanisms are in place for noncompliance."); BLUMENSCHEIN ET AL., *supra* note 5, at 2–4.

32. BLUMENSCHEIN ET AL., *supra* note 5, at 2.

33. *Id.*; Gugelmann, Perrone & Nelson, *supra* note 27, at 380.

34. BLUMENSCHEIN ET AL., *supra* note 5, at 2 (detailing that the NAMSDL model was created in an attempt to unify state PDMPs and gives recommended components for state programs).

35. *Id.* at 4 (explaining that funding issues suspended a PDMP program in Washington state).

36. *Id.* at 3 (describing the Harold Rogers Prescription Drug Monitoring Program and the National All Schedules Prescription Electronic Reporting Act, both of which provide funding for state PDMPs through grants); Gugelmann, Perrone & Nelson, *supra* note 27, at 380.

37. BLUMENSCHEIN ET AL., *supra* note 5, at 2–4 (stating that states authorize PDMPs through legislation and federal assistance is solely in funding which can be used for planning, implementation and enhancement of PDMPs).

38. Gugelmann, Perrone & Nelson, *supra* note 27, at 383; *see* FINKLEA, SACCO & BAGALMAN, *supra* note 1, at 9 (stating that evidence shows effectiveness for law enforcement and health care purposes); *see generally* PRESCRIPTION MONITORING PROGRAM CTR OF EXCELLENCE, BRANDEIS UNIV., BRIEFING ON PMP EFFECTIVENESS 2 (March 2012) ("[P]rescription monitoring programs are effective in reducing diversion of controlled substances, improving clinical decision-making, and assisting in other efforts to curb the prescription drug abuse epidemic.").

39. BRIEFING ON PMP EFFECTIVENESS, *supra* note 38, at 2–3.

40. *Id.*

that states with operational PDMPs have lower rates of hospital admissions for opioid or prescription drug problems.[41]

However, the effectiveness of PDMPs is still challenged due to the limitations on how research can be conducted.[42] A leading issue is defining "effectiveness" for a PDMP.[43] Because states individually organize PDMPs, it is difficult to create a single definition of effectiveness for PDMPs to be measured by.[44] Other issues in the study of PDMP effectiveness stem from organizational differences of the state programs, including the wide variety of controlled substances reported, varying baselines for substance abuse, and the reactive or proactive approach of the PDMPs themselves.[45]

III. OPIOID OVERDOSE PROGRAMS: SUPERVISED INJECTION FACILITIES

A. Global Supervised Injection Facilities

Supervised Injection Facilities (also commonly referred to as safe injection facilities) provide sanitary spaces where drug users can self-administer their drug of choice in a protected environment.[46] The users administer their drug of choice under medical supervision using clean instruments provided by the facility.[47] Trained medical personnel oversee patient rooms at all times, but cannot assist in the administration of the drugs.[48] Medical personnel are present only for intervention purposes if the user exhibits symptoms of overdose, in which case the medical personnel may intervene and attempt to resuscitate or provide medication, like Narcan, to reverse the effects.[49] Narcan (also known as Naloxone) is a medication used to reverse opioid overdoses and is neither addictive nor harmful if taken

41. *Id.*

42. FINKLEA, SACCO & BAGALMAN, *supra* note 1, at 10; Rebecca L. Haffajee, *Preventing Opioid Misuse with Prescription Drug Monitoring Programs: A Framework for Evaluating the Success of State Public Health Laws*, 67 Hastings L.J. 1621, 1673 (2016).

43. FINKLEA, SACCO & BAGALMAN, *supra* note 1, at 10.

44. *Id.* (stating that outcomes of PDMPs can be measured through a wide variety of issues including shipment and sales of controlled substances, opioid consumption, substance abuse treatment admissions, drug overdose mortality and others).

45. *Id.* at 10–11; *see generally* BLUMENSCHEIN ET AL, *supra* note 5, at 5–9 (detailing the differences between state PDMPs including: state variety in controlled substances reported from only schedule II to schedule II through V; state differences in program agency governance; states' decision to monitor non-controlled substances; states' decision to provide committee oversight; currency of database reporting; state variety in whether individuals may access databases; etc).

46. Craig Jones, *Fixing to Sue: Is There a Legal Duty to Establish Safe Injection Facilities in British Colombia?*, 35 U. BRIT. COLUM. L. REV. 393, 394 (2002).

47. *Id.*; Wood et al., *supra* note 10, at 1399.

48. Jones, *supra* note 46, at 399. Wood et al., *supra* note 10, at 1399.

49. *2015 Symposium: New Legal Strategies to Prevent Drug Overdoses*, supra note 2, at 593–94; Jones, *supra* note 46, at 399; Wood et al., *supra* note 10, at 1399.

by accident.[50] In the Vancouver supervised injection facility alone, Narcan is used frequently and prevented nearly 5,000 overdoses since the facility opened in 2003.[51] Although medical personnel cannot assist in drug administration, they can educate individuals on injection "best practices."[52] Most individuals lack knowledge of how to properly inject themselves with the least amount of risk of infection.[53] These facilities can teach users how to minimize risk through injection "best practices," thereby reducing the likelihood of skin infections in the wound and the transmission of HIV.[54] Medically trained personnel can also refer users to rehabilitation centers, treatment centers, or other outside counseling services.[55] Supervised injection facilities frequently keep addiction counselors onsite to assist individuals with these requests and help simplify the referral process.[56]

European supervised injection facilities have been in existence since the 1970s; currently, with approximately one hundred facilities in nine countries around the world, including Canada, Australia and many countries throughout Europe.[57] Supervised injection facilities in Europe and Australia have three health-related objectives: "to provide sanitary conditions and clean equipment for injection drug use, to provide supervision by of [sic] medically-trained personnel who can intervene immediately in the case of an overdose, and to provide a 'gateway' through which injection drug users can interface with the health care system."[58] A variety of studies illustrate that supervised injection facilities have four major benefits: "reduced public nuisance; improved access and uptake of health and other welfare services; reduced opioid related overdose risk; and reduced risk of blood-borne virus transmission."[59]

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50. Davis et al., *supra* note 17, at 1; Eveline L.A. van Dorp, Ashraf Yassen & Albert Dahan, *Naloxene Treatment in Opioid Addiction: The Risks and Benefits*, 6 EXPERT OPINION ON DRUG SAFETY 81, 84 (2007) (explaining that Naloxone is a safe drug to use and can quickly reverse the effect of opioids in some instances); Daniel P. Wermeling, *Review of Naloxone Safety for Opioid Overdose: Practical Considerations for New Technology and Expanded Public Access*, 6 THERAPEUTIC ADVANCES DRUG SAFETY 20, 22 (2015) ("[I]n the absence of narcotics, naloxone exhibits essentially no pharmacologic activity.").

51. David Gutman, *Safe Heroin Injection Sites Get OK from King County Health Board*, SEATTLE TIMES (Jan. 19, 2017, 11:16 PM), http://www.seattletimes.com/seattle-news/health/safe-injection-sites-get-ok-from-king-county-health-board/.

52. Wood et al., *supra* note 10, at 1401.

53. *Id.*

54. *Id.*

55. Jones, *supra* note 46, at 400; Wood et al., *supra* note 10, at 1402.

56. Wood et al., *supra* note 10, at 1402.

57. Beletsky et al., *supra* note 10, at 232; Jones, *supra* note 46, at 399; *Supervised Injection Facilities: Fact Sheet*, *supra* note 7, at 1.

58. Jones, *supra* note 46, at 399.

59. Beletsky et al., *supra* note 10, at 232 (addressing similar benefits of safe injection facilities); Dolan et al., *supra* note 10, at 340.

Generally, studies indicate that communities with supervised injection facilities experience favorable results.[60] Pilot supervised injection facilities in Sydney, Australia and Vancouver, Canada suggest positive results.[61] Both cities reported higher rates of safe injection practices, such as the more frequent use of sterile syringes and less needle sharing among users.[62] Additionally, studies revealed that these pilot facilities became an effective "gateway" for addiction treatment and users were more likely to request treatment than users who do not visit these facilities.[63] Moreover, other injection facilities in Germany and Switzerland also reported a positive change in the community.[64] These European facilities discovered a "general reduction in the visibility and public nuisance in the drug scene" as users found a safe place to privately use.[65] Overall, supervised injection facilities all convey similar positive results toward drug users and the surrounding communities and ultimately decrease overdose death rates.[66]

B. Local Supervised Injection Facilities

Multiple states in the United States have pushed for supervised injection facilities.[67] Last year, New York proposed a study focused on supervised injection facilities, Massachusetts proposed legislation for these facilities in January of this year, and certain California cities are becoming more amenable to the idea of supervised injection facilities.[68] Earlier this year, Washington became the first state in the United States to approve the opening of multiple supervised injection facilities.[69]

Seattle's King County Board of Health voted and unanimously endorsed two of these facilities.[70] The decision was in response to the increasing epidemic and the rise of overdose deaths in certain counties of the state.[71] Various officials commented that these supervised injection facilities save

60. Beletsky et al., *supra* note 10, at 232; Dolan et al., *supra* note 10, at 340-41; Wood et al., *supra* note 10, at 1400–03 (summarizing findings from a three-year pilot study in Vancouver, Canada).

61. Beletsky et al., *supra* note 10, at 232.

62. *Id.*

63. *Id.*

64. Dolan et al., *supra* note 10, at 340.

65. *Id.*

66. *Id.* at 343–44; Beletsky et al., *supra* note 10, at 232.

67. Zezima, *supra* note 9.

68. *Id.*; S. Res. 1775, 190th Leg., (Mass. 2017); Francie Diep, *Seattle's Mayor Agrees to Open Two Supervised Injection Sites*, PAC. STANDARD (Jan. 30, 2017), https://psmag.com/seattles-mayor-agrees-to-open-two-supervised-injection-sites-1717197b64ca#.fbqookzdb.

69. Zezima, *supra* note 9.

70. *Id.*

71. *Id.*

lives and that implementing these facilities will be crucial in reducing the overdose death rate.[72] Seattle and King County's health officers ensured that the purpose of these supervised injection facilities is not to provide a place for users to "have a good time," but to provide a place for treatment and medical care in case of an overdose.[73]

Although several states endorsed supervised injection facilities, the federal Controlled Substances Act currently prevents these facilities from opening in the United States.[74] A main obstacle imposed by the federal government is that possession of heroin and non-prescription controlled substances is illegal; it is also illegal to provide a site specifically for drug use.[75] Even the Vancouver supervised injection facility is not legally authorized and operates through an exception by its Supreme Court.[76] However, despite the illegality of these facilities, local law enforcement of cities that approved supervised injection facilities agreed not to arrest individuals at these facilities.[77] For example, in Seattle, the sheriff warned that although local police departments will not arrest individuals coming and going from these facilities, federal law enforcement "could camp out in front of the site and arrest anyone in possession" of drugs.[78]

In addition to federal law obstacles to supervised injection facilities in the United States, neighborhood counties and state senators expressed doubt about introducing these facilities into their respective communities.[79] For example, a Seattle state senator introduced a bill to counter these facilities by removing local authority to approve them.[80] Furthermore, although a California senator is now amenable to the idea of supervised injection facilities, the senator vigorously opposed the facilities previously as enabling addiction and promoting individual self-destruction.[81] Regardless of current

72. *See id.* (sharing quotes from Seattle's mayor and the CMO of Boston Health Care for the Homeless Program who both support the implementation of supervised injection facilities).

73. *Id.*

74. *Id.*

75. *Id.*; Beletsky et al., *supra* note 10, at 231, 234.

76. Diep, *supra* note 68.

77. *Id.*

78. Beletsky et al., *supra* note 10, at 231–33; Zezima, *supra* note 9.

79. Zezima, *supra* note 9; Emily Green, *Lee Now Open to Safe Injection Sites, Yet Not Fully Convinced*, SF GATE (Jan. 13, 2017, 7:37 PM), http://www.sfgate.com/politics/article/Lee-now-open-to-safe-injection-sites-yet-not-10857060.php.

80. Zezima, *supra* note 9; S.B. 5223, 2017 Leg., 65th Sess. (Wash. 2017); Joseph O'Sullivan, *State Senator Wants to Ban Safe-Injection Sites for Drug Users*, SEATTLE TIMES (Jan. 17, 2017, 6:57 PM), http://www.seattletimes.com/seattle-news/politics/gop-state-lawmaker-wants-to-ban-safe-injection-sites-for-drug-users/.

81. Green, *supra* note 79.

opposition, more people may become receptive to the idea of supervised injection facilities with evidence of effectiveness and its international success.[82]

IV. COMBINING THE EFFORTS: PRESCRIPTION DRUG MONITORING PROGRAMS AND SUPERVISED INJECTION FACILITIES

By combining the efforts of the PDMPs and supervised injection facilities, the United States can assist opioid abusers and decrease the amount of overdose deaths. Under the supervision of a state PDMP, supervised injection facilities can carry out its intentions of creating a safe space for individuals to use their drug of choice, as well as offer treatment options.

Supervised injection facilities have the potential to add information to the PDMP databases, which could result in earlier recognition of abuse potential. Medical personnel in supervised injection facilities can use the state PDMP database, which is connected to the individual supervised injection facility's database, to monitor patient drug use habits. The supervised injection facilities' individual database, similar to a traditional medical records system, would maintain detailed records of every patient's visit to the supervised injection facility.[83] The records may include names of the individuals using the facilities, drug of choice, the number of visits, how drugs are obtained, preferred method of usage, and other pertinent information.[84] Like emergency room reports, the detailed records could then be seen by prescribers and other physicians to alert them of a patient's drug habits and their overall medical and health condition.[85] Record transparency like this can provide benefits to the prescribers and the patient through earlier detection of potential abuse and additional opportunities for treatment.[86]

Including supervised injection facility access to PDMP databases, prescribers could be alerted to abuse earlier than by simply analyzing the database for "doctor shopping." The supervised injection facility personnel can add pertinent information to the PDMP database which may signal that a

82. *Id.* (detailing a senator's change of mind regarding supervised injection facilities after looking at medical evidence of effectiveness and its ability to potentially save lives).

83. *Electronic Health Records*, CTR. FOR MEDICARE & MEDICIAD SERV., https://www.cms.gov/Medicare/E-health/EHealthRecords/index.html (last updated Mar. 26, 2012); Peter G. Goldschmidt, *HIT and MIS: Implications of Health Information Technology and Medical Information Systems*, 48 COMM. ACM 69, 71 (2005) (stating that electronic health records substitute a patient's chart that maintains a person's medical information).

84. *Electronic Health Records*, *supra* note 83.

85. *Patient Medical Records in an Emergency Department*, AM. C. OF EMERGENCY PHYSICIANS, https://www.acep.org/Clinical—-Practice-Management/Patient-Medical-Records-in-the-Emergency-Department/ (last visited Apr. 30, 2017).

86. *Electronic Health Records*, *supra* note 83 (explaining that transparency of medical records systems promotes performance and improves the quality of care).

patient possesses an excess of a controlled substance allowed for a single monthly prescription. This type of signal can alert a patient's physician and other medical treatment providers that the individual might be "doctor shopping" for excess drugs and potentially requires intervention.[87] The overall goal of both the supervised injection facilities and PDMPs to identify individuals with a potential for abuse and to provide treatment options would be achieved.[88]

In addition to earlier recognition of "doctor shopping," the combination of PDMP and supervised injection facility databases can assist in physician prescribing.[89] By adding a patient's controlled substances use to his or her health record, prescribers now have more information to make informed decisions and can reduce the potential of adverse drug interactions.[90] This additional information can benefit prescribers with their medication choices and benefit patients by reducing the likelihood of potentially fatal drug interactions.[91]

One possible downside to a combined system is that law enforcement, which has access to PDMP databases for drug investigations, may now have access to unnecessary confidential information.[92] This might deter patients from visiting supervised injection facilities and using their services. However, law enforcement investigations usually only target individuals suspected of distribution, diversion, or other misuse of controlled substances.[93] Therefore, it is likely that the combination of PDMPs and supervised injection facilities will not discourage individuals from using the facilities for safe personal use.

Another potential issue of combining database systems involves the

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87. *Prescription Drug Monitoring Programs: Tools for Education, Epidemiological Surveillance, Prevention, and Early Intervention*, ASSOC. OF STATE & TERRITORIAL HEALTH OFFICIALS 1, 4 (2013) http://www.astho.org/Rx/Brandeis-PDMP-Report/ ("A number of PDMPs proactively send reports or electronic alerts to prescribers and dispensers concerning patients who may be at risk of prescription drug misuse or abuse.") [hereinafter *Tools for Education]*.

88. *Id.* at 1; Beletsky et al., *supra* note 10, at 231.

89. *Tools for Education*, *supra* note 87, at 4.

90. *Id.* (stating that PDMPs improve prescriber decisions, thus improving patient care); *Clues to Opioid Abuse from State Prescription Drug Monitoring Programs*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/media/releases/2015/p1015-opioid-abuse.html (last updated Oct. 15, 2015) (suggesting that prescribers do not always look at potential adverse reactions that may result) [hereinafter *Clues to Opioid Abuse]*.

91. *Tools for Education*, *supra* note 87, at 3–4; *Clues to Opioid Abuse*, *supra* note 90.

92. David B. Brushwood, *Unauthorized Police Access to PDMP Data*, AM. PHARMACISTS ASSOC. (July 1, 2013), http://www.pharmacist.com/unauthorized-police-access-pdmp-data (discussing a case where a police officer inappropriately accessed a PDMP database for personal information).

93. *Id.* (stating that law enforcement officials usually need to show that there is a reasonable belief of illegal use of controlled substances).

Health Insurance Portability and Accountability Act ("HIPAA").[94] Although patient information is shared through these databases, HIPAA provides exceptions which would apply to PDMPs.[95] The trained medical personnel involved in supervised injection facilities, like any other medical personnel in a medical office or hospital setting, would be trained in HIPAA compliance and other patient safety features.[96] Further, states limit access to the confidential information in PDMP databases to certain groups and entities; some states even allow individuals to access their own information.[97] Supervised injection facilities will also have access to the database, but similarly, only to input and look up medical information of patients currently in the facility. Therefore, the databases are not open to the public and patient information is only shared among individuals who must remain HIPAA compliant.[98]

In addition to these proposals, immunity and mitigation statutes should be more widely implemented and allow for more thorough protections. Both versions of the statutes can be applied nationwide to offer protections to those who seek help in an overdose emergency for himself or for another.[99] Moreover, these statutes can be strengthened by providing a definite shield against prosecution from drug possession charges to minimize a person's fear of prosecution. Specifically, these immunity protections can ensure a shield for individuals from minor (small amount) possession charges. Furthermore, mitigation features for other crimes should also be implemented.[100] Although not every crime should be excused, other minor crimes that may deter a person from seeking medical assistance can be mitigated. Such crimes may include underage consumption of alcohol or controlled substances, possession of counterfeit controlled substances or paraphernalia and contribution to the delinquency of a minor. By providing individuals with guaranteed immunity and mitigation from prosecution, they are more likely

94. HIPAA PRIVACY RULE AND PRESCRIPTION DRUG MONITORING PROGRAMS, NAT'L ALLIANCE FOR MODEL STATE DRUG LAWS 1, 1 (2010), http://www.namsdl.org/library/BB52D3BB-1372-636C-DD90AC3AAB8D724F/ (discussing generally the potential impact of HIPAA on PDMPs; summarizing that HIPAA "addresses the use and disclosure of protected health information (PHI) by those subject to the privacy rule. . .").

95. *Id.* at 1–3 (describing the ways disclosure can be bypassed in HIPAA and how they can apply to PDMPs).

96. *Id.* at 4 (describing certain personnel allowed access to PDMPs [which are similar to supervised injection facility personnel]).

97. *Id.* at 3–4; BLUMENSCHEIN ET AL., *supra* note 5, at 13-20.

98. HIPAA PRIVACY RULE AND PRESCRIPTION DRUG MONITORING PROGRAMS, *supra* note 94, at 3–4.

99. *MENU OF STATE LAWS*, *supra* note 3, at 2–4 (discussing immunity and mitigation statutes).

100. *Id.* at 3–4 (describing certain crimes that are currently mitigated in some state statutes).

to seek assistance during an overdose emergency instead of failing to seek assistance because of a fear of being arrested.[101]

V. CONCLUSION

Despite criticisms, supervised injection facilities have been implemented with measureable benefits and successes throughout the world.[102] Countries have demonstrated a decrease in the overdose death rate,[103] have educated individuals on injection "best practices,"[104] and have provided more users with treatment options and referrals[105] through sanitary and safe facilities to administer opioids and other drugs.[106] The supervision afforded by PDMPs ensures that the facility operates efficiently and contributes information to PDMP databases, which ultimately helps users.

The United States can use examples of supervised injection facilities throughout the world as a model to implement its own facilities. The benefits of supervised injection facilities have been demonstrated and with the increasingly expanding opioid epidemic, the United States could benefit from offering these types of facilities to its citizens. Supervised injection facilities, combined with prescription drug monitoring programs and immunity and mitigation statutes, can be implemented within the United States to help reduce the growing overdose epidemic through decreasing the death rate, increasing safe usage education, and promoting treatment opportunities.

101. Davis, *supra* note 17, at 2.
102. Dolan et al., *supra* note 10, at 338–340.
103. *Id.* at 341.
104. Wood et al., *supra* note 10, at 1401.
105. *Id.* at 1402.
106. *Id.*