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Duty to Protect: Enhancing the Federal Framework to Prevent Childhood Lead Poisoning and Exposure to Environmental Harm

Emily A. Benfer, Emily Coffey, Allyson E. Gold, Mona Hanna-Attisha, Bruce Lanphear, Helen Y. Li, Ruth Ann Norton, David Rosner, Kate Walz*

ABSTRACT

Scientific evidence indisputably demonstrates that lead poisoning causes permanent neurological damage and numerous co-morbidities for children and adults. Exposure to lead hazards irreversibly harms individuals and, left unchecked, can devastate communities into the future. In recognition of these threats, the President’s Task Force on Environmental Health Risks and Safety Risks to Children (Task Force) was established by Executive Order in 1997. The original Task Force created the first coordinated federal response to eliminate childhood lead poisoning in the United States and set an ambitious ten-year timeline to achieve its goals of prevention, treatment, research, and progress management. However, the most recent Task Force retreated from these bold goals. Rather than eliminating lead poisoning, in 2018 the Task Force sought merely to reduce it. This Article provides a comprehensive overview of the dangers of lead exposure, details the federal government’s evolving response to lead poisoning, and, for the first time, disseminates previously unpublished comments on “Drafting a New Federal Strategy to Reduce Childhood Lead

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Exposures and Impacts,” submitted to the Task Force in 2017, ahead of its most recent report. By providing these comments publicly, this Article creates a record of critical recommendations to the Task Force, provides best practices for the federal government's response to lead poisoning, and encourages federal policymakers to take the necessary steps to meet the original goal of eradicating lead hazards and protecting children from lead poisoning.

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INTRODUCTION

The devastating effects of lead poisoning cannot be overstated. Lead poisoning poses the greatest risk to children, whose developing bodies are especially susceptible to the harmful neurotoxin, and undermines both the ability to perform well in school and lifetime trajectory. At the lowest levels, lead may cause a decrease in IQ, while higher levels may result in a variety of negative health outcomes, such as hypertension, coma, and death.¹ Even after removing the source of exposure, the damage to the body and brain cannot be repaired.² Given the severity of its effects, the need to eradicate lead poisoning is urgent.

In recognition of the importance of mitigating threats to children's health, the Presidents' Task Force on Environmental Health Risks and Safety Risks to Children (Task Force) was formed by executive order in 1997.³ In 2000, the Task Force released the first coordinated federal program to eliminate childhood lead poisoning in the United States, setting an ambitious 10 year timeline to achieve its goals of prevention, treatment, research, and progress measurement.⁴ Building on the work of the first Task Force, the 2016 Task Force expanded the focus beyond lead paint to include drinking water, soil, consumer products, and other lead sources.⁵ Notably, the 2016 Task Force expressly recognized the disproportionate effect of lead poisoning on African-American and low-income children.⁶

In contrast, the most recent Task Force delayed the development of a plan and abruptly shifted its focus. Whereas the 2000 and 2016 reports aimed to *eliminate* lead poisoning, the 2018 Federal Action Plan to Reduce Childhood Lead Exposure and Associated Health Impacts merely seeks to *reduce* lead exposure.⁷ Moreover, the 2018 Plan focuses on already well-established science related to lead

1. See generally Talia Sanders et al., *Neurotoxic Effects and Biomarkers of Lead Exposure: A Review*, 24 REV. ENVIRON HEALTH 15, 16 (2009).

2. David Rosner & Gerald Markowitz, *Building the World That Kills Us: The Politics of Lead, Science, and Polluted Homes, 1970–2000*, 42 J. URB. HIST. 340 (2016).

3. Exec. Order No. 1,304,552, Fed. Reg. 19885 (Apr. 21, 1997).

4. Task Force on Environmental Health Risks and Safety Risks to Children, *Eliminating Childhood Lead Poisoning: A Federal Strategy Targeting Lead Paint Hazards* (2000), <https://www.cdc.gov/nceh/lead/about/fedstrategy2000.pdf>.

5. President's Task Force on Environmental Health Risks and Safety Risks to Children, *Key Federal Programs to Reduce Childhood Lead Exposures and Eliminate Associated Health Impacts* (Nov. 2016), https://ptfceh.niehs.nih.gov/features/assets/files/key_federal_programs_to_reduce_childhood_lead_exposures_and_eliminate_associated_health_impactspresidents_508.pdf.

6. *Id.* at 4.

7. President's Task Force on Environmental Health Risks and Safety Risks to Children, *Federal Action Plan to Reduce Childhood Lead Exposures and Associated Health Impacts* (December 2018), https://www.epa.gov/sites/production/files/2018-12/documents/fedactionplan_lead_final.pdf.

contamination.⁸ As a result, the Task Force ignored comments from advocates, scientists, and public health officials on critical policies to prevent irreparable harm to children from exposure to lead hazards.

This Article examines the role of the Task Force, and participating federal agencies, in eradicating lead poisoning and proceeds in three parts. Part I provides an overview of the dangers of lead poisoning, including the negative health consequences of lead exposure and how rates of exposure have changed over time. Part II details the federal government's evolving response to lead poisoning with specific focus on the role of the Task Force. Finally, Part III provides previously unpublished recommendations submitted in 2017 in response to the Task Force's request for comments on "Drafting a New Federal Strategy to Reduce Childhood Lead Exposures and Impacts." In doing so, Part III creates the only publicly accessible record of the recommendations, thereby providing a critical resource to other advocates and policymakers engaged in the fight to eradicate lead poisoning. For a detailed examination of best practices to eliminate lead poisoning on the local, state, and federal level, please see the companion article.⁹

I. RISKS OF LEAD POISONING

Lead exposure is an ongoing public health crisis in the United States. While blood lead levels have decreased since 1971,¹⁰ the toxic substance continues to pose a serious threat to health and well-being. The most common sources of lead exposure are lead-based paint and lead-dust in the home.¹¹ However, individuals may be exposed to lead by a variety of sources including, but not limited to, air, soil, water, food, gasoline, folk remedies, spices, toys, and cosmetics.¹²

There is no safe level of lead exposure and its effects are far reaching. Exposure can result in hypertension, cardiovascular dysfunction, and renal disease. Adults exposed to lead may experience "decreased fertility, cataracts, nerve

8. *Id.*

9. Emily A. Benfer, Emily Coffeey, Allyson E. Gold, Bruce Lanphear, Helen Y. Li, Ruth Ann Norton, David Rosner, Kate Walz, *Health Justice Strategies to Eradicate Lead Poisoning: An Urgent Call to Action to Safeguard Future Generations*, 19 YALE J. HEALTH L. & POL'Y (forthcoming 2019).

10. Timothy Dignam et al., *Control of Lead Sources in the United States, 1970 – 2017*, 25 J. PUB. HEALTH MANAGEMENT & PRACTICE S13 (2019), https://journals.lww.com/jphmp/Fulltext/2019/01001/Control_of_Lead_Sources_in_the_United_States,4.aspx.

11. Adrienne S. Ettinger, Perri Z. Ruckart & Timothy Dignam, *Lead Poisoning Prevention: The Unfinished Agenda*, 25 J. PUB. HEALTH MANAGEMENT & PRACTICE S1 (2019), https://journals.lww.com/jphmp/Fulltext/2019/01001/Lead_Poisoning_Prevention__The_Unfinished_Agenda.1.aspx.

12. *Id.*; see generally Dignam et al., *supra* note 10.

disorders, muscle and joint pain, and memory or concentration problems.”¹³ High levels of exposure may result in lack of muscular coordination, convulsions, coma, and even death. Lead’s effects are even more severe for children, whose developing brains make them particularly susceptible to the dangerous neurotoxin. In children, lead exposure causes “intellectual and behavioral deficits...including hyperactivity; deficits in fine motor function, hand-eye coordination, and reaction time; and lowered performance on intelligence tests.”¹⁴ Compounding this, the effect of lead on the body and brain are irreparable.¹⁵ Even if lead is successfully removed from the body, the damage cannot be undone.¹⁶

The definition of lead poisoning has evolved with advances in science and medicine. Originally, lead poisoning was defined as a blood lead level of 60 micrograms per deciliter ($\mu\text{g}/\text{dL}$).¹⁷ Reflecting this, U.S. blood lead levels were nearly universally elevated in the 1970s. At that time, nearly 80% of individuals under the age of seventy-five had blood lead levels of 10 $\mu\text{g}/\text{dL}$ or higher.¹⁸ Of children aged five and under, nearly 90% had blood lead levels of 10 $\mu\text{g}/\text{dL}$ or higher.¹⁹ In 1991, the Centers for Disease Control and Prevention (CDC) established a blood lead level of 10 $\mu\text{g}/\text{dL}$ as the level of concern. Since 2012, the CDC recommends health intervention when a child has a blood lead level of 5 $\mu\text{g}/\text{dL}$ or higher.²⁰ As a result of increased federal regulations,²¹ which were documented in the 2016 Task Force Report [Figure 1], the average blood lead level of the US population under the age of seventy-five decreased from 12.8 $\mu\text{g}/\text{dL}$ in 1976 – 1980 to 0.82 in 2015 – 2016.²²

13. Talia Sanders et al., *supra* note 1.

14. *Id.* at 16.

15. David Rosner & Gerald Markowitz, *supra* note 2.

16. *Id.*

17. Emily A. Benfer, *Contaminated Childhood: The Chronic Lead Poisoning of Low-Income Children and Communities of Color in Federally Assisted Housing*, 41 HARV. ENVTL. L. REV. 493, 499 (2017).

18. Dignam, *supra* note 10, at S13 (“In the late 1970s, the first nationally representative, population-based survey of blood lead levels in the United States was conducted.”).

19. *Id.*

20. CTRS. FOR DISEASE CONTROL & PREVENTION, CDC RESPONSE TO ADVISORY COMMITTEE ON CHILDHOOD LEAD POISONING PREVENTION RECOMMENDATIONS, 6-7 (2012), <https://perma.cc/7SHP-E9Y2>.

21. For a detailed history on federal regulation of lead-based substances, see Benfer, *supra* note 17.

22. *Id.*

times as likely, and Latino children *two times* as likely, to have elevated blood lead levels as compared to Caucasian children.²⁶

The costs of lead poisoning for a single cohort of children in the United States with blood levels above 5 µg/dL can be as high as \$10.9 billion, with tenant-based federally assisted housing accounting for \$1.2 billion.²⁷ These costs include \$8.7 million in immediate medical intervention,²⁸ \$58 million in lead-related ADHD treatment,²⁹ \$37 million in parental work loss due to time taken off to care for lead-poisoned children,³⁰ \$18.3 million in special education costs, and up to \$10.8 billion in loss of potential earnings.³¹ A recent report funded by the Robert Wood Johnson Foundation documented the costs of blood lead levels above 2 µg/dL or higher. The researchers determined that for a single cohort born in 2019, estimated to include 341,602 children, the total lifetime economic burden is 72.6 billion in costs, including reduced lifetime productivity; increased health care, education, and social assistance spending; and premature mortality.³² According to the Pew Charitable Trusts Health Impact Project report, “eradicating lead paint hazards from older homes of children from low-income families would provide \$3.5 billion in future benefits, or a return of approximately \$1.39 per dollar invested, and protect more than 311,000 children.”³³ Removing lead service lines from one

26. Robert L. Jones et al., *Trends in Blood Lead Levels and Blood Lead testing Among US Children Aged 1 to 5 Years, 1988–2004*, 123 PEDIATRICS e376 at e381 (2009) (emphasis added).

27. HEALTH JUSTICE ADVOCACY CLINIC, COLUMBIA LAW SCHOOL, SUMMARY OF COSTS OF LEAD POISONING FOR U.S. CHILDREN UNDER 6 YEARS OLD (2019). Numbers in this summary are based off the calculations used in TRACY SWINBURN, ECONOMIC IMPACTS OF LEAD EXPOSURE AND REMEDIATION IN MICHIGAN (2014).

28. According to CDC recommendations and Kemper et al. (1998), the cost (from Gould 2009) for treatment of children with BLL between 10–19 would cost \$94.20 and the cost for children with BLL between 20–44 would cost \$1,313.26. Costs are inflated to reflect 2019 prices. Alex R. Kemper et al., *Cost Effectiveness Analysis of Lead Poisoning Screening Strategies Following the 1997 Guidelines of the Center for Disease Control and Prevention*, 152 ARCHIVES PEDIATRIC ADOLESCENT MED. 1202, 1202–08 (1998); see also Elise Gould, *Childhood Lead Poisoning: Conservative Estimates of the Social and Economic Benefits of Lead Hazard Control*, 117 ENVTL. HEALTH PERSP. 1162–67 (2009).

29. According to the CDC (2016), 9.4% of children aged 3–17 in the US have been diagnosed with ADHD. U.S. Ctrs. for Disease Control & Prevention, Data and Statistics about ADHD, <https://www.cdc.gov/ncbddd/adhd/data.html>. Gould estimates 21.1% of ADHD cases in children aged 4–15 are associated with elevated BLLs and the cost of medication and counseling for 1 year per child to be \$724.28 (inflated to reflect 2019 cost). See Gould, *supra* note 29.

30. According to Gould’s estimates, parents will lose \$152.55 (inflated to 2019 cost) per year for every child that has medical treatment due to lead poisoning. This cost was applied to children who received immediate medical attention and ADHD medication and counseling. See Gould, *supra* note 29.

31. *Id.*

32. These figures include the calculations for every state. Altarum, VALUE of Lead Prevention Calculator at <http://www.valueofleadprevention.org>.

33. PEW CHARITABLE TRUSTS, 10 POLICIES TO PREVENT AND RESPOND TO CHILDHOOD LEAD EXPOSURE: AN ASSESSMENT OF THE RISKS COMMUNITIES FACE AND KEY FEDERAL, STATE, AND LOCAL

cohort of children would yield \$2.7 billion in future benefits, or \$1.33 per dollar invested.³⁴ In addition, targeted evidence-based academic and behavioral interventions could increase lifetime family incomes, likelihood of graduating from high school and attending college and decrease teen parenthood and criminal conviction.³⁵ In light of this, the federal government must continue to enact policies that prevent exposure to lead and eliminate lead poisoning.

II. THE PRESIDENTIAL TASK FORCE AND THE FEDERAL GOVERNMENT'S RESPONSIBILITY TO ELIMINATE LEAD POISONING

The federal government has a duty to protect children from environmental health risks and numerous federal agencies have critical roles in the elimination of lead poisoning in the United States. Yet, the current federal legal framework does not adequately protect all children from exposure to lead hazards. The goals of the Task Force to children fail to include primary prevention of lead poisoning, despite the urging of stakeholders regarding the known risks and costs of continuing to pursue predominantly reactive public health policies. This section provides an overview of the current federal legal and regulatory scheme pertaining to lead poisoning and includes model federal approaches spanning numerous agencies and departments.

In analyzing model federal approaches, this section incorporates previously unpublished comments on “Drafting a New Federal Strategy to Reduce Childhood Lead Exposures and Impacts”³⁶ submitted to the Task Force in 2017, which outline the role of the Executive Branch in lead poisoning prevention. Prior to this Article, the comments were not publicly available. The authors’ goal in including substantive portions of the comments is to create a public record of critical recommendations to the Task Force and thereby encourage federal policymakers to take the necessary steps to eradicate exposure to lead hazards at the federal level.

The federal government plays a critical role in eliminating lead poisoning and numerous federal departments and agencies must be responsible for setting lead poisoning prevention standards, implementing lead poisoning prevention laws and administering lead poisoning prevention programs, among other activities.

Over twenty years ago, on April 21, 1997, President William J. Clinton signed Executive Order 13045, creating a federal Task Force. The Task Force is

SOLUTIONS 2 (2017).

34. Id.

35. Id.

36. *Drafting a New Federal Strategy to Reduce Childhood Lead Exposures and Impacts: Request for Information*, <https://www.federalregister.gov/documents/2017/10/24/2017-23039/drafting-a-new-federal-strategy-to-reduce-childhood-lead-exposures-and-impacts-request-for>.

composed of representatives from over eighteen federal agencies³⁷ and offices and is charged with recommending to the President strategies for children’s environmental health and safety that include a) statements of principles, general policy and targeted annual priorities; b) coordinated research agenda for the Federal Government including steps to implement review of research databases; c) recommendations for appropriate partnerships; d) proposals to enhance public outreach and communication to assist families in evaluating risks to children; e) identification of high-priority initiatives that the federal government has undertaken or will undertake in advancing protection of children’s health and safety; and f) a statement regarding the desirability of new legislation to fulfill or promote the order.³⁸

Among the Task Force’s early recommendations was the elimination of childhood lead poisoning, with the primary goal of addressing lead-based paint hazards in housing, especially low-income housing. In 2000, the Clinton administration Task Force released a report, “Eliminating Childhood Lead Poisoning: A Federal Strategy Targeting Lead Hazards,” that represented the first coordinated federal program to eliminate childhood lead poisoning in the United States and set a ten year timeline for protecting children from lead poisoning. The core strategies included: 1) act before children are poisoned, 2) identify and care for lead-poised children through early identification and intervention, 3) conduct research to improve prevention strategies, and 4) measure progress through monitoring and surveillance programs.³⁹ In 2016, the Obama Administration Task Force renewed its commitment to addressing lead exposure in children and extended its focus beyond lead paint to include, among others, drinking water, soil, and consumer products.⁴⁰ According to the 2016 Task Force, “addressing these exposures is a matter of environmental justice.”⁴¹ The Task Force recognized that

37. These agencies include Assistant to the President for Economic Policy, Assistant to the President on Domestic Policy, Consumer Product Safety Commission, Council of Economic Advisers, Council on Environmental Quality, Department of Agriculture, Department of Commerce, Department of Education, Department of Energy, Department of Health and Human Services, Department of Homeland Security, Department of Housing and Urban Development, Department of Justice, Department of Labor, Department of Transportation, Environmental Protection Agency, Office of Management and Budget, Office of Science and Technology Policy, <https://ptfceph.niehs.nih.gov/about/index.htm>

38. Exec. Order No. 1304552 Fed. Reg. 19885 (Apr. 21, 1997).

39. President’s Task Force on Environmental Health Risks and Safety Risks to Children, *Eliminating Childhood Lead Poisoning: A Federal Strategy Targeting Lead Paint Hazards* (2000), <https://www.cdc.gov/nceh/lead/about/fedstrategy2000.pdf>.

40. President’s Task Force on Environmental Health Risks and Safety Risks to Children, *Key Federal Programs to Reduce Childhood Lead Exposures and Eliminate Associated Health Impacts*, 7 (Nov. 2016), https://ptfceph.niehs.nih.gov/features/assets/files/key_federal_programs_to_reduce_childhood_lead_exposures_and_eliminate_associated_health_impactspresidents_508.pdf.

41. *Id.* at 4.

“lead exposure is not equal for all children” and highlighted the higher blood lead levels among African American and low-income children.⁴²

A year later, the Office of Lead Hazard Control and Healthy Homes at the U.S. Department of Housing and Urban Development under the Trump Administration issued a Request for Information seeking public comment on a new federal lead strategy. Over a year later, the Task Force released the “Federal Action Plan to Reduce Childhood Lead Exposure and Associated Health Impacts.”⁴³ Rather than outlining the necessary steps to address lead contamination, the plan dwells on evaluating lead contamination issues that are well-established and settled.⁴⁴ Notably, the plan shifted from the 2000 strategy of *eliminating* lead poisoning. The Trump Administration plan aims to *reduce* childhood lead exposure. “This war on lead from EPA starts with a retreat on the goals. Instead of speaking to eliminate lead-based paint exposure, it wants to just reduce that exposure by *some* time in the future.”⁴⁵ At the same time, the Task Force’s Federal Action Plan does not reflect commenter recommendations as described in the Task Force Letter in Section III.

In response to the 2017 request for comments on “Drafting a New Federal Strategy to Reduce Childhood Lead Exposures and Impacts,”⁴⁶ numerous nonprofit organizations⁴⁷ and lead poisoning prevention experts, including author

42. *Id.* at 7.

43. President’s Task Force on Environmental Health Risks and Safety Risks to Children, Federal Action Plan to Reduce Childhood Lead Exposures and Associated Health Impacts (December 2018), https://www.epa.gov/sites/production/files/2018-12/documents/fedactionplan_lead_final.pdf.

44. Yvette Cabrera, *Federal Action Plan to Reduce Childhood Exposure Falls Short, Experts Say*, HUFFPOST (Dec. 19, 2018), https://www.huffingtonpost.com/entry/childhood-lead-exposure-plan_us_5c1af848e4b08aaf7a84c750.

45. Tom Neltner, Environmental Defense Fund, quoted in Yessenia Funes, *The Trump Administration Hyped Plan to Reduce Childhood Lead Exposure Includes No Actual Plans*, EARTHER (Dec. 20, 2018), <https://earther.gizmodo.com/the-trump-administration-s-hyped-plan-to-reduce-childho-1831239202>

46. Drafting a New Federal Strategy to Reduce Childhood Exposures and Impacts: Request for Information, 82 Fed. Reg. 49226 (Oct. 24, 2017).

47. The following organizations submitted the comments reproduced herein: Sargent Shriver National Center on Poverty Law; Health Justice Innovations, LLC; Green & Healthy Homes Initiative; National Health Law Program; Natural Resources Defense Council; Poverty & Race Research Action Council; Lawyers’ Committee for Better Housing; Advocates for Basic Legal Equality, Inc.; Center for Civil Justice; Cleveland Lead Safe Network; Columbia Legal Services; Connecticut Legal Services; Elevate Energy; Empire Justice Center; Fair Housing Council of the San Fernando Valley; Florida Legal Services; Hawai’i Appleseed Center for Law and Economic Justice; Kansas Appleseed Center for Law & Justice; Legal Aid Society of the District of Columbia; Legal Council for Health Justice; Legal Services of New Jersey; Loyola University Chicago School of Law Civitas ChildLaw Center;

Emily Benfer, the Shriver Center on Poverty Law, Green & Healthy Homes Initiative, Natural Resources Defense Center, National Health Law Project, Northwestern Environmental Law Clinic, Poverty & Race Research Action Center, among others, submitted comprehensive comments in response to the request.⁴⁸ The Task Force did not make the comments publicly available and essentially ignored the signatories' demand for primary prevention.⁴⁹ Because there is no other publicly available method for accessing the comments, we have elected to dedicate Part III of this article to publishing the substantive portions of the comments in their entirety. Our goal is to create a public record of the recommendations to the Task Force, which the authors believe outline the ideal and necessary federal response to the lead epidemic. The Task Force has yet to respond or adopt these recommendations.

III. RECOMMENDATIONS TO FEDERAL AGENCIES AND THE PRESIDENT'S TASK FORCE ON ENVIRONMENTAL RISKS AND HEALTH RISKS TO CHILDREN: MODEL FEDERAL POLICIES TO ELIMINATE LEAD POISONING

This section replicates comments to the Task Force in response to the request, "Drafting a New Federal Strategy to Reduce Childhood Lead Exposures and Impacts: Request for Information," submitted November 24, 2017. Ellipses represent content that was not included because it was previously discussed in this Article. No recommendations were excluded from the Comments reproduced

Massachusetts Law Reform Institute, Inc.; Mississippi Center for Justice; National Housing Law Project; National Low-Income Housing Coalition; New Mexico Center on Law and Poverty; North Carolina Justice Center; Northwestern University School of Law Bluhm Legal Clinic's Environmental Advocacy Center; Ohio Poverty Law Center; South Carolina Appleseed Legal Justice Center; Tennessee Justice Center; Texas Appleseed; Texas Legal Services Center; Western Center on Law & Poverty

48. Letter from Emily Coffey & Emily Benfer et al. to Scott Pruitt, Co-Chair, President's Task Force on Environmental Health and Safety Risks to Children, Administrator, U.S. Environmental Protection Agency; Eric Hargan, Co-Chair, President's Task Force on Environmental Health and Safety Risks to Children, Acting Secretary, U.S. Department of Health & Human Services; Warren Friedman, Office of Lead Hazard Control and Healthy Homes, Department of Housing and Urban Development, November 24, 2017 RE: Comments on "Drafting a New Federal Strategy to Reduce Childhood Lead Exposures and Impacts: Request for Information" Docket No. FR-6049-N-01.

49. Press Release, EPA Administrator Scott Pruitt Hosts Nation's Leaders to Discuss Efforts to Reduce Childhood Lead Exposure (Feb. 2018

<https://www.epa.gov/newsreleases/epa-administrator-scott-pruitt-hosts-nations-leaders-discuss-efforts-reduce-childhood-0> (The five goals the Principals set for the federal lead strategy are:

- 1, Reduce sources of lead in children's environments;
- 2, Improve identification and monitoring of lead exposure to children;
- 3, Improve the health of children identified as lead-exposed;
- 4, Communicate effectively and consistently with stakeholders about childhood lead exposure; and
- 5, Plan cross-federal research to advance our scientific understanding of the effects, evaluation and control of lead hazards in children's environments).

herein.

We respectfully submit comments in response to the request for information, “Drafting a New Federal Strategy to Reduce Childhood Lead Exposures and Impacts.” We commend the President’s Task Force on Environmental Health Risks and Safety Risks to Children (Task Force) for its commitment to developing strategies to protect children from environmental health risks and appreciate the opportunity to comment. The undersigned organizations advocate for policies to ensure individuals, families, and communities have access to safe and healthy homes, including prevention against lead poisoning that results in devastating and permanent harm. Some of the undersigned organizations represent families and communities exposed to lead poisoning in East Chicago, Indiana; Flint, Michigan; and countless cities and states across the United States. Others have members concerned with the ongoing impacts of lead poisoning and work on policy solutions to ensure children are not exposed to lead in their homes and communities. With that knowledge in mind, we urge you to swiftly develop a comprehensive federal strategy to *eliminate* lead from children’s environments. At a minimum, the strategy must set as the first priority primary prevention practices to eliminate legacy lead, halt the current use of lead, and prohibit industrial processes that contaminate the environment with lead. The following recommendations focus on 1) priority risks and goals, 2) strategy development and implementation, and 3) messaging and outreach.

In addition, we support and incorporate by reference responses to this Request for Information from Earthjustice and Green & Healthy Homes Initiative and direct the Task Force to the following previously submitted comments⁵⁰ for additional

50. Comments to Notice of Demonstration to Test Proposed New Method of Assessing the Physical Conditions of Voucher-Assisted Housing, 24 CFR Part 982, Docket No. FR-5928-N-01, July 5, 2016 (submitted by Health Justice Project, Sargent Shriver National Center on Poverty Law, National Housing Law Project);

Comments to “Reducing Regulatory Burden; Enforcing the Regulatory Reform Agenda Under Executive Order 13777,” Docket No. HUD-FR-6030-N-01, June 14, 2017 (submitted by Green & Healthy Homes Initiative, National Center for Healthy Housing, Environmental Defense Fund, Earthjustice, Sargent Shriver National Center on Poverty Law, National Low-Income Housing Coalition, Housing Justice Network, and National Housing Law Project, Health Justice Project, and many of the undersigned organizations);

Comments regarding U.S. Environmental Protection Agency’s Response to Executive Order 13777, “Enforcing the Regulatory Reform Agenda,” Docket No. EPA-HQ-OA-2017-0190-0042, May 12, 2017 (submitted by Environmental Defense Fund, Health Justice Project, Green & Healthy Homes Initiative, Sargent Shriver National Center on Poverty Law, Earthjustice);

Comments on Proposed Rule “Requirements for Notification, Evaluation and Reduction of Lead-Based Paint Hazards in Federally Owned Residential Property and Housing Receiving Federal Assistance; Response to Elevated Blood Lead Levels” (Docket No. FR-5816-P-01), October 31, 2016 (submitted by Environmental Defense Fund, Green & Healthy Homes Initiative, National Center for Healthy Housing, Sargent Shriver National Center on Poverty Law, Health Justice Project, National Housing Law Project, Earthjustice, Environmental Defense Fund, National Housing Law Project);

recommendations

PRIORITY RISKS AND GOALS

We urge the Task Force to address all priority risks, including sources of lead exposure from housing, air, water, soil, food, and environment, in the new federal lead strategy. We provide recommendations for addressing each of these risks and the obligations of numerous federal agencies herein.

STRATEGY DEVELOPMENT AND IMPLEMENTATION

1. *The Task Force must emphasize primary prevention as a critical strategy to protecting children from the permanent effects of lead poisoning.*

...

According to the CDC, “because no level of lead in a child’s blood can be specified as safe, primary prevention must serve as the foundation of the effort.”⁵¹ “Primary prevention is necessary because the effects of lead appear to be irreversible . . . Screening children for elevated [blood lead levels] and dealing with their housing only when their [blood lead level] is already elevated should no longer be acceptable practice.”⁵²

2. *Numerous federal agencies have a critical role in identifying, eliminating, and preventing lead in children’s environment and any strategy must engage cross-agency collaboration.*

In order to fully address lead hazards and end the lead poisoning epidemic threatening families across America, the President’s Task Force on Environmental

October 2016 Letter to the President’s Task Force on Environmental Health and Safety Risks to Children from over forty nonprofit and advocacy organizations regarding a plan of action to prevent childhood lead exposure.

51. CTRS. FOR DISEASE CONTROL AND PREVENTION, PREVENTING LEAD POISONING IN YOUNG CHILDREN: A STATEMENT BY THE CENTERS FOR DISEASE CONTROL AND PREVENTION (Aug. 2005), <http://www.cdc.gov/nceh/lead/publications/PrevLeadPoisoning.pdf>.

52. *See generally*, ADVISORY COMM. ON CHILDHOOD LEAD POISONING PREVENTION OF THE CTRS. FOR DISEASE CONTROL & PREVENTION, LOW LEVEL EXPOSURE HARMS CHILDREN: A RENEWED CALL FOR PRIMARY PREVENTION, (Jan. 4, 2012), *available at* http://www.cdc.gov/nceh/lead/acclpp/final_document_030712.pdf; *cf.* PRESIDENT’S TASK FORCE ON ENVIRONMENTAL HEALTH RISKS AND SAFETY RISKS TO CHILDREN, FEDERAL ACTION PLAN TO REDUCE CHILDHOOD LEAD EXPOSURES AND ASSOCIATED HEALTH IMPACTS at 8 (December 2018), (hereinafter “2018 Federal Action Plan”), *available at* https://www.epa.gov/sites/production/files/2018-12/documents/fedactionplan_lead_final.pdf (seeking okay to “[r]educe children’s exposure to lead-based paint, lead-contaminated drinking water and lead-contaminated soil” rather than make comprehensive push toward primary prevention.)

Health Risks and Safety Risks to Children must take a proactive approach that leverages the combined resources and expertise of the participating departments and agencies. Only by combining resources and expertise can participating members meet the strategy's goal of fully eliminating lead hazards in *all* housing, including federally assisted, privately rented, or owner-occupied.

*A. HUD must identify lead in housing and remove it before children are exposed and must collaborate with other federal, state, and local agencies to ensure children are protected from lead.*⁵³

...

1. HUD must do more to protect children under the Lead Safe Housing Rule (24 C.F.R. part 35).

The recent amendments to the Lead Safe Housing Rule improved standards, but alone will not prevent children from being lead poisoned in federally assisted housing.⁵⁴ HUD can, and should, do more to protect children. HUD must engage in primary prevention to end lead poisoning among children participating in federally assisted housing. Yet, HUD's Lead Safe Housing Rule does not apply primary prevention to all housing programs, placing children in the Housing Choice Voucher (HCV) Program and project-based Section 8 at risk of lead poisoning.⁵⁵ In recognition of increasing reports of lead poisoning in federally assisted housing and lack of compliance with lead poisoning prevention laws, Congress included numerous directions to HUD in the recently passed Consolidated Appropriations Act of 2017, including:

- improved lead hazard inspections;
- preference for UPCS inspections;
- updated lead hazard definitions based on health standards;
- removing the Title X zero-bedroom dwelling unit exemption;
- identification of lead service lines;
- increased data collection, training, compliance, and oversight.

Congress has recognized that more is needed to protect children from lead

53. This section is drawn from previously submitted comments for *FR-6030-N-01 Reducing Regulatory Burden; Enforcing the Regulatory Reform Agenda Under Executive Order 13777*, submitted on June 14, 2017, by Health Justice Project, Sargent Shriver National Center on Poverty Law, and many of the undersigned organizations.

54. See Benfer, *supra* note 17; Emily A. Benfer, *Contaminated Childhood: The Chronic Lead Poisoning of Low-Income People and Communities of Color in Federally Assisted Housing*, HEALTH AFFAIRS HEALTH EQUITY BLOG (August 8, 2017).

55. *Id.*

poisoning, and has taken action accordingly. Again, HUD can, and should, do the same. We commend Secretary Carson for his stated commitment to making lead poisoning prevention a priority and these comments are intended to provide support and direction toward meeting that goal. At a minimum, HUD must comply with Congressional direction by mandating primary prevention practices to identify and remediate lead hazards before a child is poisoned.

a. Require lead hazard risk assessments in all federally assisted housing.

HUD must require lead hazard risk assessments in all federally assisted housing. Visual assessments, alone, are an insufficient screening mechanism for identifying lead-based paint or lead hazards in the form of lead-dust and lead-soil, which are a major source of lead exposure.⁵⁶ In fact, HUD has classified lead-dust and lead-soil in the residential environment as among “the most important preventable exposure sources for children.”⁵⁷ Yet, HUD only requires ineffective visual assessments in the Housing Choice Voucher (HCV) program and project-based Section 8 receiving less than \$5,000 per unit.⁵⁸ HUD cited to Congressional intent to justify a tiered approach to lead hazard inspection.⁵⁹ Any question regarding HUD’s authority to require lead hazard risk assessments and the ineffectiveness of visual inspections was settled in the 2017 Consolidated Appropriations Act, where Congress expressly clarified and confirmed that HUD has the authority to provide more rigorous inspections in all federally assisted housing, stating, “HUD has the statutory authority necessary to require more stringent inspections when checking homes for lead paint. HUD’s current visual lead inspections have proven insufficient, and more rigorous standards, such as requiring risk assessments prior to a family moving into a home, should be implemented to ensure that children living in federally assisted housing are

56. OFF. OF LEAD HAZARD CONTROL, U.S. DEP’T OF HOUS. & URBAN DEV., GUIDELINES FOR THE EVALUATION AND CONTROL OF LEAD-BASED PAINT HAZARDS IN HOUSING 1-7 (July 2012), available at http://portal.hud.gov/hudportal/documents/huddoc?id=second_edition_2012.pdf (“The most common cause of poisoning is the ingestion -through hand-to-mouth transmission- of lead-contaminated surface dust”) [hereinafter HUD 2012 GUIDELINES]; U.S. Dep’t of Hous. & Urban Dev., “Congressional Justifications” 33-6 (2016), <http://portal.hud.gov/hudportal/documents/huddoc?id=FY16-CJE-EntireFile.pdf> (HUD’s 2016 Fiscal Budget notes that “the most important preventable exposure sources for children are lead hazards in their residential environment: deteriorated lead paint, house dust, and lead-contaminated soil”). See also Bruce Lanphear et al., *Lead-Contaminated House Dust and Urban Children’s Blood Lead Levels*, 86 AM. J. PUB. HEALTH 1416, 1420 (1996).

57. U.S. DEP’T OF HOUS. & URBAN DEV., CONGRESSIONAL JUSTIFICATIONS 33-6 (2016), available at <http://portal.hud.gov/hudportal/documents/huddoc?id=FY16-CJE-EntireFile.pdf>.

58. Requirements for Notification, *supra* note 29. (Commenter statements to the original Lead Safe Housing Rule in 1999 remain true today: “Letting our standards be set by appropriation levels is dreadful public policy when the health of children [is] at stake.”).

59. U.S. DEP’T OF HOUS. & URBAN DEV., CONGRESSIONAL JUSTIFICATIONS, *supra* note 34.

protected from lead poisoning.”⁶⁰

A continued reliance on visual assessments would not only ensure that lead hazard control occurs only after the child suffers permanent harm, it would also contravene Congressional intent. To ensure that no families move into a unit with a lead hazard, it is critical that HUD amend its regulations to replace visual assessment with the more accurate and reliable evaluation tool of risk assessment in all pre-1978 construction in all programs. Risk assessment, which should include visual assessment plus the collection of dust, soil, water, and paint samples in homes, is proven to more accurately identify lead hazards than visual assessment alone. Lead hazard inspections should be conducted in all federally assisted units whether or not a child is expected to reside in them. This is an important preventative measure, because children are often regular visitors to relatives’ or neighbors’ homes that do not have a permanent child resident.

b. Adopt the Universal Physical Condition Standards (UPCS) that include the identification of lead hazards in all federally assisted housing.

In May 2017, Congress indicated its preference for UPCS inspections over Housing Quality Standards inspections for the assessment of lead hazards in properties.⁶¹ HUD should incorporate risk assessments into the newly created Universal Physical Condition Standards inspection protocol for HCV program homes constructed before 1978. This will eliminate the cost associated with a second inspection solely for the purpose of identifying lead hazards. In addition, PHAs can support the certification of existing staff members as risk assessors or enter into staffing or equipment sharing agreements with local public health departments. We incorporate by reference the comments submitted by the Sargent Shriver National Center on Poverty Law, Health Justice Project, and National Housing Law Project on the UPCS-V demonstration (Docket No. FR-5928-N-01) on July 5, 2016.

c. Amend the Lead Safe Housing Rule to extend protections to zero bedroom dwelling units.

In May 2017, Congress amended the Lead-Based Paint Poisoning Prevention Act (LPPPA) to remove from the definition of target housing the exception for zero-bedroom dwellings, in which any child under the age of six resides or is expected to reside. In many cities where affordable housing is scarce, families and single parent households commonly live in efficiency, or zero bedroom dwelling units, where their children could be exposed to lead-based paint hazards in pre-1978 housing. To protect these children and to comply with Title X, as amended,

60. H. REP. 114-606, at 94 (2016).

61. S. REP. 114-243, at 97-98 (2016).

HUD must update the Lead Safe Housing Rule at 24 C.F.R. 35.100, 35.115 by removing the zero-bedroom dwelling unit from the exemptions to the rule.

d. Include the identification of lead risks from lead water service lines in Environmental Investigations and the full replacement of any lead service lines.

In the 2017 Consolidated Appropriations Act, Congress dedicated significant funding to address lead-contaminated water and directed the General Accountability Office to assess the number of lead service lines in the United States.⁶² It is critical that HUD identify lead exposure caused by lead service lines and subsequent lead in drinking water as part of its Environmental Investigations and ensure that full lead service lines are eliminated from federally assisted housing. While HUD guidelines have long recommended sampling water in limited circumstances, the recent findings of lead contamination in water in almost 2,000 water systems, serving more than three million Americans across the country, increased knowledge and highlighted the importance eliminating exposure to the neurotoxin in all forms.⁶³ HUD should require designated parties to determine the presence or absence of a lead service line and develop a timeframe for full replacement.

e. Increase oversight and data collection to ensure Public Housing Authorities (PHAs) are in compliance with the lead poisoning prevention laws.

Congress recently expressed concern over HUD's oversight and quality assurance capacity, especially in light of media coverage related to lead poisoning in federally assisted housing, despite a mandate to abate lead hazards in public housing and protect residents from lead poisoning. Congress directed HUD to establish and "implement a process that improves data collection and analysis of actions PHAs are taking to comply with lead-based paint regulations in housing choice voucher units by March 31, 2017."⁶⁴ Congress also directed HUD to report on the incidences of lead poisoning in federally assisted housing, specifically the HCV Program and to issue Guidance and provide trainings on recent amendments to the Lead Safe Housing Rule and best practices in applying lead-safe standards, especially for maintenance and property management staff.

In addition, HUD lacks stated methods to compel compliance when designated parties fail to adhere to the Lead Safe Housing Rule. 24 C.F.R. §35.170

62. H. REP. 115-632, at 5 (2016).

63. Alison Young and Mark Nichols, *Beyond Flint: Excessive lead levels found in almost 2,000 water systems across all 50 states*, USA TODAY (Mar. 11, 2016) available at <https://www.usatoday.com/story/news/2016/03/11/nearly-2000-water-systems-fail-lead-tests/81220466/>

64. S. REP. 114-243, at 97-98 (2016).

only states that designated parties “shall be subject to the sanctions available under the relevant Federal housing assistance or ownership program and may be subject to other penalties authorized by law.” We believe HUD can and should go beyond this generic language. HUD grant and contract documents should include clear and specific monetary holdbacks for the failure to adhere to lead poisoning prevention regulations. For example, HUD should ensure that PHAs comply with the data collection and record keeping requirements described at 24 C.F.R. §35.1225(g). Without a clear system for monitoring compliance and enforcement, these and other requirements hold little value. To ensure that lead hazards are correctly identified and repaired, HUD should require intervention on behalf of noncompliant designated parties and HUD should conduct monitoring activities to ensure compliance with the rule, with any costs recovered from the designated party.

HUD should be granted subpoena authority and other enforcement tools as necessary to more effectively enforce the Lead Safe Housing Rule, Title X and other federal lead regulations. Subpoena power will enable HUD to be more efficient and impactful in its enforcing actions. The failure to grant HUD authority to subpoena non-compliant parties hampers HUD’s ability to thoroughly investigate matters and obtain the documents, contracts, inspection reports and other materials relevant to its ability to conduct enforcement and potentially prosecute or reach favorable settlements in cases under the Lead Safe Housing Rule and Title X. Having to rely on other agencies to pursue cases that reach the stage where subpoenas are warranted is an inefficient process. We recommend that HUD be given subpoena power so it can compel designated parties to produce documents that may support findings essential to address non-compliance and to enforce against parties more fully.

f. Abatement, not just interim controls, must be required when addressing hazards in homes or buildings where a child with an elevated blood lead level (EBLL) is identified.

Once a child is lead poisoned in a unit and lead hazards are identified, interim controls are insufficient. The disrepair or underlying conditions that resulted in a lead hazard is an indication of poor maintenance and increases the likelihood that the hazard will return. In this case, the child has already been harmed and it is likely that other children in the building are at risk of lead poisoning. In addition, while all children should be in an environment free from lead hazards, it is especially important to restrict additional potential exposures for children who have already been exposed. For these reasons, it is critical that HUD require lead abatement in units that have poisoned a child.

g. Immediately temporarily relocate children during remediation of lead

hazards in the home pursuant to Chapter 16 of the HUD Guidance.

HUD must protect children from continued exposure to lead hazards as soon as the hazard is identified and throughout the duration of hazard reduction activities. Relocation requirements, under 24 C.F.R. § 35.1345, are only triggered upon the actual commencement of hazard reduction activities, not the discovery of a documented lead hazard, and only under certain circumstances if no exceptions are met. To protect residents from lead exposure, HUD should require designated parties to relocate families immediately upon identification of a lead hazard in their housing. This is consistent with Chapter 16 of HUD's Guidance: "In cases where lead hazard control measures are ordered, relocate the child to a lead-safe environment until the work is completed and clearance is achieved"⁶⁵

2. HUD should better integrate the Lead Safe Housing Rule with EPA's Lead Renovation, Repair, and Painting Rule (RRP)

Since HUD originally promulgated the Lead Safe Housing Rule, EPA, as directed by Title X, issued regulations under section 402(c) of Toxic Substances Control Act (TSCA) regulating renovation, repair and painting activities in all target housing. While HUD's Lead Safe Housing Rule as originally promulgated clearly worked hand-in-hand with EPA's rules under 402(b) governing abatement, this same degree of coordination is now lacking for interim controls. In various public statements and web posts since EPA promulgated its 402(c) rule, HUD staff have sought to clarify how to address the overlap and gaps between HUD's interim control requirements and EPA's rules. HUD neglected, however, to propose any rule changes to codify this advice, support EPA's requirements, or clarify conflicts.

It is imperative, however, that any effort to integrate the Lead Safe Housing Rule or other HUD lead regulations with the RRP Rule does not result in the lowering of lead safety standards and practices for HUD assisted housing. While maintaining the additional protections in its rules as appropriate for federally assisted projects, HUD should better integrate the Lead Safe Housing Rule with EPA's. We strongly support HUD's existing provisions that are more protective than EPA's – including the requirement for quantitative lead risk assessment and lead and dust testing (clearance) procedures, smaller "de minimis" areas, requiring all workers to be trained, and stricter work practice requirements. However, HUD should utilize and mandate EPA's training and certification program. In particular, 24 C.F.R. § 35.1330(a)(4) should specifically require the work to be performed by a firm certified by the EPA under 40 C.F.R. § 745.89 and require all workers to be trained in accordance with 40 C.F.R. § 745.90 (unless supervised by a lead abatement supervisor). Additionally, HUD should modify its notification requirements at 24 C.F.R. § 35.125 and § 35.130 to assure compliance with, and

65. See HUD 2012 GUIDELINES, *supra* note 33, at 16–4.

minimize unnecessary overlap, with the EPA requirements at 40 C.F.R. § 745.84. HUD should monitor for noncompliance and routinely take appropriate remedial action to ensure compliance. HUD should require RRP training by a certified EPA trainer for every PHA employee or contractor.

3. *HUD and EPA must update the lead-based paint definition to accurately identify the presence of lead that is hazardous to health.*

In addition, HUD must update the definition of lead-based paint. HUD has the express authority under LPPPA to revise its standard for lead-based paint in housing constructed prior to 1978.⁶⁶ LPPPA directs HUD to periodically review its standards as the technology makes lower detection feasible and the medical evidence warrants a lower level.⁶⁷ The technology and science on lead-based paint have dramatically improved since the standards for lead-based paint were last reviewed in 1992 and detecting paint with low content levels of lead is possible today. The current technological and medical evidence necessitate that HUD and EPA update the lead-based paint definition.⁶⁸

EPA indicated that it would work with HUD to establish a lower lead content in lead-based paint.⁶⁹ In 2012, in response to a request from the agency, EPA's Science Advisory Board issued a final report that supported updated standards.⁷⁰ HUD has both the statutory authority and obligation to act to ensure the standards reflect current science, and there is no rationale that could justify creating an "illusion of safety" without outdated standards and placing children in both private and federally assisted housing in grave danger.⁷¹ HUD and EPA should act based on the information that we have and know to be true – and that could save a child's life.

4. *Affirmatively further fair housing includes improving health outcomes among low-income communities of color.*

We urge HUD to take action to address lead poisoning, and provide guidance to program recipients to do the same, as part of its obligation to affirmatively

66. 42 U.S.C. § 4822(c).

67. *Id.*

68. *Cf.* 2018 Federal Action Plan at 8 (making no mention of lead-based paint standards).

69. EPA RESPONSE CITIZEN PETITION TO EPA (2009), available at <https://www.epa.gov/sites/production/files/2015-10/documents/epa-response.pdf>; *In re A Community Voice, et al, v. U.S. EPA, Gina McCarthy* (U.S. App 9th Cir. 2016).

70. EPA Science Advisory Board, *Lead Paint Hazard Standards for Residential Buildings, Public and Commercial Buildings, and Renovations of Exteriors of Public and Commercial Buildings* (2012) <https://yosemite.epa.gov/sab/sabproduct.nsf/0/9c733206a5d6425785257695004f0cb1!OpenDocument&TableRow=2.3#2>.

71. *See generally* Council on Env'tl. Health, *Prevention of Childhood Lead Toxicity*, 138 PEDIATRICS 1 (2016), available at <https://perma.cc/KM7D-PGFT>

further fair housing. The duty to affirmatively further fair housing is codified in Section 3608 of the Fair Housing Act.⁷² This mandate requires HUD and its recipients to not only refrain from discrimination but also to take actions to overcome the effects of historic patterns of segregation and other forms of discrimination, promote integration, and increase fair housing choice and access to opportunity.⁷³ In 2015, HUD issued the Affirmatively Furthering Fair Housing (AFFH) rule to clarify the definition of AFFH and establish a standardized framework for coordinated consultation and planning on fair housing priorities and goals to help HUD program participants meet their AFFH obligation.⁷⁴ Specifically, the AFFH rule facilitates cross-agency and sector collaboration to address fair housing issues.⁷⁵

Under the rule, participants are required to conduct an Assessment of Fair Housing (AFH) that examines barriers to opportunity, including environmental health hazards, using HUD's Environmental Health Index which is based on EPA data.⁷⁶ HUD's AFH assessment tool directs participants to analyze a variety of issues related to lead exposure. This includes disparities in access to opportunity (specifically including access to environmentally healthy neighborhoods), patterns of residential segregation, and disproportionate housing needs.⁷⁷ Participants are also encouraged to evaluate "other indicators of environmental health, based on local data and local knowledge" and to evaluate contributing factors for fair housing issues, such as the location of environmental health hazards including lead-based paint.⁷⁸ To conduct an AFH, participants may use HUD's AFFH Data and Mapping Tool which allows access to HUD-provided data and maps on environmental health, residential segregation, and other information such as racially and ethnically concentrated areas of poverty.⁷⁹ All of these data may be used to help identify areas where residents may be at risk of lead exposure and develop actions to address such exposure. In addition, the AFH process includes an enhanced community participation requirement which provides opportunities for public health officials and advocates to consult with program participants on

72. 42 U.S.C. § 3608.

73. 80 Fed. Reg. 42,272 (July 16, 2015).

74. *Id.*

75. Brian Smedley and Philip Tegeler, "Affirmatively Furthering Fair Housing": A Platform for Public Health Advocates, *AMER. J. PUB. HEALTH*, Vol. 106, No. 6 (June 2016), http://prprac.org/pdf/place_based_interventions.pdf

76. 24 C.F.R. § 5.150-5.168; Poverty & Race Research Action Council, "Comments on Draft EJ 2020 Action Agenda," July 28, 2016, available at http://prprac.org/pdf/EPA_2020_AFFH_letter.pdf.

77. U.S. DEP'T OF HOUS. & URBAN DEV., ASSESSMENT OF FAIR HOUSING TOOL, available at <https://www.hudexchange.info/resource/4865/assessment-of-fair-housing-tool/>

78. *Id.*

79. *Id.*

public health issues such as lead poisoning.⁸⁰ The AFH tool also requires jurisdictions to develop a set of concrete fair housing goals and strategies that can be incorporated into future consolidated plans and public housing authority plans for the use of HUD funds.⁸¹ The AFH process thus provides an important platform for advocates to address lead hazards nationwide. HUD should work with grantees and stakeholders and provide targeted resources to enable them to use the AFH process to protect children from lead poisoning in their homes and neighborhoods.

There are specific, concrete steps that HUD can take to prevent lead exposure and fulfill its duty under AFFH. HUD should provide further guidance to participants on how to use local data and knowledge during the AFH process to assess the impact of lead and to develop goals and strategies designed to abate lead exposure. Doing so will make the AFH process a more effective way to identify and remediate lead hazards. Additionally, HUD and its recipients should take consistent action to prevent lead exposure through siting reviews for subsidized housing, including HUD programs such as the Rental Assistance Demonstration and HOME. This is critical for protecting the safety of low-income families, particularly low-income families of color. HUD should also promote fair housing choice by increasing resources for counseling and housing mobility options to assist families that are at risk of lead exposure. In addition, HUD should make additional Housing Choice Vouchers (HCV) available for families with an EBL child. In Baltimore, GHHI has awarded 250 vouchers to at risk families affected by lead poisoning and seen great success due to the ability to relocate from the lead hazardous home.⁸² In many cases, without the HCV, the family would be unable to move.

5. Low-income families with mortgages insured through the Federal Housing Administration (FHA) Mortgage Programs need increased access to no and low-interest loan programs and grants to abate lead hazards in their homes.

HUD should ensure families purchasing and residing in FHA insured homes have access to low-interest and no-interest loans and HUD grants to remediate lead hazards.⁸³ FHA insured mortgages have created a pathway for low-income families, and especially families of color, to become homeowners. Many of these homes contain lead hazards that families are unable to afford to remediate. When a buyer, seller, or current homeowner does not have funds to pay for abatement,

80. Smedley & Tegeler, *supra* note 49.

81. *Id.*

82. See Green & Healthy Homes Initiative, *Healthy Homes, Healthy Families*, 3.1 available at http://www.greenandhealthyhomes.org/sites/default/files/HHHF_3.1_webres1_0.pdf

83. 12 U.S.C. § 1715k

HUD should increase access to Section 203(k) loans for lead remediation.⁸⁴ HUD should proactively advertise this program as an option to increase the safety of homes insured by FHA and should work with lenders to make this available and accessible to low-income homeowners.

Additionally, FHA inspections should include risk-assessments to identify the presence of lead hazards. When families have low incomes, it is essential that when lead hazards are identified, there are programs tailored to low-income homeowners to remediate the hazard. For many low-income families, and especially families of color, the home is their sole asset. It is critical that these homes are safe and the outcome of the risk assessment includes a viable solution to protect all current and future homeowners and their families.

HUD should also collaborate with other agencies to find creative solutions to remediating hazards in FHA insured homes. Other agencies, including the USDA, have created a direct loan program specifically to repair, improve or modernize homes or remove health and safety hazards.⁸⁵ Community Development Block Grant (CDBG) funds or other eligible federal public dollars should be specifically allocated for this purpose in communities across the country. HUD could create a specific program to finance the remediation of lead hazards in FHA insured homes.

B. EPA and HUD must immediately address lead hazards from industrial contamination on or near federally assisted housing.

Over 400 lead smelting plants deposited dangerous levels of lead and other contaminants in communities across the country.⁸⁶ About 70% of Superfund sites, with contaminants including lead, are within a mile of public housing or HUD multifamily housing.⁸⁷ The USS Lead Superfund Site, as the name indicates, is a lead-contaminated site in East Chicago, Indiana. Lead smelters and a lead-arsenate pesticide facility surrounded the residents' homes. Many of the homes were also built on wetlands that had been filled with contaminated material. The housing on the Superfund site is a mix of public housing, Low Income Housing Tax Credit housing, rental housing (including units rented with Housing Choice Vouchers), and single family homes. A majority of the homes were built before 1978 with known lead paint content.⁸⁸ Residents are exposed to lead in the soil and lead dust

84. See U.S. DEP'T OF HOUS. & URBAN DEV., 203(K) MORTGAGE INSURANCE available at https://www.hud.gov/program_offices/housing/sfh/203k/203k--df

85. See U.S. DEP'T OF AGR., SINGLE FAMILY HOUSING REPAIR LOANS & GRANTS, available at <https://www.rd.usda.gov/programs-services/single-family-housing-repair-loans-grants>.

86. See USA TODAY, *Ghost Factories: Poison in the Ground*, (Apr. 25 2012) [<https://perma.cc/9NSQ-C7ZJ>].

87. Sylvia Carignan, *Majority of Superfund Sites Near Low-Income Housing*, BLOOMBERG, May 9, 2017.

88. Lauren Cross and Sarah Reese, "Righting an 'Injustice' An Environmental Threat: The

in their homes; the lead dust stems from particulate being tracked and blown in from contaminated topsoil, as well as from lead-based paint. In addition, it is estimated that 90% of the East Chicago homes have lead service lines, which present an additional lead hazard. In fact, the EPA concluded that based on a drinking water pilot study in 2016, East Chicago's drinking water had system-wide elevated lead levels due to inadequate corrosion control treatment and the presence of lead service lines. This community has unacceptable cumulative exposures to lead. The incidence of elevated blood lead levels—lead above the CDC's current 5 µg/dL standard—is notably high. Between 2005-2015, 19% of children six years of age and under tested had an elevated blood lead level.⁸⁹ Parents in this community report in high numbers that their children have been diagnosed with ADHD, have developmental problems, or require educational intervention or supports.

HUD must ensure that all residents of federally assisted housing—whether it is public housing, project-based Section 8, or through the HCV program—who live within a Superfund site receive a disclosure explaining that they live within a Superfund site, listing the primary contaminants. The families at the West Calumet Housing Complex (WCHC) did not receive a notice that they lived on the footprint of a lead smelter plant until many years after federal officials began investigating the contamination. This lack of notice meant families were completely unaware that the soil their children were playing in was causing extreme damage to their developing bodies.

To date, HCV holders living within the Superfund site have not been notified that they live within a Superfund site and have not been given the opportunity to move. Since the contamination in East Chicago became a national story in 2016, advocates and residents have asked HUD and East Chicago Housing Authority (ECHA) to offer assistance, including notice and a chance to move, to approximately 40 HCV households who live within the boundaries of the Superfund site and are not a part of the WCHC relocation. Only the landlords of these voucher holders have received any notice and that notice came from the EPA.

In March 2017, the ECHA notified residents of its intention to involuntarily relocate on an emergency basis the remaining households from the West Calumet Public Housing Complex, HUD and ECHA assured all involved that the transfer units would be inspected for the presence of lead-based paint and that no residents would be moved to lead contaminated units. In fact, nearly half of the transfer units did have lead-based paint. In spite of this fact, ECHA staff signed certifications to

East Chicago Lead Crisis One Year Later," THE TIMES OF NORTHWEST INDIANA (Aug. 16, 2017) available at http://www.nwitimes.com/news/special-section/ec-lead/an-environmental-threat-the-east-chicago-lead-crisis-one-year/article_d19a5de7-5bc0-5292-9fe7-29a6e999ade4.html

89. U.S. ENV. PROT. AGENCY, ACTION MEMORANDUM – 4TH AMENDMENT, 5 (Oct. 24, 2016). Available at <https://semspub.epa.gov/work/05/929998.pdf>

residents that no lead-based paint was identified in the buildings. Residents relied upon those certifications to keep their children safe. We understand that HUD is reviewing compliance but has not taken any action against ECHA.

This issue is not limited to East Chicago and many housing authorities across the country are likely out of compliance with the Lead Disclosure Rule. As discussed in Section 1.e. above, we recommend that HUD conduct a thorough audit of federally assisted housing, and take appropriate enforcement action, to ensure compliance with the Lead Disclosure Rule and the Lead Safe Housing Rule.

C. The Environmental Protection Agency must eliminate lead in water, air, and soil.

At its founding and authorization, EPA was charged with protecting human health and the environment.⁹⁰ During his confirmation hearings, [former] EPA Administrator Pruitt committed to EPA's mission: "I am a firm believer in the EPA's mission to protect the environment and look forward to the opportunity to lead the agency to help provide our future generations with a better and healthier environment."⁹¹ He also said, "If confirmed, I would work to faithfully execute the laws EPA is responsible for administering, in order to protect human health and the environment for all Americans." Former Administrator Pruitt pledged to move EPA "back to the basics of protecting human health and the environment."⁹² Protecting children from the debilitating effects of lead poisoning must be one of the basic priorities.

Indeed, former Administrator Pruitt recognized that protecting children from lead poisoning is central to this duty. In fact, the fulfillment of this duty is statutorily required and prescribed in detail in Title IV of the Toxic Substances Control Act (TSCA) and the Residential Lead Based Paint Hazard Reduction Act (Title X).⁹³ Specifically, EPA must regulate the standards for performing lead-based paint activities, set the levels of lead in dust and soil based on prevailing science, and require lead disclosure for real estate or lease transactions, among other obligatory actions.

90. See U.S. ENV. PROT. AGENCY, EPA MISSION REORGANIZATION PLAN NO. 3, *available at* <https://www.epa.gov/aboutepa/our-mission-and-what-we-do>

91. SENATE ENV. AND PUB. WORKS COM'T HEARING, "NOMINATION OF ATTORNEY GENERAL SCOTT PRUITT ADMINISTRATOR OF THE U.S. ENVIRONMENTAL PROTECTION AGENCY," (Jan. 18, 2017) *available at* https://www.epw.senate.gov/public/_cache/files/6d95005c-bd1a-4779-af7e-be831db6866a/scott-pruitt-qfr-responses-01.18.2017.pdf

92. U.S. ENV. PROT. AGENCY, EPA ADMINISTRATOR VISITS CONTAMINATED SITE EAST CHICAGO AND PLEDGES COORDINATED CLEANUP AMONG FEDERAL, STATE AND LOCAL PARTNERS (Apr. 19, 2017) *available at* <https://www.epa.gov/newsreleases/epa-administrator-visits-contaminated-site-east-chicago-pledges-coordinated-cleanup>

93. 42 U.S.C. § 4851; 15 U.S.C. § 2681.

1. EPA's lead hazard standards must be updated immediately to reflect the current science.

EPA's current definitions of lead-contaminated dust and lead-contaminated soil are not protective enough to identify "threats to adverse health effects in pregnant women or young children," as required by TSCA.⁹⁴ Pursuant to Title IV of TSCA, EPA must immediately update these standards based on current science and health standards.⁹⁵ In addition, pursuant to the 2017 Omnibus appropriations bill, EPA must, in consultation with CDC and HUD, provide to Congress a report on the progress related to updating lead dust and soil standards.

Without protective standards, lead hazard inspection and clearance testing following interim control, renovation, or abatement is unreliable. EPA's current standards, which were established based on pre-1995 research, are not set low enough for a risk assessment or a clearance test to identify a lead hazard and protect children from lead poisoning. For example, the current definition of lead paint as 5,000 ppm does not capture lead content that would create a lead dust hazard if dry sanded. In one study, dust-lead levels much lower than the current floor standard of 40 $\mu\text{g}/\text{ft}^2$ "were associated with a considerable excess risk of children having blood lead levels [greater than or equal to] 10 $\mu\text{g}/\text{dL}$."⁹⁶ In another, tests using the current residential floor standard failed to identify 85% of housing units of children who had a blood lead concentration of 10 $\mu\text{g}/\text{dL}$.⁹⁷ In response to a 2009 petition for rulemaking, EPA has acknowledged the need to update the standards for lead in dust and lead in paint and EPA's Science Advisory Board issued a final report that supported updated standards.⁹⁸ Despite these agency findings, citizen complaints, and litigation, the EPA has taken no action.

TSCA requires that regulations for lead-based paint activities take into account "reliability, effectiveness, and safety."⁹⁹ The success of all of EPA's lead exposure reduction regulations and the ability to identify a potential lead hazard hinge on the protectiveness of the lead hazard definitions. EPA must act immediately to align these standards with the irrefutable science in a manner that will truly protect the health of workers and occupants.

94. 15 U.S.C. § 2681.

95. Cf. 2018 Federal Action Plan at 8 ("Consider revisions, as appropriate, to the dust-lead hazard standards. . .")

96. Bruce Lanphear et al., *Screening Housing to Prevent Lead Toxicity in Children*, 120 PUB. HEALTH REPORTS 305, 308 (2005).

97. *Id.*

98. U.S. ENV. PROT. AGENCY SCIENCE ADVISORY BOARD, LEAD PAINT HAZARD STANDARDS FOR RESIDENTIAL BUILDINGS, PUBLIC AND COMMERCIAL BUILDINGS, AND RENOVATIONS OF EXTERIORS OF PUBLIC AND COMMERCIAL BUILDINGS (2012) *available at* <https://yosemite.epa.gov/sab/sabproduct.nsf/0/9c733206a5d6425785257695004f0cb1!OpenDocument&TableRow=2.3#2>.

99. 15 U.S.C. § 2682(a)(1)

2. *EPA must address lead in drinking water to reduce childhood lead exposure.*¹⁰⁰

Drinking water is a major source of lead for many of the most vulnerable, including children, infants, pregnant women and fetuses. Lead in drinking water is dangerous because drinking water can make up 20 percent or more of a person's total exposure to lead."¹⁰¹ A person's exposure to lead starts very early, with a woman's lead levels relevant to or impacting her fetus: "[d]uring pregnancy, lead is often remobilized from bone and may be transferred from mother to fetus. Approximately 80 percent of lead in fetal cord blood appears to derive from maternal bone stores. Maternal lead can also be transferred to infants during breastfeeding."¹⁰² For infants whose diet consists of baby formula made with drinking water, lead in drinking water can make up over 85 percent of total lead exposure.¹⁰³ Moreover, adding contaminated water to other significant sources of lead, such as paint, air and soil, poses an exceptional cumulative threat to public health.

As an August 2017 report by The Health Impact Project (of the Robert Wood Johnson Foundation and The Pew Charitable Trusts) notes, "a robust body of academic literature from the U.S. and Canada links lead in drinking water to increases in blood lead levels. For example, one cross-sectional study of 183 children randomly selected from urban areas found that an increase in water lead concentrations from background levels to 15 ppb was associated with a nearly 14

100. See "Plan of Action to Prevent Childhood Lead Exposure" signed by four dozen community groups and public interest organizations around the country, including Earthjustice, Physicians for Social Responsibility, and United Parents Against Lead re-submitted to the Task Force on Nov. 21, 2017, available at <https://earthjustice.org/sites/default/files/files/President%27s%20Task%20Force%20Letter%20FINAL.pdf> (hereinafter "Earthjustice Plan of Action to Prevent Childhood Lead Exposure").

101. U.S. ENV. PROT. AGENCY, LEAD AND COPPER RULE: A QUICK REFERENCE GUIDE FOR SCHOOLS AND CHILD CARE FACILITIES THAT ARE REGULATED UNDER THE SAFE DRINKING WATER ACT (Oct. 2005), available at <https://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=P10058C5.txt>.

102. CAL. ENV. PROT. AGENCY, OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT, PUBLIC HEALTH GOALS FOR CHEMICALS IN DRINKING WATER: LEAD (Apr. 2009), at 6 (internal citations omitted), available at https://oehha.ca.gov/media/downloads/water/chemicals/phg/leadfinalphg042409_0.pdf

103. Maximum Contaminant Level Goals and National Primary Drinking Water Regulations for Lead and Copper, 56 FED. REG. 26,460, 26,468 (June 7, 1991) (codified at 40 C.F.R. Part 141 Subpart I) ("Lead and Copper Rule") (cited by Ex. 25, Triantafyllidou, S., and Edwards, M., Lead (Pb) in tap water and in blood: implications for lead exposure in the United States. *Critical Reviews in Environmental Science and Technology*, 42(13), 1297-1352 (2012), excerpt provided, in turn cited in Ex. 26, U.S. ENV. PROT. AGENCY, PROPOSED MODELING APPROACHES FOR A HEALTH-BASED BENCHMARK FOR LEAD IN DRINKING WATER, at 20, available at https://www.epa.gov/sites/production/files/2017-01/documents/report_proposed_modeling_approaches_for_a_health_based_benchmark_for_lead_in_drinking_water_final_0.pdf.

percent jump in the share of children with estimated blood lead over 10 µg/dL.”¹⁰⁴ Elevated lead levels in drinking water have been associated with an increase in the rate of individuals with elevated blood lead levels.¹⁰⁵ Exposure to lead-contaminated drinking water has also been associated with fetal death and reduced birth rates.¹⁰⁶ As EPA has recognized, “[i]nfants and children who drink water containing lead in excess of the action level could experience delays in their physical or mental development.”¹⁰⁷

Lead in water is a concern due to lead-bearing plumbing in over 10 million pipes across the country. Potential sources of lead in plumbing include “lead pipes, lead solder, leaded brass, galvanized iron (which can “absorb” lead from other plumbing materials and later release it into water), and copper (which can trigger galvanic corrosion of other leaded materials); lead poses a health threat even when water is properly treated for corrosion control; and individual water consumers are expected to and must take actions on their own to protect themselves from lead in water, even when water is properly treated for corrosion control.”¹⁰⁸

EPA must educate the public about the ubiquitous sources of lead in water and improve oversight and enforcement of the revised Lead and Copper Rule (LCR) and strengthen its provisions in revisions to the LCR to remove the sources of lead in water and protect public health. Over 5,363 community water systems serving over 18 million people committed 8,093 violations of the LCR in 2015 alone. Only 11.2 percent of violations resulted in formal enforcement action by EPA.¹⁰⁹

EPA should require the proactive full replacement of all lead service lines

104. See Health Impact Project of the Robert Wood Johnson Foundation and The Pew Charitable Trusts, “10 Policies to Prevent and Respond to Childhood Lead Exposure: An assessment of the risks communities face and key federal, state, and local solutions,” (Aug. 2017), available online http://www.pewtrusts.org/~media/assets/2017/08/hip_childhood_lead_poisoning_report.pdf. (“hereinafter Health Impact Project, 10 Policies to Prevent Lead Exposure”)

105. Ronnie Levin et al., *Lead Exposure in U.S. Children, 2008: Implications for Prevention*, 116 ENVIRON. HEALTH PERSPECT. (1) 1285-93 Ex. 27, (2008), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2569084/>; CTRS. FOR DISEASE CONTROL & PREV., *Blood Lead Levels in Residents of Homes with Elevated Lead in Tap Water—District of Columbia, 2004*, 53 MMWR Weekly (No. 12) 268-70 (Apr. 1, 2004), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5312a6.htm>.

106. Marc Edwards, *Fetal Death and Reduced Birth Rates Associated with Exposure to Lead-Contaminated Drinking Water*, 48 ENVTL. SCI. & TECH. 739-40 (2013), available at <http://pubs.acs.org/doi/pdf/10.1021/es4034952>.

107. U.S. ENV. PROT. AGENCY, *Basic Information about Lead in Drinking Water*, available at <http://water.epa.gov/drink/contaminants/basicinformation/lead.cfm>.

108. See “Plan of Action to Prevent Childhood Lead Exposure” *supra* note 72.

109. Erik D. Olson & Kristi Pullen Frederick, Natural Resources Defense Council, *What's In Your Water? Flint and Beyond* at 5 (June 28, 2016), available at <https://www.nrdc.org/resources/whats-your-water-flint-and-beyond>. (This figure includes failures to follow LCR provisions for testing of water, reporting of contamination, and treatment to prevent lead pipe corrosion.)

(LSL). LSLs are the main source of lead in drinking water, and the problem of lead service lines is enormous and widespread. While there is no comprehensive national inventory of lead service lines, experts have estimated that 6 to 10 million lead service lines are being used in the United States, serving 15 to 22 million Americans.¹¹⁰ The revised LCR should require that all water systems adopt a proactive full LSL replacement program and numeric enforceable deadlines for meeting them. EPA must ban partial LSL replacements.¹¹¹ Under the current LCR system, homeowners are typically asked to pay out of pocket for the cost of replacing any portion of an LSL on the private property. Homeowners and landlords who cannot afford to pay this price are forced to accept partial LSL replacement, a practice that has been shown to *increase* lead levels at the tap.¹¹² Tens of thousands of families have thus been put at greater risk of lead contamination in their drinking water simply because of their inability to pay. Moreover, these families do not receive meaningful education regarding the risks of lead, and are not given water filters, replacement cartridges, and training on how to properly install and maintain a point of use filter.¹¹³

EPA should require more frequent and extensive monitoring for lead, and explicitly prohibit sampling techniques that result in underreporting of water lead levels. For example, many water systems have used sampling techniques that are designed to reduce lead identification, such as aerator removal, pre-flushing, and the use of small-mouthed bottles,¹¹⁴ in order to avoid finding lead. Without improved sampling and monitoring techniques, violations are not recorded and

110. David A. Cornwell, Richard A. Brown, and Steve H. Via, "National Survey of Lead Service Line Occurrence," *JOURNAL OF THE AM. WATER WORKS ASS'N.* 108, no. 4 (Apr. 2016): E182-E191, *available at* dx.doi.org/10.5942/jawwa.2016.108.0086.

111. EPA included this requirement when it first promulgated the LCR. *See* Maximum Contaminant Level Goals and National Primary Drinking Water Regulations for Lead and Copper, 56 *FED. REG.* 26460, 26503-09 (June 7, 1991). This provision was never enforced: In response to a challenge by the American Waterworks Association, the D.C. Circuit struck down EPA's definition of "control" in the final 1991 rule, solely on the grounds that "EPA failed to provide adequate notice that it would adopt a novel definition of control." *Am. Water Works Ass'n v. EPA*, 40 F.3d 1266, 1275 (D.C. Cir. 1994); *cf.* 2018 Federal Action Plan at 9 (making no distinction between full and partial replacement).

112. U.S. ENV. PROT. AGENCY, SCIENTIFIC ADVISORY BOARD EVALUATION OF THE EFFECTIVENESS OF PARTIAL LEAD SERVICE LINE REPLACEMENTS at 12-13 (Sept. 28, 2011), *available at* http://www.epa.gov/sites/production/files/2015-09/documents/sab_evaluation_partial_lead_service_lines_epa-sab-11-015.pdf.

113. Sheila Kaplan & Corbin Hiar, *Toxic Taps: Lead is Still the Problem*, AM. UNIV. INVESTIGATIVE REPORTING WORKSHOP (Aug. 8, 2012), <http://investigativereportingworkshop.org/investigations/toxic-taps/story/toxic-taps-lead-is-still-the-problem>

114. Oliver Milman, *US authorities distorting tests to downplay lead content of water*, *THE GUARDIAN*, Jan. 22, 2016, *available at* <https://www.theguardian.com/environment/2016/jan/22/water-lead-content-tests-us-authorities-distorting-flint-crisis>

reported and consumers receive false assurances regarding lead levels in their water. EPA has advised against the use of several of these misleading sampling techniques,¹¹⁵ but without reform, these practices will continue.

EPA must reduce its drinking water action level, which is now set at 15 parts per billion (ppb).¹¹⁶ While no level of lead in water is safe, lowering the action level would help to result in more effective corrosion control, and further reduce exposure to lead in water.

Finally, EPA should collaborate with HUD to ensure that HUD develops and implements safe water requirements in its administration of its programs and makes available the provision of water testing and filters to ensure potable drinking water wherever appropriate.

3. EPA's Lead Repair, Renovation and Painting (RRP) Rule and Abatement Rule must be enforced to protect occupants and workers.

Both the Repair, Renovation and Painting (RRP) Rule¹¹⁷ and Abatement Rule¹¹⁸ protect children and their families by establishing the minimum standards for the level of protection from lead-based paint hazards. Home renovation and lead-based paint activities are among the greatest sources of lead contamination and lead hazard exposure to occupants. Lead in the environment does not dissipate, making it likely that a developing child will inhale or ingest it and become lead poisoned.

Both the RRP Rule and Abatement Rule are mandated by Title IV of TSCA. Title IV requires the EPA Administrator to promulgate and maintain guidelines for the conduct of renovation and remodeling activities, which may create a risk of exposure to dangerous levels of lead.¹¹⁹ Pursuant to Title IV, EPA must maintain “regulations governing lead-based paint activities to ensure that individuals engaged in such activities are properly trained; that training programs are accredited; and that contractors engaged in such activities are certified.”¹²⁰ In addition, TSCA mandates that such “regulations shall contain standards for performing lead-based paint activities, taking into account reliability, effectiveness, and safety.”¹²¹

115. MEMORANDUM FROM PETER GREVATT, DIRECTOR, EPA OFFICE OF GROUND WATER AND DRINKING WATER TO WATER DIVISION DIRECTORS ON CLARIFICATION OF RECOMMENDED TAP SAMPLING PROCEDURES FOR PURPOSES OF THE LEAD AND COPPER RULE (Feb. 29, 2016), *available at* https://www.epa.gov/sites/production/files/2016-02/documents/epa_lcr_sampling_memorandum_dated_february_29_2016_508.pdf

116. 40 C.F.R. § 141.80(c).

117. 40 C.F.R. § 745.80 *et seq.*

118. 40 C.F.R. § 745.220 *et seq.*

119. 42 U.S.C. § 2682(c)(1).

120. 42 U.S.C. § 2682(a)(1).

121. *Id.*

The RRP Rule is based on EPA's scientific study finding that renovation and repair activities that disturb lead-based paint "have the highest potential for generating lead exposure."¹²² The RRP Rule applies to 37.8 million facilities, including 37.7 million target housing units.¹²³ It is estimated that annually the RRP Rule protects 1.3 million children under six years of age and between five and eleven million adults and children over six years of age from lead poisoning.¹²⁴ However, the current "wipe cloth" clearance testing is not effective and was never validated. It must immediately be replaced with a validated wipe sampling method. At the same time, the lead in many of these homes was not abated and the lead hazard could return if not closely monitored or maintained. In fact, numerous homes where a lead hazard was previously identified have resulted in lead poisoning in future occupants below six years of age.¹²⁵ If the lead in a pre-1978 home is not abated, the home requires constant surveillance and maintenance to address the high risk of lead poisoning for future occupants.

EPA's primary objective in promulgating the Abatement Rule was "to ensure that individuals and firms conducting lead-based paint activities in target housing and child-occupied facilities will do so in a way that safeguards the environment and protects the health of building occupants, especially children aged 6 years and under."¹²⁶ The Regulatory Impact Analysis of the Abatement Rule estimated the benefits to be as much as \$54 billion over 50 years.¹²⁷ In the Regulatory Impact Analysis, EPA justified the federal standards as being more efficient than standards adopted independently by each individual state.¹²⁸ EPA must continue to increase education and enforcement of the RRP Rule and Abatement Rule to ensure that the burden of identifying a hazard does not rest on a developing child's blood lead levels.¹²⁹

122. U.S. ENV. PROT. AGENCY, LEAD EXPOSURE ASSOCIATED WITH RENOVATION AND REMODELING ACTIVITIES (May 1997).

123. ECONOMIC AND POLICY ANALYSIS BRANCH ECONOMICS, EXPOSURE AND TECHNOLOGY DIVISION OFFICE OF POLLUTION PREVENTION AND TOXICS, U.S. ENV. PROT. AGENCY, ECONOMIC ANALYSIS FOR THE TSCA LEAD RENOVATION, REPAIR, AND PAINTING PROGRAM FINAL RULE FOR TARGET HOUSING AND CHILD-OCCUPIED FACILITIES" Table 2-31, p. 33-4 (Mar. 2008), available at http://www.nchh.org/Portals/0/Contents/EPA-HQ-OPPT-2005-0049-0916_Final_Economic_Analysis_3-08.pdf.

124. *Id.*

125. Reys et al., *Identifying Housing That Poisons: A Critical Step in Eliminating Childhood Lead Poisoning*, JOURNAL OF PUBLIC HEALTH MANAGEMENT AND PRACTICE (Nov. 2006).

126. 61 FED. REG. 45779 (Aug. 29, 1996).

127. Nicolaas Bouwes, U.S. ENV. PROT. AGENCY, TSCA TITLE IV, SECTIONS 402(A) AND 404: TARGET HOUSING AND CHILD-OCCUPIED FACILITIES FINAL RULE REGULATORY IMPACT ANALYSIS vii (1996). Additionally, researchers estimate that for each cohort of children aged 0-6, preventing lead poisoning saves taxpayers \$51 billion in societal costs. See Gould, *supra* note 2.

128. *Id.* at 3-14.

129. In 2015 and 2016, EPA enforced the RRP Rule against Lowes, Sears and The Home Depot, even seeking criminal sanctions for repeated failure to use certified contractors. See

4. *The Lead Disclosure Rule promotes the necessary education on the risks of lead hazards and must be enforced.*

The Lead Disclosure Rule¹³⁰ is mandated by Title X and gives “prospective home purchasers and lessees access to information that might otherwise have been unavailable or that they might have been able to acquire only through their own effort and at some cost.”¹³¹ In promulgating the rule, the EPA stated that, “the information will generate health benefits by leading many purchasers and lessees to modify their behavior in a way that will reduce risks from lead-based paint.”¹³² As a result, the rule ensures that purchasers and renters of older housing make informed housing and maintenance decisions before they become obligated under purchase or lease contracts. It also serves to educate all participants in target housing sales and leasing transactions of their rights and obligations, as well as the dangers of lead poisoning.

Ultimately, the Lead Disclosure Rule is dependent upon HUD’s and EPA’s diligent enforcement. At the same time, Title X mandated that EPA promulgate regulations for the disclosure of lead-based paint hazards before the sale or rental of a property and gave EPA subpoena power to enforce the disclosure rule.¹³³ We request that EPA increase enforcement activities to better educate the public and protect children from exposure to lead hazards.

EPA should improve this rule by requiring risk assessments and abatement of lead hazards in homes prior to the sale or rental of a property . . . EPA should integrate lead in drinking water into lead hazard disclosure requirements in connection with buying or renting housing, in addition to the presence of lead-based paint. This would result in much greater protections, increased business for lead hazard renovation firms and contractors, and, ultimately, the end of lead poisoning.

5. *EPA should better coordinate with other federal agencies in Environmental Justice Communities and ensure that residents in lead-contaminated communities receive increased coordination to limit exposure.*

Environmental Justice Communities rely on myriad environmental laws to provide protection of residents from cumulative lead hazards. TSCA, Title X, the Lead Disclosure Rule, RRP Rules and updated lead hazard standards are critical for reducing the overall risk posed to their communities by lead. Congress recognized the need for these rules when it enacted TSCA. The language of TSCA explicitly requires EPA to develop and enforce rules to further the mission of the

<https://www.epa.gov/enforcement>.

130. 40 C.F.R. § 745.100.

131. 61 Fed. Reg. 9080 (Mar. 6, 1996).

132. *Id.*

133. 42 U.S.C. § 4852d (2012); 15 U.S.C. § 2689 (2012).

statute.¹³⁴ The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) also covers lead contamination in soil and indoor dust. EPA must address such contamination in the remediation of hazardous waste sites. When a CERCLA site involves residential homes, the TSCA and CERCLA requirements must work together to reduce the residents' cumulative exposures to lead. For instance, in the Omaha Lead Superfund Site, EPA specifically noted in its record of decision that “[s]ampling data transmittals constitute a lead hazard record under HUD and TSCA regulations, which must be disclosed by property owners to buyers prior to purchase, and must be disclosed by landlords to tenants upon lease signing and renewal.”¹³⁵ Yet, at the USS Lead Superfund Site, many homeowners have bought homes without the proper disclosures. All lead-related programs must be better coordinated and strengthened in order to increase enforcement of the disclosure and certification requirements.

6. *EPA should protect children's health by eliminating exposure to lead in the air.*¹³⁶

New lead hazards are introduced into children's environments due to a variety of industrial sources, including battery recyclers, aviation fuel, and power plants, among others. These sources emit new lead, contaminating homes, schools, parks, playgrounds, and daycare centers. Children's exposure to lead from air pollution must be addressed.

EPA should set significantly stronger national emission standards for battery recyclers (also known as secondary lead smelters), which are currently under reconsideration at EPA.¹³⁷ These sources use smelting or processing techniques that emit lead. More than 80,000 people experience elevated health threats from the 14 facilities currently operating in 11 states and Puerto Rico. Children, low-income households, and communities of color are disproportionately exposed to these facilities. In the most-affected communities, children are 30 percent of the exposed population, 41 percent are people of color, and 52 percent are Latino or

134. 15 U.S.C. § 2683; 15 U.S.C. § 2686.

135. *Omaha Lead Superfund Site Record of Decision*, 27 (2009), https://archive.epa.gov/region07/cleanup/npl-archive/web/pdf/record_of_decision.pdf

136. See “Plan of Action to Prevent Childhood Lead Exposure” *supra* note 72.

137. See *Sierra Club et al.*, PETITION FOR RECONSIDERATION OF NATIONAL EMISSIONS STANDARDS FOR HAZARDOUS AIR POLLUTANT EMISSIONS FROM SECONDARY LEAD SMELTING AND SUPPLEMENTS TO THIS PETITION, 77 FED. REG. 556 (Jan. 5, 2012), Dkt. ID Nos. EPA-HQ-OAR-2011-0344-0211 (Mar. 5, 2012), EPA-HQ-OAR-2011-0344-0189 (June 21, 2012) and SUPPLEMENT TO GRANTED PETITION FOR RECONSIDERATION OF NATIONAL EMISSIONS STANDARDS FOR HAZARDOUS AIR POLLUTANTS FROM SECONDARY LEAD SMELTING (filed Jan. 31, 2014); see also U.S. ENV. PROT. AGENCY, OFC. OF AIR QUAL. PLANNING & STANDARDS, OFC. OF AIR & RADIATION, RESIDUAL RISK ASSESSMENT FOR SECONDARY LEAD SMELTING SOURCE CATEGORY (Dec. 2011), Dkt. ID No. EPA-HQ-OAR-2011-0344-0160.

Hispanic.¹³⁸ At the same time, EPA should create a plan to reduce children's exposure to new lead-in-air emissions from other major industrial sources. For example, electric power plants emit about 63,711 pounds of lead per year.¹³⁹ The Toxic Release Inventory for 2014 documented a total of 367,761 pounds per year of lead air emissions from all reporting industries.¹⁴⁰ Reducing these exposures will protect children and is necessary to protect workers at these facilities.

EPA should immediately ban leaded aviation fuel (avgas), which contributed 59 percent of the National Emission Inventory in 2011 and is the single largest source of lead in the air.¹⁴¹ Studies have shown that children's blood lead levels increase dose-responsively in proximity to the airports used by piston engine aircraft¹⁴² A recent MIT study estimated nationwide economic losses of over \$1 billion annually due to the IQ deficits caused by leaded avgas emissions alone.¹⁴³ EPA must issue an endangerment finding and ban or phase out leaded avgas in general aviation aircraft. In the meantime, EPA should require airports where leaded fuel is in use to monitor and report ambient air.

Additionally, EPA should protect children's health by strengthening the National Ambient Air Quality Standard (NAAQS) for lead to reduce ambient air levels.¹⁴⁴ The Lead NAAQS established in 2008 are insufficient to protect children's health.¹⁴⁵ EPA must lower the NAAQS for lead, and we support the

138. EC/R INC., MEMO, PREPARED FOR .S. ENV. PROT. AGENCY OAQPS, RISK AND TECHNOLOGY REVIEW -- FINAL ANALYSIS OF SOCIO-ECONOMIC FACTORS FOR POPULATIONS LIVING NEAR SECONDARY LEAD SMELTING FACILITIES (Dec. 2011), Dkt ID No. EPA-HQ-OAR-2011-0344-0161.

139. See Env'tl. Integrity Project, *America's Top Power Plant Toxic Air Polluters* (Dec. 2011), available at <http://www.environmentalintegrity.org/documents/Report-TopUSPowerPlantToxicAirPolluters.pdf>.

140. U.S. ENV. PROT. AGENCY, 2014 TRI NATIONAL ANALYSIS (updated Jan. 2016) available at https://www.epa.gov/sites/production/files/2016-01/documents/tri_na_2014_complete_english.pdf

141. EMISSIONS INVENTORY & ANALYSIS GRP., OFFICE OF AIR QUALITY PLANNING & STANDARDS, U.S. ENV. PROT. AGENCY, PROFILE OF THE 2011 NATIONAL AMBIENT AIR EMISSIONS INVENTORY at 20 (Apr. 2014), available at https://www.epa.gov/sites/production/files/2015-08/documents/lite_finalversion_ver10.pdf; cf. 2018 Federal Action Plan at 10 (stating that EPA should "evaluate the impacts of lead emissions from aircraft using leaded aviation fuel" rather than acknowledge established science on its impacts).

142. See Marie Lynn Miranda et al., *A Geospatial Analysis of the Effects of Aviation Gasoline on Childhood Blood Lead Levels*, 119 ENVTL. HEALTH PERSP. 1513 (Oct. 2011); Sammy Zahran et al., *The Effect of Leaded Aviation Gasoline on Blood Lead in Children* (Aug. 2014), available at <http://mpira.ub.uni-muenchen.de/62238/>.

143. See Philip J. Wolfe et al., *Costs of IQ Loss from Leaded Aviation Gasoline Emissions*, 50 ENVTL. SCI. & TECH. 9,026 (2016).

144. See R. Chari et al., Integrating Susceptibility into Environmental Policy: An Analysis of the National Ambient Air Quality Standard for Lead, Mar. 27, 2012, INT'L J. ENVIRON. RES. PUBLIC HEALTH 2012, 9, 1077-1096, at 1084-85 (Mar. 27, 2012) (summarized in NRDC et al. Follow-up and Supplement to Petition for Reconsideration on Secondary Lead Smelting (June 27, 2012)).

145. LETTER FROM SHEELA SATHYANARAYANA, CHPAC TO GINA MCCARTHY, U.S. ENV. PROT. AGENCY (Jan. 8, 2015) ("CHPAC 2015 Letter"), available at

Children’s Health Protection Advisory Committee’s 2015 recommendations to: (1) Reduce the standard to 0.02 $\mu\text{g}/\text{m}^3$ or below; (2) Require a more robust lead particulate monitoring network; and (3) Base the standard’s measurements on an averaging period of one month.

The current NAAQS only seeks to avoid an air-related *population mean* IQ loss in excess of 2 points.¹⁴⁶ The federal government should not accept such a significant IQ loss in children, especially when these impacts do not fall equally across the country, but hit poor children and communities of color the hardest.

D. U.S. Department of Health and Human Services (HHS) must ensure universal lead testing for children and increase funding for programs that combat the effects of lead poisoning.

1. The Centers for Medicare & Medicaid Services should enforce existing protections and increase activities to identify and treat lead hazards and exposure.

The Centers for Medicare & Medicaid Services (CMS) should enforce existing protections and use available innovations to identify and treat lead exposure in Medicaid-eligible populations, particularly children. Children served by Medicaid have the greatest risk of exposure to lead, but are currently screened at low rates despite the federal early, periodic, screening, diagnostic, and treatment (EPSDT) requirements.¹⁴⁷ Adults exposed to lead also require treatment and access to ongoing care to ameliorate the effects of lead exposure as much as possible. CMS should focus on helping states meet existing requirements for children and using existing tools to innovate programs to identify and address lead exposure in high-risk areas. CMS should also coordinate with other federal programs to identify individuals at high-risk for lead exposure, screen for lead exposure and side effects, and provide treatment and appropriate services to ameliorate the effects of exposure and remediate the exposure source.

a. CMS should focus efforts on helping states meet the affirmative obligation to inform families of lead screening and to ensure children are screened, diagnosed, and have ongoing access to appropriate treatment.

Under the Medicaid Act, states have an affirmative obligation to conduct outreach efforts to inform parents and caregivers about EPSDT services and the

https://www.epa.gov/sites/production/files/2015-01/documents/naaqs_for_lead_letter.pdf

146. 73 FED. REG. at 67,006 (stating that EPA set the NAAQS at 0.15 $\mu\text{g}/\text{m}^3$ based on the finding that “the estimated mean IQ loss from air-related Pb in the subpopulation of children exposed at the level of the standard would generally be somewhat to well below 2 IQ points”).

147. Jaime Raymond et al., *supra* note 15; Joshua Schneyer & M.B. Pell, *Unsafe at Any Level: Millions of American children missing early lead test, Reuters finds*, REUTERS (June 9, 2016), available at <https://www.reuters.com/investigates/special-report/lead-poisoning-testing-gaps/>.

importance of preventive care and early detection of health and mental health conditions in children.¹⁴⁸ Information about EPSDT benefits and services must be provided in a format that can be easily understood, including translated written materials and oral interpretation if the child's family has difficulty reading or understanding English. States must also offer assistance in scheduling appointments prior to each due date of a child's periodic examination, as well as transportation services to get children to and from health providers.¹⁴⁹ However, parents, such as those in East Chicago as discussed above, often report lack of knowledge about lead screening, treatment, assistance with appointments, and transportation. In other areas, parents report that although they can get a child to the appointment, the barriers associated with getting blood test results prevent the parent from obtaining the screening results and often subsequent treatment for the child.¹⁵⁰

In addition to ensuring parents and caregivers understand the EPSDT benefits available, states must also ensure that children have access to providers who are qualified and willing to provide EPSDT services. States must "arrang[e] for (directly or through referral to appropriate agencies, organizations, or individuals) corrective treatment" that a child needs.¹⁵¹ Medicaid programs are required to "correct or ameliorate physical and mental illnesses and conditions" that are detected in Medicaid eligible children.¹⁵² However, certain types of service providers, such as pediatricians, are sometimes difficult to access. Even when children have pediatricians, they may not be receiving all of the appropriate screens. Although states have this affirmative obligation, the screening rates for children receiving Medicaid benefits are shockingly low. Despite the requirements that children be screened at 12 and 24 months, no state had a screening rate of more than 10 percent for children under the age of one in 2015.¹⁵³ Citing the public health crisis in Flint, Michigan, which was identified initially through EPSDT data, CMS issued an informational bulletin in late 2016 regarding lead screening.¹⁵⁴ This letter reviewed the Medicaid and CHIP requirements for lead screening and some ideas for states to increase screening rates. While this information is helpful to

148. 42 U.S.C. § 1396a(a)(43)(A); 42 C.F.R. §§ 441.50-441.62.

149. 42 U.S.C. § 1396a(a)(43)(C); *O.B. v. Norwood*, 2014 WL 5335494 (7th Cir. 2016).

150. For example, in the District of Columbia parents are expected to take the blood sample across town to a lab. Even if the parent has transportation, this may cost the family such time and money that a significant barrier to care is created by the District's policies.

151. *Id.*

152. 42 U.S.C. § 1396d(r)(5).

153. Medicaid.gov, FY 2015 EPSDT Data, available at <https://www.medicaid.gov/medicaid/benefits/epsdt/index.html>.

154. CMS INFORMATIONAL BULLETIN, COVERAGE OF BLOOD LEAD TESTING FOR CHILDREN ENROLLED IN MEDICAID AND THE CHILDREN'S HEALTH INSURANCE PROGRAM (Nov. 30, 2016) available at <https://www.medicaid.gov/federal-policy-guidance/downloads/cib113016.pdf>.

states, CMS should take a more active role in monitoring screening rates and providing strong technical assistance to states to increase those rates, put in place robust programs for outreach and treatment, and resolve barriers to lead screening and treatment for both Medicaid and CHIP.

Medicaid is somewhat limited in what it can cover in terms of remediating the source of exposure, but most state policies only focus on the screening requirements and do not include other available related services. Policies on blood lead level screening and treatment are often not robust and at times may even be inaccurate. For example, some states have outdated policies that do not reflect the change from 10 µg/dL to 5 µg/dL or say that a child should meet risk factors before being screened for blood lead levels. We recommend that CMS direct states to adopt an action level of 5 µg/dL or lower in order to intervene early and potentially prevent lead poisoning among siblings and other children residing in the building.

Many state policies do not include the availability of an environmental survey under Medicaid which is used to identify the sources of exposure in a child's environment; such a survey is critical to minimizing further exposure. In addition, although the American Academy of Pediatrics has issued guidance on the services that a child should receive based on the screened blood lead level, most states have minimal EPSDT policies that only cite the requirements of screening at 12 and 24 months.¹⁵⁵ State policies as they currently exist often fail to give providers guidance as to the treatment services that will be covered at different blood levels. EPSDT requires the state Medicaid program to cover medically necessary services so this type of guidance may seem unnecessary, but it can help providers by giving them a clear indication of the services that will be covered without additional authorization hurdles.

To effectively address lead exposure, there should be strong coordination between the state Medicaid agency, housing authorities, local code enforcement, and educational entities. Such coordination would ensure a child has the best opportunity for strong development and adults have access to the services they need. Information for families and those affected about the exposure and available resources that is provided in an effective and accessible way is also critical. Many families also need assistance with understanding and accessing services targeted to remediating and preventing further lead exposure. This information and assistance should be provided to families on an ongoing basis until the exposure source is remediated. Even after a family moves out of an exposure area, they would need continued monitoring, screening, and treatment as a previously exposed child develops to check for side effects and provide appropriate services.

155. AAP COUNCIL ENVTL. HEALTH, *Prevention of Childhood Lead Toxicity*, 138(1) PEDIATRICS 1, 10 (June 2016), available at <http://pediatrics.aappublications.org/content/early/2016/06/16/peds.2016-1493>.

For example, a developmental screen at the pediatrician's office may require ongoing coordination with medical services and the child's school system to ensure that child's needs are met over several years.

As explained previously, children exposed to lead are known to have an array of immediate and long-term side effects. States should not only have clear policies about the immediate services that would be authorized, but should also have longer term services identified to screen and treat known side effects of lead. Monitoring programs for children identified with elevated blood lead levels would also help ensure the state Medicaid program is meeting the ongoing EPSDT requirements. This could occur through targeted care coordination or other mechanisms. The long-term effects of EPSDT and the need for ongoing monitoring are exactly the type of issues EPSDT is intended to address, as shown by the history and purpose of the benefit.¹⁵⁶ CMS should work with states, clinicians, and advocates to identify best practices and then provide guidance and technical assistance to states, incentivizing implementation of such practices where possible.

b. Adults eligible for Medicaid benefits must also have access to services related to lead exposure.

The State's obligation to correct or ameliorate the adverse effects of lead poisoning extends not only to the children with detectable EBLs. Children have specific rights in regards to lead screening and treatment under EPSDT, but adult Medicaid beneficiaries must have access to covered services that are related to lead exposure.¹⁵⁷ Adults must have access to providers for treating both the physical and behavioral side effects of lead exposure. As discussed previously, there are both immediate and long-term side effects to lead exposure. Not only do individuals need treatment for their own exposure, but caregivers may also need mental health services stemming from a child's exposure to lead and the lifelong, harmful effects such exposure has on a child. In addition, pregnant women and nursing mothers need access to information and services to address issues related to their exposure and any effects on a fetus or breastfeeding child. Pregnant women and children are particularly vulnerable to lead exposure, as they can absorb more

156. Sara Rosenbaum, *When old is new: Medicaid's EPSDT benefit at fifty, and the future of child health policy*, MILLBANK QUARTERLY (Dec. 2016), available at <https://www.milbank.org/quarterly/articles/old-new-medicaids-epsdt-benefit-fifty-future-child-health-policy/>. EPSDT was not part of the original Medicaid Act but was added in two years later as a policy response to the research carried out by Head Start that documented the extent of physical and mental conditions that could have lifelong consequences in the children served by the program that could be ameliorated, but were not being treated. The increased focus on services for children was also a response to the report on the high disqualification rates of Select Service draftees due to physical and mental disabilities, which illustrated the consequences for national security of child health neglect.

157. 42 U.S.C. § 1396d(r)(1)(B)(iv); 42 U.S.C. § 1396a(a)(43)(C); § 1396a(30)(A).

ingested lead than the general adult population.¹⁵⁸

Medicaid managed care and section 1115 demonstration projects offer other mechanisms for Medicaid to provide focused efforts to identify, treat, monitor, and coordinate care for individuals exposed to lead. States that use managed care should use performance improvement projects to increase screening rates, improve treatment, and provide long-term monitoring. Depending on which authority a state uses to implement managed care, a state could direct that managed care savings or in lieu of services be used to target lead screening, treatment, and amelioration. States could also use the section 1115 demonstration authority to offer a targeted program to screen Medicaid beneficiaries and then provide services, including enhanced coordination of services and resources, and other tools to address the exposure. Currently, Michigan has a Section 1115 demonstration waiver to help address the lead exposure in Flint. While this demonstration provides expanded eligibility and services for city residents, the section 1115 demonstration authority could be used to innovate programs that would focus on areas with high exposure risks for lead. Although states have the authority under EPSDT to screen and treat children, including providing targeted case management, a section 1115 demonstration project could provide a more comprehensive program with an array of Medicaid services specific to lead exposure to more than just Medicaid eligible children and coordinate with EPSDT to provide a systemic approach to addressing areas with high risk of lead exposure. Preventing and remediating lead exposure is critical to health, especially long-term health and well-being, and should be a target of CMS and its focus on innovation and flexibility for states.

2. *Centers for Disease Control and Prevention (CDC) must update the reference value for lead poisoning.*

The CDC should fulfill its commitment to updating the definition of the elevated blood lead “reference value.”¹⁵⁹ In 2012, the CDC stated that it would update the reference value every four years, based on the most recent NHANES data.¹⁶⁰ HHS and CDC should mandate that state agencies move to the more protective level, to ensure environmental investigations and medical case management services in each state follow the CDC blood lead reference level. Currently, many states utilize outdated reference levels, depriving children with

158. Suzanne McDermott et al., *Probability of Intellectual Disability is Associated with Soil Concentration of Arsenic and Lead*, 84 CHEMOSPHERE 32 (2011).

¹⁵⁹ Cf. 2018 Federal Action Plan at 12 (committing only to “evaluat[ing] updating the blood lead reference value” rather than fulfill its commitment to do so.”)

160. See CTRS. FOR DISEASE CONTROL & PREV., NEW BLOOD LEAD LEVEL INFORMATION (last updated Mar. 15, 2016), http://www.cdc.gov/nceh/lead/acclpp/blood_lead_levels.htm. (“CDC will update the reference value every 4 years using the two most recent NHANES surveys.”).

elevated blood lead level access to resources and assistance to mitigate the harm from lead exposure.

3. *HHS should increase funding for Head Start and Early Head Start Child Care Partnership Programs in communities with high levels of lead.*

Especially in communities at risk of cumulative exposure from lead from lead in paint, soil, and/or pipes, HHS should increase funding for Head Start and the Early Head Start Child Care Partnership programs. In Flint, Michigan, HHS expanded Head Start and Early Head Start Partnership Program to address the lead epidemic in the community in an effort to combat the effects of lead poisoning.¹⁶¹ It is essential that children in communities with cumulative exposure obtain all interventions that are known to help children at risk of developmental disabilities from lead poisoning.

4. *The National Institute of Health should increase research on the effects of lead poisoning.*

The National Institutes of Health (NIH) should continue to fund research into the effects of lead poisoning at even lower levels of lead exposure. Research has been critical to improving our understanding of the substantial impairment and long-term effects that can occur at lower lead poisoning levels. NIH should also fund research into other treatments and methodologies to mitigate the effects and impact of childhood lead poisoning on health, behavioral, education and social outcomes.

5. *The Children's Bureau should collaborate with other agencies to ensure children in foster care and in programs aimed at keeping families together receive priority access to lead abatement funds.*

Section 42 U.S.C. § 671(a)(10)(A) requires states to establish standards for foster family homes and child care institutions which “are reasonably in accord with recommended standards of national organizations concerned with standards for the institutions or homes, including standards related to . . . safety”¹⁶² The Lead Safe Housing Rule does not cover foster homes and foster children are thus at risk of moving to homes with lead hazards. Federal policy should ensure that foster homes and programs that work to keep families together receive expedited

161. Michigan Head Start Association, “Genesee County Receives \$5.5 Million for Early Head Start” (Mar. 20, 2017) available at <http://michheadstart.org/news/genesee-county-receives-55-million-early-head-start>

162. See e.g. Ana Beltran and Heidi Redlich Epstein “Improving Foster Care Licensing Standards around the United States: Using Research Findings to Effect Change” (Mar. 2012) available at https://www.americanbar.org/content/dam/aba/administrative/child_law/FC_Licensing_Standards.authcheckdam.pdf

access to grant programs for lead hazard abatement after receiving a risk assessment. It is vital that a strong partnership occur with foster parents to ensure education of lead hazards and abatement protocols are affordable for foster parents and incentivize families to participate in the foster program. Priority funding is likewise necessary to ensure that children who are most at risk are protected. Without this, states receiving federal funding are not adequately ensuring that children are living in lead safe homes.¹⁶³

6. *The Health Resources and Services Administration's (HRSA) Maternal and Child Bureau should prioritize lead poisoning prevention and risk identification in all programs.*

The Maternal and Child Health Services Block Grant Program (Title V) has provided critical support to improve the health of the nation's women, mothers, children, and youth. At least 30% of federal Title V funds are designated for children with special health care needs. States can use these funds to provide education and counseling to families with EBLL at or above 5 µg/dL. Title V is an ideal vehicle for lead poisoning prevention and identification of at risk children and infants. It requires states to work collaboratively, a unique partnership between federal, state, and local entities, and includes infrastructure, population-based, enabling and direct services for the maternal and child population.¹⁶⁴ In addition, each state must identify priorities to comprehensively address the needs of the population and may serve as the payer of last resort for direct services. HRSA should issue guidance and best practices directing states to use Title V funds for lead poisoning prevention education and the identification of at risk children and infants. In addition, HRSA should direct states to use Title V funds to address lead poisoning and lead hazards in order to prevent poor health outcomes among women and children.

HRSA also implements the Maternal, Infant, and Early Childhood Home Visiting Program to provide pregnant women resources and skills to raise children. Professionals conducting home visits should be trained in educating families about lead poisoning prevention and identifying those families who are at high risk of lead poisoning. Social service supports should include assistance contacting providers to schedule blood lead level tests and public health departments for lead hazard risk assessments where indicated.

163. Marissa Hauptman & Alan D. Woolf, "Lead Poisoning and Children in Foster Care: Diagnosis and Management Challenges" *CLINICAL PEDIATRICS* (Oct. 3, 2017), *available at* <https://doi.org/10.1177/0009922817734364>

164. U.S. DEP'T OF HEALTH & HUMAN SERVS., EDUCATIONAL SERVICES FOR CHILDREN AFFECTED BY LEAD EXPERT PANEL. EDUCATIONAL INTERVENTIONS FOR CHILDREN AFFECTED BY LEAD. (2015) *Available at* https://www.cdc.gov/nceh/lead/publications/educational_interventions_children_affected_by_lead.pdf (hereinafter EDUCATIONAL SERVICES FOR CHILDREN AFFECTED BY LEAD EXPERT PANEL).

7. *The Food and Drug Administration (FDA) should protect the public from lead in personal care products, as well as in imported food, folk medicines and cosmetics.*¹⁶⁵

Currently, lead acetate is permitted and used in various hair dye and hair conditioning products. In 1962, Congress made clear that the FDA may only register a color additive if it finds “convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of the color additive.”¹⁶⁶ A peer-reviewed study determined that the use of these products results in the widespread contamination of household surfaces and exposes all family members to the toxin.¹⁶⁷ The FDA states that lead acetate is safe because these products do not penetrate the scalp.¹⁶⁸ The FDA’s assertions are flawed because they do not take into account the dangers to children when lead residue is spread throughout the home through the user’s hands. As one study noted, “Given the requirement to continually reapply these hair coloring agents, the user becomes a living purveyor of lead contamination.”¹⁶⁹ FDA should immediately withdraw approval of lead acetate as a color additive in hair dye, and in any other personal care product or cosmetic. The FDA was petitioned by 61 organizations, 217 individuals, and 26,198 signatures to ban lead acetate from hair dye and has since missed the statutory deadline to respond. The agency must fulfill its obligations under the Federal Food, Drug, and Cosmetic Act immediately.

Lead is also found in a variety of FDA-regulated products imported into this country, such as traditional folk remedies,¹⁷⁰ cosmetics, face paint, and contaminated foods—significant sources of exposure in some communities. FDA must do more to ensure that these products are lead-free.¹⁷¹

E. *The Consumer Product Safety Commission (CPSC) should protect*

165. See “Plan of Action to Prevent Childhood Lead Exposure” *supra* note 72.

166. 21 CFR § 70.1(i).

167. Mielke, Howard W. Taylor, Myiesha D. Gonzales, Chris R. et al., *Lead-Based Hair Coloring Products: Too Hazardous for Household Use*. J. AM. PHARM. ASS’N, Volume 37, Issue 1, 85 - 89.

168. FOOD & DRUG ADMIN., LEAD ACETATE IN “PROGRESSIVE” HAIR DYE PRODUCTS (*last updated* Mar. 13, 2014), <http://www.fda.gov/Cosmetics/ProductsIngredients/Products/ucm143075.htm>

169. Mielkem *supra* note 138.

170. U.S. DEP’T OF HEALTH & HUMAN SERVS., DC, FOLK MEDICINE (last updated Oct. 15, 2013), available at <https://www.cdc.gov/nceh/lead/tips/folkmedicine.htm>; DEP’T OF PUB. HEALTH, CNTY OF LOS ANGELES, TRADITIONAL AND HOME REMEDIES KNOWN TO CONTAIN LEAD, available at <http://publichealth.lacounty.gov/eh/docs/Lead/FolkRemediesFlyer.pdf> (last visited Nov. 24, 2017).

¹⁷¹ Cf. 2018 Federal Action Plan at 11 (“Issue final guidance for a *maximum lead level* in cosmetic products”) (emphasis added)

*consumers from lead in household products.*¹⁷²

CPSC also has the authority and obligation to protect consumers from lead in household products. CPSC should use its authority under the Federal Hazardous Substances Act to ensure that all consumer products are free of lead. Although lead in excess of 100 ppm is banned in “children’s products,” lead is still used in other common household products with which children come into contact, such as popular reclaimed wood products, or are used by children but which do not fall within the definition of “children’s products,” such as novelty jewelry.¹⁷³ CPSC should move forward promptly to protect children by banning lead in all household products.

CPSC must do more—using its recall authority under the Federal Hazardous Substances Act—to protect children from lead in products that remain in many homes, even if they are no longer sold in this country, such as Christmas tree lights, vinyl mini-blinds and other kinds of plastic that contain lead, which release lead-contaminated dust as the plastic breaks down.¹⁷⁴

F. U.S. Department of Education must include lead poisoning as an automatic qualifier for early intervention and appropriate special education services.

The Department of Education (DOE) should issue guidance on the special education and early intervention services available to assist children who have been lead poisoned. As described above, low-level lead exposure has negative effects on the brain’s learning systems, including “overall intellectual ability, speech and language, hearing, visual-spatial skills, attention, executive functions, social behavior, and fine and gross motor skills.”¹⁷⁵ Studies demonstrate that children with, or at high risk for, developmental delays benefit most from interventions that start at an early age.¹⁷⁶ DOE administers the Individuals with Disabilities Education Act (IDEA), which provides federal funds and oversight for early intervention and special education and related services for children with

172. EDUCATIONAL SERVICES FOR CHILDREN AFFECTED BY LEAD EXPERT PANEL, *supra* note 135.

173. For example, a 2015 report on toxic substances in items sold in dollar stores identified earrings sold at Family Dollar containing 6,500 ppm of lead. ECOLOGY CTR., 2015 DOLLAR STORE REPORT (Feb. 4, 2015), *available at* <http://www.ecocenter.org/healthy-stuff/reports/dollar-store-report>.

174. EPA has acknowledged the lead hazard posed by some vinyl mini-blinds. U.S. ENV. PROT. AGENCY, HOME DANGER ZONE FINDER (last updated Dec. 28, 2015), *available at* <https://www.epa.gov/lead/home-danger-zone-finder-0> (“Some imported, non-glossy vinyl mini-blinds can be a lead hazard. Sunlight and heat can break down the blinds and may release lead-contaminated dust.”).

175. EDUCATIONAL SERVICES FOR CHILDREN AFFECTED BY LEAD EXPERT PANEL, *supra* note 135.

176. *Id.*

disabilities. Part C of IDEA serves infants and toddlers through age 2. Part B of IDEA funds special education services for children ages 3-21 with disabilities. Child Find is an identification program that places an obligation on states to identify and evaluate children for services, including those with a history of exposure to lead or a history of EBLL. In order to qualify for services, infants or toddlers must meet their state's eligibility definition of developmental delay or have a diagnosed condition that carries a high probability of causing developmental delays.¹⁷⁷ States have the discretion of providing services to infants and toddlers who are at risk for substantial developmental delays if they do not receive appropriate early intervention services.¹⁷⁸ Established risks include "exposure to toxic substances."¹⁷⁹ States may include a child who is at risk for experiencing developmental delays because of biological or environmental factors that can be identified.¹⁸⁰ Yet, as of 2012, only eight states explicitly mention lead exposure as an eligible condition for services or tracking.¹⁸¹ Twelve states include EBLL levels ranging from >10 µg/dL to >45 µg/dL as meeting early intervention eligibility.¹⁸² Thirteen states mention "toxic" exposures as meeting eligibility criteria.¹⁸³ Similarly, children with lead poisoning or a past EBLL may be eligible for Part B under the "other health impairment" category in the eligibility criteria. DOE should issue guidance recommending that all states include lead poisoning and/or "exposure to toxic substances" in the eligibility criteria for Part C and a history of lead poisoning in the "other health impairment" category for Part B eligibility.

G. U.S. Department of Agriculture (USDA) should ensure that children have access to healthy foods, children are not exposed to hazards while living in Rural Development (RD) housing, and families have access to loans to abate lead hazards.

1. The USDA should increase funding for programs in at-risk communities, especially in communities at high risk of cumulative exposure from lead in paint, soil, and/or pipes or where high levels are identified

177. 20 U.S.C. §1432(5).

178. 20 U.S.C. § 1432(1); 20 U.S.C. § 1432(5)(B).

179. Barth, R. P., Scarborough, A., Lloyd, E. C., Losby, J., Casanueva, C., & Mann, T. *Developmental Status and Early Intervention Service Needs of Maltreated Children* U.S. DEP'T OF HEALTH & HUMAN SERVS, OFFICE OF THE ASSISTANT SECRETARY FOR PLANNING AND EVALUATION (Washington DC, 2007) available at <http://aspe.hhs.gov/hsp/08/devneeds/apa.htm>.

180. 20 U.S.C. § 1432(3)(B); 34 C.F.R. § 303.10.

181. See Appendix 2, EDUCATIONAL SERVICES FOR CHILDREN AFFECTED BY LEAD EXPERT PANEL, *supra* note 135.

182. *Id.*

183. *Id.*

through any individual source.

The USDA should increase access to public benefits and funding for programs in at-risk communities, especially in communities at high risk of cumulative exposure from lead in paint, soil, and/or pipes or where high levels are identified through any individual source. It is essential that children in communities with cumulative exposure obtain all interventions that are known to help children at risk of developmental disabilities from lead poisoning.

The response in Flint, Michigan is illustrative of the type of response essential to combat the effects of lead that should be expanded to all high risk communities.¹⁸⁴ In Flint, USDA expanded programs that promote access to healthy school lunches and encouraged all eligible schools to participate the Community Eligibility Provision that ensures access to free school meals for all eligible school children. This response, when coupled with an increase in funding through the Fresh Fruit and Vegetables Program, provided healthy foods that can combat the effects of lead poisoning for vulnerable children. Additionally, the USDA granted funds to Michigan to extend Summer Electronic Benefit Transfer (EBT) funds to ensure greater access to healthy meals in the summer. Families who qualified for Women, Infants, and Children (WIC) assistance were also allowed to use WIC benefits for ready-to-feed formula that did not need to be mixed with water, and for lead testing for WIC recipients¹⁸⁵, and the WIC Farmers Market Nutrition program was expanded to provide access to healthy foods that lead absorption.¹⁸⁶ The USDA also worked with local partners through The Emergency Food Assistance Program (TEFAP) to deliver foods rich in calcium, iron, and Vitamin C (nutrients—which are known to help combat lead absorption in the body) to the local food banks. Last, USDA worked with local partners to ensure greater community nutrition education targeted to limit absorption of lead.

2. USDA Rural Development Housing should update its guidance under the Lead Safe Housing Rule and increase lead hazard remediation services

184. U.S. DEP'T OF AGR., FACT SHEET: USDA ASSISTANCE TO RESIDENTS AFFECTED BY THE WATER EMERGENCY IN FLINT, MICHIGAN"(Last Updated: Aug. 16, 2016) *available at* <https://www.usda.gov/media/press-releases/2016/02/10/fact-sheet-usda-assistance-residents-affected-water-emergency-flint>

185. U.S. DEP'T OF AGR., USDA TO TEMPORARILY ALLOW WIC FUNDS TO BE USED FOR LEAD TESTING FOR FLINT-AREA WIC RECIPIENTS, ANNOUNCES OTHER MEASURES TO EXPAND ACCESS TO HEALTHY FOODS (Last Updated: Oct. 17, 2017) *available at* <https://www.fns.usda.gov/pressrelease/2016/003716>

186. U.S. DEP'T OF AGR., WIC FARMERS' MARKET NUTRITION PROGRAM (FMNP) (Last Updated: June 8, 2017) *available at* <https://www.fns.usda.gov/fmnp/wic-farmers-market-nutrition-program-fmnp>

in rural areas.

Rural Development should update its guidance¹⁸⁷ to comply with the recommendations set forth in Section I (1) of this letter. The USDA should also increase the level of housing repair and housing rehabilitation funding that is made available in rural areas for lead hazard remediation. The USDA should more directly market the use of those housing rehabilitation funds to owners for the permissible use on lead hazard interventions.

H. Funding for the Department of Energy Weatherization Assistance Program and the Department of Health and Human Services Low-Income Home Energy Assistance Program should be increased to allow for the replacement of leaded windows with lead free Energy Star windows under WAP and LIHEAP Programs respectively.

The Department of Energy (DOE) and HHS should recognize the expansive benefits that Weatherization Assistance Program (WAP) and the Low-Income Home Energy Assistance Program (LIHEAP) offers to reduce health and safety risks within the home. It is well established that a comprehensive housing intervention that integrates weatherization, energy efficiency, and healthy homes produces cost effective benefits that mitigate environment-related health problems and enhances the well-being of low-income households. In February 2012, HUD released the Lead-Paint Hazard Control Grant Program follow-up evaluation study, which was the first study to examine the long-term effects of window replacement. Of the 181 homes examined, most “were low-income at 12 years, with 65% under \$20,000/year, 17% from \$20,000–\$29,999/year, and 18% for \$30,000 or more per year”.¹⁸⁸ Twelve years following the intervention, homes that replaced all of their windows had 41% lower interior floor dust lead and 51% lower window sill dust lead compared to homes with non-replacement.¹⁸⁹ A testament that full window replacement yields a benefit that should be considered and funded.

Currently, under WAP’s technical manual window replacement is typically not allowed because it is not considered a justifiable cost; however, we propose the alternative, the Savings to Investment Ratio (SIR) should consider that replacing leaded windows is a justifiable cost because it directly correlates to lead

187. Tony Hernandez and Lillian Salerno Administrator, *Rural Development Compliance with Lead-Based Paint Rule*, RD AN No.4780 (1924-A), (Nov. 12, 2014) available at <https://www.rd.usda.gov/files/an4780.pdf>.

188. Sherry L. Dixon, David E. Jacobs, Jonathan W. Wilson, Judith Y. Akoto, Rick Nevin, and C. Scott Clark. *Window Replacement and Residential Lead Paint Hazard Control 12 Years Later*. ENVIRONMENTAL RESEARCH 113, 14-20 (2012).

189. *Id.*

prevention. Lead-free windows promotes an improved healthy home that produces benefits for the life of the home and its occupants. Therefore, we highly recommend that SIR for WAP and LIHEAP allow for lead free window replacement by including the monetized health benefits of lead free window replacement, which are \$6,847 in housing units built before 1940, \$2,847 in units built from 1940-1960, and \$632 in units built from 1960-1978 (in 2005 dollars).¹⁹⁰

I. Increased funding for lead hazard identification and remediation¹⁹¹ is essential to ending the lead epidemic.

Congress allocates funding annually to address lead hazards throughout the country. All agencies described above should request increased funding for lead hazard remediation to ensure children are no longer exposed to lead poisoning. While this section primarily focuses on HUD programs, all agencies with a role in lead poisoning prevention should dedicate increased funds to ending the lead epidemic.

1. Title X – Lead-Based Paint Hazard Reduction Act of 1992.

Each year, HUD uses funds to provide grants to states for the purposes of lead hazard control and elimination. The Lead-Based Paint Hazard Control (LHC) and Lead Hazard Reduction Demonstration (LHRD) Grant Programs are the primary grant source and are vital in reducing the amount of lead-based hazards present in our housing stock. As a result of these grants, lead hazards in over 190,000 housing units have been remediated or eliminated. In 2018, HUD is proposing to use these funds to address lead hazards in at least 8,400 units. With more support, these programs can target a greater number of at-risk housing units and continue to reduce the prevalence of childhood lead poisoning. To end lead poisoning as a major public health threat by remediating the most at risk housing in the US, low-income homes with lead hazards that are occupied by children under age 6, HUD and Congress should increase the budget for lead hazard reduction funding from \$110-\$130 million to \$2.5 billion annually for the next five years.¹⁹²

HUD should allow grantees of the HUD Office of Lead Hazard Control and Healthy Homes and other HUD programs to use funds to replace leaded water

190. *Id.*

191. This section was drawn from Green & Healthy Homes Initiative Comments to “Reducing Regulatory Burden; Enforcing the Regulatory Reform Agenda Under Executive Order 13777,” Docket No. HUD-FR-6030-N-01, June 14, 2017.

¹⁹² While HUD’s Office of Lead Hazard Control and Healthy Homes increased to \$230 million in FY 2019, and proposed a \$290 million budget in FY 2020, it is still insufficient to effectuate lead hazard reduction. HUD *Budget in Brief* 17 (2019) available at <https://www.hud.gov/sites/dfiles/CFO/documents/HUD2020BudgetinBrief03072019Final.pdf>

fixtures and lead service lines in homes in addition to paint related hazards. Other recommended key revisions to Title X include: mandate that lead risk assessments and testing be performed in pre-1978 properties of paint, soil and water prior to sale for any property not previously determined to be lead free; remove the exemption for zero bedroom dwelling units; and expand eligible HUD lead hazard reduction grantees to include nonprofit organizations.

2. *Healthy Homes Supplemental Funds.*

The HUD Healthy Homes Supplemental Funds provide grants to supplement Lead Hazard Control and Lead Hazard Reduction Demonstration Program grants to remediate other home-based environmental health hazards that contribute to asthma episodes, cancer, and unintentional injuries. In 2018, HUD is proposing to use these important funds to mitigate unhealthy conditions in 6,700 low-income older homes that will make homes healthier while supporting the expansion of healthy homes assessment and intervention practices in the field. We strongly urge HUD to keep funding for the Healthy Homes Supplemental Funds and Healthy Homes Technical Studies Grant Program. HUD should also adopt a healthy housing standard for HUD owned and assisted properties

3. *Community Development Block Grant Program.*

The CDBG Program is vital in supporting safer housing in low- and moderate-income communities. CDBG funds may be used directly to fund lead-hazard identification and abatement activities and may also be used to supply required matches to receive other lead control funding. CDBG funding is not listed in the 2016 inventory of federal programs addressing lead hazards, but should be recognized as an opportunity to provide federal support to local partnerships designed to reduce and eliminate lead hazards. In 2017, CDBG funds were expected to reach 1,200 entitlement grantees, 49 states, Puerto Rico, 3 non-entitled communities in Hawaii, and 4 Insular Areas. Many jurisdictions rely heavily on these funds to provide for lead hazard reduction grant resources and to support healthy housing measures and this program should not be eliminated from the HUD budget.

4. *HOME Investment Partnerships Program.*

The HOME Program provides grants to fund activities to build, buy, and rehabilitate affordable housing. The HOME Program's application and scoring criteria, along with technical assistance, should consider the proportion of housing in an applicant's jurisdiction that presents lead hazards and emphasize lead-abatement activities as a recommended use of HOME funds.

5. *Improving lead standards for HUD owned or assisted housing.*

HUD should require identification and lead hazard remediation of lead based paint hazards and lead service lines in all federally owned homes and homes with federally supported or insured mortgages through enhanced regulations and improved LSHR enforcement where applicable. HUD should require the remediation prior to sale of any lead hazards identified.

6. *203(k) loans and other financial incentives.*

Incentivize investment in lead-based paint remediation through creating a very low or no interest loan program accessible to homeowners and rental property owners. The program should be available as a loan product or mortgage instrument as well as a program to provide a solution for owners to identify, finance, and remediate lead hazards. HUD should support greater use of 203(k) loans for lead-based paint hazard remediation.

J. *Enhance Enforcement of the Lead-Protective Laws Through Greater Information-Sharing.*

The 2016 inventory includes Department of Justice (DOJ) activities around enforcing the protections secured by the Residential Lead Based Hazard Reduction Act and the Lead Renovation, Repair, and Painting Rule. The inventory notes that these actions recover funds that can be used for lead-abatement activities. By increasing information-sharing among local, state, and federal entities (e.g., local and state health departments and local building departments) about where lead hazards persist, enhanced enforcement of lead-protective laws can generate funding for abatement activities while also holding landlords accountable for identified but unaddressed lead hazards on their premises. HUD should also review local administrative plans to ensure compliance with recently enacted changes to the Lead Safe Housing Rule and associated guidance.

1. *Continued Research in lead hazard identification, remediation, and prevention is critical to eliminating lead poisoning*

The Task Force has requested recommendations for areas to focus on improving hazard controls and treatment of lead poisoning symptoms. In order to advance knowledge on the effects of lead hazards and to inform lead policies, programs, and legislation, the Task Force should analyze the likelihood that a property assessed to contain lead hazards will result in a child being poisoned by lead in the home.¹⁹³ The Task Force should analyze the effect of energy efficiency

193. GREEN & HEALTHY HOMES INITIATIVE, "STRATEGIC PLAN TO END CHILDHOOD LEAD POISONING: A BLUEPRINT FOR ACTION" (Oct. 2016), available at <http://www.greenandhealthyhomes.org/sites/default/files/GHHI-BlueprintforAction-Final.pdf>.

and weatherization on residents' health and safety outcomes as well as the value added to properties after receiving remediation services. In addition, the task force should investigate predictive modeling strategies to identify lead hazards before a child is lead poisoned.

The Task Force should work to improve public access to data that is currently not accessible.¹⁹⁴ Federal agencies should work with state and local agencies together to make lead-risk data and maps publicly available for families and policymakers alike. This data can help families and policymakers understand where there are sources of exposure, such as property-specific information on leaded drinking water pipes and lead in the water, dust, paint, and soil at or near homes, schools, and child care facilities.

Additionally, the Task Force should fill in gaps in research to better target prevention and response efforts. New studies should identify populations at greatest risk and identify the sources of lead exposure in various communities.

*2. Engage affected community members, state agencies and local stakeholders to address environmental health risks and safety risks of lead exposure in children.*¹⁹⁵

The success and sustainability of community-based interventions are dependent upon community engagement in identifying and defining the problems as well as setting and achieving goals for improvement.¹⁹⁶ The community-based participatory approach allows the members of the community to develop strategies that will address social determinants of poor health and is well suited to public health interventions.¹⁹⁷ In order to successfully engage disadvantaged communities, it is critical to provide technical and material support as well as the transfer of expertise, equal decision-making authority, and the ownership of the research.¹⁹⁸ "Participating in and sharing control of important events affecting their lives might be especially key for socially disadvantaged individuals, who have few opportunities to weigh in on such matters and often cannot prevent undesirable events or bring about good things."¹⁹⁹ Community based approaches that empower

194. Health Impact Project, *supra* note 76.

195. This recommendation is based on the recommendations included in Emily A. Benfer & Allyson E. Gold, *There's No Place Like Home: Reshaping Community Interventions and Policies to Eliminate Environmental Hazards and Improve Population Health for Low-Income and Minority Communities*, 11 HARVARD L. & POL'Y REV. 1 (2017).

196. See Wilhelmine D. Miller et al., *Healthy Homes and Communities: Putting the Pieces Together*, 40 AM. J. PREVENTIVE MED. 48, 49 (2011).

197. Emily Benfer, *Health Justice: A Framework (and Call to Action) for the Elimination of Health Inequity and Social Injustice*, 65 AM. U.L. REV. 275 (2015).

198. See Wilhelmine D. Miller et al., *Healthy Homes and Communities: Putting the Pieces Together*, 40 AM. J. PREVENTIVE MED. 48, 49 (2011).

199. *Id.*

community members may also lead to increased political and community participation, which can result in the reduction of social inequity and improved community health common in bonded communities.²⁰⁰

On the stakeholder level, numerous organizations and community development agents have worked to improve the physical and economic design of low-income neighborhoods with the goal of eliminating poverty. At the same time the public health and medical fields focus on improving the health of low-income populations through community investment and healthy homes approaches. These entities are often working in the same communities at high risk of lead hazard exposure. As David Erickson, the Director of the Center for Community Development Initiatives at the Federal Reserve Bank of San Francisco said:

There is an entire industry—community development—with annual resources in the tens of billions of dollars that is in the ‘ZIP-code-improving’ business. And in the health field, there is increasing recognition of the need to act on the social determinants of health. The time to merge these two approaches—improving health by addressing its social determinants and revitalizing low-income neighborhoods—is now.²⁰¹

The Task Force must collaborate with hospitals and health systems to identify ways to utilize their resources to measure and achieve healthy communities. In the long run, it will benefit the health system through lower readmission rates and better health outcomes for the target population. Together, the community development and health sectors can design holistic interventions to improve the health and environment of the community.²⁰²

In practice, the health care entity should regard the entire neighborhood, and not just the individual, as the patient.²⁰³ Hospitals spend more than \$340 billion each year on goods and services.²⁰⁴ “Redirecting even a small portion of that spending could have a tremendous impact on helping to restore local economic vitality, providing jobs for hard-to-employ people, and rebuilding urban fabrics

200. Emily Benfer, *Health Justice: A Framework (and Call to Action) for the Elimination of Health Inequity and Social Injustice*, 65 AM. U.L. REV. 275 (2015).

201. See Ctr. on Social Disparities in Health et al., *Making the Case for Linking Community Development and Health* 2 (2015), available at http://www.buildhealthyplaces.org/content/uploads/2015/10/making_the_case_090115.pdf

202. *Id.* at 15.

203. Matthew E. Dupre et al., *Place-Based Initiatives to Improve Health in Disadvantaged Communities: Cross-Sector Characteristics and Networks of Local Actors in North Carolina*, 106 AM. J. PUB. HEALTH 1548, 1548 (2016).

204. See Tyler Norris & Ted Howard, Can Hospitals Heal America’s Communities? “All in for Mission” is the Emerging Model for Impact,” DEMOCRACY COLLABORATIVE 1,2 (2015).

and rural value chains.”²⁰⁵ In a high impact approach, “hospitals and integrated health systems are increasingly stepping outside of their walls to address social, economic and environmental conditions that contribute to poor health outcomes, shortened lives, and higher costs in the first place.”²⁰⁶ For their efforts to be effective, cross-sector collaboration is critical.

It is equally important that the Task Force increase support to local initiatives to implement or expand proactive rental inspections. Many cities across the country have adopted or are contemplating enacting proactive rental inspection programs. These programs often prioritize identification and abatement of lead hazards, correctly considering lead hazards to be dangerous to residents’ present and future wellbeing. Although these programs are often designed to be self-sustaining, in smaller or less-resourced communities, federal funding or technical support could encourage additional adoption and implementation of inspection programs, or creation of an abatement fund for lower-income rental properties. Engaging the advocacy community and other interprofessional actors will be critical for success.

By highlighting these current and potential opportunities for interdepartmental, intergovernmental, and public-private collaboration, the strategy can better leverage limited funding available for lead testing and abatement activities and lift up best practices. The taskforce is in a unique position to lead a coordinated national effort to eliminate lead hazards.²⁰⁷ Rather than cataloguing individual departments’ activities, the taskforce should encourage, build, and emphasize collaborative activities essential to meeting the federal lead strategy’s ambitious goals.

[End Excerpt]

As the stakeholder comments demonstrate, a comprehensive and robust federal strategy to *eliminate* lead from children’s environments is critical and must prioritize primary prevention practices to eliminate legacy lead, halt the current use of lead, and prohibit industrial processes that contaminate the environment with lead.

CONCLUSION

The creation of the President’s Task Force in 1997 signaled a renewed commitment to the prevention of lead exposure and elimination

205. *Id.* at 13.

206. *Id.* at 1.

²⁰⁷ *Cf.* 2018 Federal Action Plan at 8 (committing only to reducing rather than eliminating lead hazards).

of lead poisoning among children in the United States. The Task Force made important progress and developed an ambitious four-pronged plan to protect children from lead poisoning within ten years. Building on this work, the 2016 Task Force recognized that “addressing . . . exposures is a matter of environmental justice” and expanded its focus to include drinking water, soil, and consumer products. The 2016 Task Force also noted the disproportionate effect of lead exposure on African-American and low-income children. Most recently, however, the Task Force missed a critical opportunity to establish bold goals and embrace primary prevention. Whereas before the Task Force was focused on *eliminating* lead poisoning, the most recent Task Force instead merely aims to *reduce* lead-based paint exposure. By focusing just on reduction of lead-based paint exposure, the 2018 Task Force ignores settled science and sound policy recommendations from advocates and public health experts. Doing so unnecessarily risks the health of millions of children. Unless and until the Task Force adopts and builds upon the aforementioned policy recommendations, children will continue to suffer irreparable damage from lead poisoning. In addition, the proven societal and governmental cost savings from primary preventive policies will not be fully realized. With the proper allocation of resources and the political will to perform, the nation can and will achieve the end of childhood lead poisoning once and for all. The success and livelihood of our children, future generations, and ultimately society, depend upon it.

Healing the Healers: Legal Remedies for Physician Burnout

Sharona Hoffman*

ABSTRACT

A career as a doctor was long considered to be among the best professional paths that one could pursue. But medicine may no longer be the sought-after career that it once was. All too often, doctors, struggling with the demands of electronic health record systems and a myriad of administrative and regulatory responsibilities, find that they fail to derive much joy from their work and become victims of burnout. Physician burnout is an acute concern in the medical community, with forty-four percent of doctors reporting that they suffer from it. Physician burnout is a public health threat. Doctors who are profoundly distressed cannot provide their patients with the highest quality of care.

Thus far, physician burnout has received little if any notice in the legal literature. This Article argues that the problem deserves and requires legal attention. First, health care regulations relating to health information technology, insurance, and many other matters are partly responsible for physician burnout and must be streamlined. As a prime example, electronic health record systems are now heavily regulated, but rather than improving the quality and usability of products, the regulations needlessly overburden clinicians. Second, the government traditionally oversees and protects the health and well-being of the American workforce. This is especially true for safety-critical jobs, such as those in the transportation industry. Likewise, physicians should be understood to be doing safety-critical work because patients put their lives in clinicians' hands. This Article, therefore, aims to fill a void in the literature by analyzing physician burnout through a legal lens and by developing recommendations for legal interventions to address the problem.

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INTRODUCTION

In a 2018 article in *The New York Times Magazine*, Dr. Abraham Verghese wrote of a “disease” from which an increasing number of his colleagues are suffering.¹ He describes a young colleague who is experiencing “existential despair” at a time that should be “the honeymoon of a career.”² The “disease” is commonly known as physician burnout.

Dr. Verghese explains the problem as follows:

My young colleague slumping in the chair in my office survived the student years, then three years of internship and residency and is now a full-time practitioner and teacher. The despair I hear comes from being the highest-paid clerical worker in the hospital: For every one hour we spend cumulatively with patients, studies have shown, we spend nearly two hours on our primitive Electronic Health Records, or “E.H.R.s,” and another hour or two during sacred personal time. But we are to blame. We let this happen to our trainees, to ourselves.³

A career as a doctor has been long considered to be among the best professional paths that one could pursue.⁴ Many parents have fervently hoped that one day they would be able to say “my son/daughter the doctor,” and many students have dedicated themselves tirelessly to their studies so that they could enter medical school and ultimately enjoy the many rewards of being a physician.

But medicine may no longer be the appealing career that it once was.⁵ All too often, in light of financial, technological, regulatory, and other pressures, doctors find that they fail to derive much joy from their work and become victims of burnout.⁶ Physician burnout has become an acute concern in the medical

1. Abraham Verghese, *How Tech Can Turn Doctors into Clerical Workers*, N.Y. TIMES MAG. (May 16, 2018), <https://www.nytimes.com/interactive/2018/05/16/magazine/health-issue-what-we-lose-with-data-driven-medicine.html>.

2. *Id.*

3. *Id.*

4. Eric S. Williams et al., *Understanding Physicians' Intentions to Withdraw from Practice: The Role of Job Satisfaction, Job Stress, Mental and Physical Health*, 35 HEALTH CARE MGMT. REV. 105, 106 (2010).

5. *Id.* at 106.

6. *Id.*

community.⁷ It has been called an epidemic, pandemic, and public health crisis.⁸

Thus far, however, it has received little if any attention in the legal literature. This gap is surprising because health care regulations relating to EHRs, insurance, and many other matters are partly responsible for physician burnout.⁹ Physicians consistently report being overwhelmed by the demands of the labyrinth of American health care laws and regulations with which they must comply.¹⁰ As a prime example, electronic health record (EHR) systems are now heavily regulated, but rather than improving the quality and usability¹¹ of products, the regulations needlessly overburden clinicians. This Article, therefore, aims to begin to fill this void and to analyze physician burnout through a legal lens.

Burnout is a syndrome that is characterized by emotional exhaustion, depersonalization, and dissatisfaction with one's work accomplishments.¹² According to a recent study, in 2017, forty-four percent of U.S. doctors identified as suffering from at least one symptom of burnout, while the burnout rate was only twenty-eight percent in the general working population.¹³

A profoundly unhappy health care workforce is unlikely to provide the highest quality of care¹⁴ and at times may provide poor care that endangers patient welfare. It can also exacerbate the already worrisome problem of health care provider

7. Lotte N. Dyrbye et al., *Burnout Among Health Care Professionals: A Call to Explore and Address This Underrecognized Threat to Safe, High-Quality Care*, NAT'L ACAD. MED. (July 5, 2017), <https://nam.edu/burnout-among-health-care-professionals-a-call-to-explore-and-address-this-underrecognized-threat-to-safe-high-quality-care/>; Victor J. Dzau et al., *To Care Is Human—Collectively Confronting the Clinician-Burnout Crisis*, 378 NEW ENG. J. MED. 312, 312 (2018).

8. Lauren DeCaporale-Ryan et al., *The Undiagnosed Pandemic: Burnout and Depression Within the Surgical Community*, 54 CURRENT PROBS. SURGERY 453, 454 (2017); Uta Guo et al., *Electronic Health Record Innovations: Helping Physicians—One Less Click at a Time*, 46 HEALTH INFO. MGMT. J. 140, 140 (2017) (“Physician burnout is becoming an epidemic, given the pressures of being productive, an imperfect electronic health record (EHR) system, and limited face-to-face time with patients.”); John Noseworthy et al., *Physician Burnout Is a Public Health Crisis: A Message to Our Fellow Health Care CEOs*, HEALTH AFFS. BLOG (Mar. 28, 2017), <https://www.healthaffairs.org/doi/10.1377/hblog20170328.059397/full/>.

9. See *infra* Parts II.C and III.B.1.

10. See *infra* Parts II.C and III.B.1.

11. See *infra* note 147 and accompanying text for definition of usability.

12. Colin P. West et al., *Physician Burnout: Contributors, Consequences and Solutions*, 283 J. INTERNAL MED. 516, 516 (2018).

13. Tait D. Shanafelt et al., *Changes in Burnout and Satisfaction with Work-Life Integration in Physicians and the General US Working Population Between 2011 and 2017*, __ MAYO CLINIC PROC. 1, 7, 8 (forthcoming 2019), available at [https://www.mayoclinicproceedings.org/article/S0025-6196\(18\)30938-8/pdf](https://www.mayoclinicproceedings.org/article/S0025-6196(18)30938-8/pdf). An assessment of 4893 physician respondents revealed a 43.9% burnout rate. *Id.* at 7. A comparison of 3971 nonretired physicians aged 29 to 65 to 5198 employed nonphysician in the same age group revealed burnout rates of 39.8% and 28.1%, respectively. *Id.* at 8-10.

14. Tait D. Shanafelt & John H. Noseworthy, *Executive Leadership and Physician Well-being: Nine Organizational Strategies to Promote Engagement and Reduce Burnout*, 92 MAYO CLINIC PROC. 129, 130 (2017).

shortages.¹⁵ Many doctors have reduced their hours in order to alleviate work pressures, retired early, or abandoned clinical practice for jobs in medical education, administration, or industry.¹⁶ Medical students, perceiving clinicians' distress, may avoid fields with high burnout rates, such as general internal and emergency medicine, or may choose not to be clinical caregivers altogether.¹⁷ Burnout, therefore is a public health threat that policy-makers cannot ignore.

A variety of medical organizations have undertaken initiatives to study and formulate recommendations to alleviate physician burnout.¹⁸ One might assume that the task of solving the burnout problem should be left to the health care industry.

In truth, however, the welfare of physicians and their patients is very much a legal concern as well. Policy-makers have enacted extensive regulations to govern safety-critical jobs such as positions of responsibility in the transportation industry, and these focus in part on the well-being of workers.¹⁹ For example, a federal regulation provides that “[n]o pilot of an airplane that has a crew of two pilots may be on duty for more than 16 hours during any 24 consecutive hours.”²⁰

Likewise, doctors perform safety-critical work when they treat their patients. Doctors routinely make life and death decisions about their patients. It is often within their power to cure sick individuals but also to injure them or end their lives through medical errors. Consequently, it is both sensible and necessary for the law to be employed to minimize burnout and enhance physician well-being.

Unfortunately, there is no single legal intervention that can solve the physician burnout problem. The article suggests a variety of changes that will constitute

15. Sarah Mann, *Research Shows Shortage of More than 100,000 Doctors by 2030*, ASS'N AM. MED. COLLS. (Mar. 14, 2017), <https://news.aamc.org/medical-education/article/new-aamc-research-reaffirms-looming-physician-shor/> (discussing provider shortages).

16. Mark Linzer et al., *The End of the 15–20 Minute Primary Care Visit*, 30 J. GEN. INTERNAL MED. 1584, 1584 (2015); Janis M. Miyasaki et al., *Qualitative Study of Burnout, Career Satisfaction, and Well-Being Among US Neurologists in 2016*, 89 NEUROLOGY 1730, 1736 (2017); Sandra Gittlen, *Survey Snapshot: Fixing Burnout Through Physician Input*, NEJM CATALYST (Dec. 15, 2016), <https://catalyst.nejm.org/survey-fixing-burnout-physician-input/>. See also *infra* notes 91-97 and accompanying text.

17. Linzer et al., *supra* note 16, at 1584. See also *infra* notes 43, 85-86 and accompanying text.

18. See, e.g., Task Force on Physician Stress and Burnout, *Executive Summary Highlights of Survey Findings Fall 2016*, MED. SOC'Y ST. N. Y. (Mar. 31, 2017), <https://www.mssny.org/Documents/HOD/2017/2017resolutions/Task%20Force/Task%20Force%20-%20Physician%20Stress%20and%20Burnout%20Executive%20Summary%203-31-17%20.pdf>; Alexi A. Wright & Ingrid T. Katz, *Beyond Burnout—Redesigning Care to Restore Meaning and Sanity for Physicians*, 378 NEW ENG. J. MED. 309, 311 (2018) (discussing an initiative by the University of Colorado health system's Department of Family Medicine to institute a team-based model called APEX, standing for ambulatory process excellence).

19. See, e.g., 14 C.F.R. § 91.1062 (2018) (discussing duty periods and rest requirements for flight attendants). See also *infra* Part IV.

20. 14 C.F.R. § 121.505(b) (2018).

building blocks for addressing the physician burnout phenomenon.

The remainder of the Article proceeds as follows. Part I describes the physician burnout problem, including its nature, consequences, and causes. Part II analyzes the impact of electronic health record systems on physician burnout. It focuses on the shortcomings of the technology itself as well as on the burdens that various EHR-related regulations impose. The Article argues that rather than facilitating EHR system use and supporting physicians, the regulations worsen clinicians' work conditions and exacerbate burnout. It also critiques the certification requirements for EHR products and highlights their failure to incorporate adequate usability testing. Part III discusses an additional but interrelated source of burnout: physicians' frustration at having to rush through appointments and their inability to spend adequate time with patients. Their time is constrained both by crushing administrative burdens and by pressure to generate income. This Part also details self-help measures to which physicians have turned, namely, employing scribes to handle EHR data entry and establishing innovative direct primary care practices. Part IV develops the argument that the law is an appropriate and necessary tool for remedying the physician burnout problem. Part V proposes a series of legal interventions. These include streamlining regulatory requirements, expanding usability testing for purposes of EHR certification, enabling purchasers to conduct acceptance testing,²¹ assessing and reporting physician wellness indicators as quality measures, supporting providers' own initiatives to ease burnout, and conducting further research to better understand the problem and identify effective solutions. Part VI concludes.

I. PHYSICIAN BURNOUT: THE NATURE OF THE PROBLEM

A. Physician Burnout

Burnout can be defined as “a syndrome characterized by emotional exhaustion and depersonalization (which includes negativity, cynicism, and the inability to express empathy or grief), a feeling of reduced personal accomplishment, loss of work fulfillment, and reduced effectiveness.”²²

Burnout in the health care professions is commonly measured using the Maslach Burnout Inventory (MBI).²³ The MBI is designed to evaluate the frequency and intensity of burnout among members of the helping professions by

21. See *infra* notes 374-380 and accompanying text.

22. Dzau et al., *supra* note 7, at 312.

23. Shanafelt et al., *supra* note 13, at 3 (stating that the MBI is considered “the standard tool for measuring burnout”); *Validated Instruments to Assess Work-Related Dimensions of Well-Being*, NAT'L ACAD. MED. (2018), <https://nam.edu/valid-reliable-survey-instruments-measure-burnout-well-work-related-dimensions/#purpose> (asserting that “[t]he Maslach Burnout Inventory is the gold standard for research purposes.”).

focusing on three phenomena: 1) emotional exhaustion, 2) a sense of diminished personal accomplishment, and 3) depersonalization.²⁴ It contains twenty-two items, each of which is rated twice: once for frequency (on a seven-point scale ranging from never to every day) and once for intensity (using an eight-point scale ranging from none to major).²⁵

Several analysts have criticized the MBI and deemed it a flawed instrument.²⁶ They assert that it suffers from a number of shortcomings, including that its cutoff scores are arbitrary and that it ignores factors such as childcare pressures, having a supportive partner, and financial worries.²⁷ They also note that the MBI was developed initially to measure burnout among social service professionals and posit that it is unclear that it is an effective tool when assessing physicians.²⁸

Moreover, some experts question the distinction between burnout and depression and posit that in reality burnout is a depressive disorder.²⁹ Arguably, the term “burnout” is preferred simply because it is less stigmatizing than “depression.” In response, defenders of the burnout concept assert that burnout is “job-related and situation-specific,” whereas clinical depressive conditions are “more general and context-free.”³⁰ This controversy need not be resolved here. Whether it is called burnout or depression, it is clear that physicians are suffering work-related, adverse mental health consequences. Because the majority of the literature has embraced the term “burnout,” I will continue to use it in this Article.

24. Edward F. Iwanicki & Richard L. Schwab, *A Cross Validation Study of the Maslach Burnout Inventory*, 41 EDUC. & PSYCHOL. MEASUREMENT 1167, 1168 (1981).

25. *Id.*; Yvonne Gold, *The Factorial Validity of the Maslach Burnout Inventory in a Sample of California Elementary and Junior High School Classroom Teachers*, 44 EDUC. & PSYCHOL. MEASUREMENT 1009, 1010 (1984).

26. See Jodie Eckleberry-Hunt et al., *The Problems with Burnout Research*, 93 ACAD. MED. 367, 367-68 (2018); Thomas L. Schwenk & Katherine J. Gold, *Physician Burnout—A Serious Symptom, But of What?*, 320 JAMA 1109, 1110 (2018) (“The MBI needs further validation among physicians, particularly the interplay between the 3 domains used to assess burnout.”).

27. Eckleberry-Hunt et al., *supra* note 26, at 367-68; Raquel Marie Schears, *Defining Physician Burnout, and Differentiating between Burnout and Depression-II*, 92 MAYO CLINIC PROC. 1455, 1456 (2017).

28. Schwenk & Gold, *supra* note 26, at 1110.

29. *Id.* (“Clinical depressive disorders have more solid grounding, methods of measurement, pathophysiological foundation, and empirically proven approaches to treatment of varying levels of severity”); Kirsi Ahola et al., *Relationship Between Burnout and Depressive Symptoms: A Study Using the Person-Centered Approach*, 1 BURNOUT RES. 29, 29 (2014) (discussing “the conceptual similarity between burnout and depressive symptoms in the work context”); Renzo Bianchi & Irvin Sam Schonfeld, *Defining Physician Burnout, and Differentiating Between Burnout and Depression-I*, 92 MAYO CLINIC PROC. 1455, 1455 (2017) (asserting that “we think that a critical step is to understand burnout as a depressive condition” (emphasis omitted)); Irvin Sam Schonfeld & Renzo Bianchi, *Burnout and Depression: Two Entities or One?*, 72 J. CLINICAL PSYCHOL. 22, 22, 31-32 (2016) (“The state of burnout is likely to be a form of depression.”).

30. Edward R. Melnick et al., *In Reply—Defining Physician Burnout, and Differentiating between Burnout and Depression*, 92 MAYO CLINIC PROC. 1456, 1457 (2017) (emphasis omitted).

I will use the term “depression” when discussing that condition specifically.

By all accounts, a startling number of physicians report symptoms of burnout. Dr. Tait Shanafelt, who has studied physician burnout for many years, found that in 2017, forty-four percent of physicians in the United States suffered from one or more symptoms of professional burnout.³¹ He notes that burnout spiked in 2014, when it reached over fifty-four percent, and is now in the vicinity of its 2011 level.³² However, the percentage of physicians suffering from depression consistently increased from 38.2% in 2011 to 39.8% in 2014 to 41.7% in 2017.³³ According to the study, during these years, the rate of burnout in the general working population in the United States remained steady at approximately twenty-eight percent.³⁴

Other studies have confirmed the pervasiveness of physician burnout. In a 2015 survey, forty-six percent of physicians indicated that they suffered from burnout.³⁵ The Medical Society of the State of New York (MSSNY) conducted a survey in 2016 and concluded that fifty-seven percent of New York physicians are burned-out.³⁶ Moreover, only fifty-eight percent of New York physicians would choose to be doctors if they were currently selecting a career path.³⁷ The 2016 Physicians Foundation survey concluded that among 17,236 respondents, fifty-four percent had “somewhat or very negative” morale, forty-nine percent “often or always” felt burned-out, and forty-nine percent would counsel their children against pursuing a career in medicine.³⁸ A 2018 study of U.S. resident physicians

31. Shanafelt et al., *supra* note 13, at 7.

32. *Id.* (stating that the 2011 burnout rate was 45.5%). It is noteworthy that the 2017 study was smaller than its predecessor, involving 4893 respondents compared to 6767 in 2014 and 7227 in 2011. *Id.* The 2017 study had a 17.1% response rate compared to the 2014 study’s 19.2% response rate. See Tait D. Shanafelt et al., *Changes in Burnout and Satisfaction with Work-Life Balance in Physicians and the General US Working Population Between 2011 and 2014*, 90 MAYO CLINIC PROC. 1600, 1600 (2015). Dr. Shanafelt explains that the positive change in burnout rates between 2014 and 2017 may be attributable to several factors. Physicians may have adjusted to using EHR systems, the unhappiest doctors may have left practice or reduced their hours to alleviate stress, and some employers have instituted effective wellness initiatives. Shanafelt et al., *supra* note 13, at 11.

33. Shanafelt et al., *supra* note 13, at 7.

34. *Id.* at 8. See also, Tait Shanafelt et al., *Burnout and Satisfaction with Work-Life Balance Among US Physicians Relative to the General US Population*, 172 ARCHIVES INTERNAL MED. 1377, 1377 (2012) (“Burnout is more common among physicians than among other US workers.”). But see William B. Weeks, *Physician Burnout-Overdiagnosis and Unproven Interventions*, 178 JAMA INTERNAL MED. 576, 576 (2018) (questioning the results of the 2014 study because of its low response rate of 19.2%).

35. Carol Peckham, *Physician Burnout: It Just Keeps Getting Worse*, MEDSCAPE 1 (Jan. 26, 2015), <https://www.medscape.com/viewarticle/838437> (reporting that the self-reported burnout rate was just under forty percent in 2013 and increased to forty-six percent in 2015).

36. Task Force on Physician Stress and Burnout, *supra* note 18.

37. *Id.*

38. 2016 Survey of America’s Physicians: Practice Patterns and Perspectives, 2016 PHYSICIANS FOUND. BIANN. PHYSICIAN SURV. 1, 7 (2016), <https://physiciansfoundation.org/wp->

concluded that even these freshly-minted doctors suffer from burnout at a rate of 48.8%, which is often accompanied by “career choice regret.”³⁹

A recent large-scale international study may inform how we weigh the above conclusions. The systematic review examined 182 studies from forty-five countries that involved 109,628 physicians.⁴⁰ It found “remarkable variability in published prevalence estimates of burnout, with estimates of overall burnout ranging from 0% to 80.5%.”⁴¹ It attributed this broad range to significant differences in the ways burnout was defined and measured in the studies.⁴² Consequently, the review could reach no definitive conclusion about burnout prevalence among physicians globally. This finding may raise questions about the burnout figures cited in U.S.-focused studies as well.

The degree of physician burnout varies by specialty and demographics. Those in high-stress fields such as emergency medicine, general internal medicine, general surgery, and neurology, are at higher risk of burnout than those in dermatology, pathology, anesthesiology, or occupational medicine.⁴³ In addition, female physicians and those under fifty-five years old are more vulnerable to burnout.⁴⁴ To illustrate, according to the MSSNY study, sixty-three percent of female doctors in New York identified as experiencing burnout compared to fifty-three percent of male physicians.⁴⁵ Furthermore, peak burnout in New York was evident ten to nineteen years after the completion of training.⁴⁶ A different study involving 422 family physicians and general internists found that women physicians reported burnout nearly twice as often as did their male counterparts.⁴⁷

The burnout phenomenon has spread to other health care providers as well.

content/uploads/2017/12/Biennial_Physician_Survey_2016.pdf.

39. Liselotte N. Dyrbye et al., *Association of Clinical Specialty with Symptoms of Burnout and Career Choice Regret among U.S. Resident Physicians*, 320 JAMA 1114, 1119 (2018).

40. Lisa S. Rotenstein et al., *Prevalence of Burnout among Physicians: A Systematic Review*, 320 JAMA 1131, 1143 (2018).

41. *Id.*

42. *Id.* at 1143-44 (finding “142 unique definitions” of burnout).

43. Dyrbye et al., *supra* note 7; Dyrbye et al., *supra* note 39, at 1119, 1129; Shanafelt et al., *supra* note 13, at 7; John Squiers et al., *Physician Burnout: Are We Treating the Symptoms Instead of the Disease?* 104 ANNALS THORACIC SURGERY 1117, 1118 (2017).

44. Dyrbye et al., *supra* note 7; Mark Linzer & Eileen Harwood, *Gendered Expectations: Do They Contribute to High Burnout Among Female Physicians?*, 33 J. GEN. INTERNAL MED. 963, 963 (2018) (arguing that “gender differences in patient panels and gendered expectations of female physicians may contribute to the high rate of burnout among female clinicians, as well as to the many female physicians working part-time to reduce stress in their work lives”); West et al., *supra* note 12, at 516.

45. Task Force on Physician Stress and Burnout, *supra* note 18.

46. *Id.*

47. Joseph Rabatin et al., *Predictors and Outcomes of Burnout in Primary Care Physicians*, 7 J. PRIMARY CARE & COMMUNITY HEALTH 41, 42 (2016) (reporting, however, that there were “no differences in burnout by age”).

One study found that one-third of oncology physician assistants report burnout.⁴⁸ A different study identified burnout as a serious problem among rural physician assistants.⁴⁹ Studies of nurses have revealed alarming rates of burnout as well.⁵⁰ One investigation concluded that burnout disproportionately affects nurses in neonatal intensive care units.⁵¹ Another found high burnout rates among nurses working in hospitals and nursing homes, reaching thirty-four and thirty-seven percent respectively.⁵²

The United States is not the only country exposed to physician burnout. By many accounts, it is prevalent internationally.⁵³ For example, there are urgent calls to address physician burnout in Canada,⁵⁴ the United Kingdom,⁵⁵ Israel,⁵⁶ and even Finland.⁵⁷

48. Eric Daniel Tetzlaff et al., *National Study of Burnout and Career Satisfaction Among Physician Assistants in Oncology: Implications for Team-Based Care*, 14 J. ONCOLOGY PRAC. e11, e11 (2018).

49. Marc A. Benson et al. *Burnout in Rural Physician Assistants: An Initial Study*, 27 J. PHYSICIAN ASSISTANT EDUC. 81, 81 (2016).

50. Dyrbye et al., *supra* note 7.

51. Daniel S. Tawfik et al., *Factors Associated with Provider Burnout in the NICU*, 139 PEDIATRICS e20164134 (2017).

52. Matthew D. McHugh et al., *Nurses' Widespread Job Dissatisfaction, Burnout, and Frustration with Health Benefits Signal Problems for Patient Care*, 30 HEALTH AFFS. 202, 204-5 (2011).

53. Kamran Azam et al., *Causes and Adverse Impact of Physician Burnout: A Systematic Review*, 27 J. C. PHYSICIANS & SURGEONS PAK. 495 (2017) (reviewing studies conducted in the United States, Australia, Taiwan, Pakistan, Malaysia, Yemen, Iran, China, Hong Kong, Denmark, Japan, Germany, France, and Italy); Carolyn S. Dewa et al., *The Relationship Between Physician Burnout and Quality of Healthcare in Terms of Safety and Acceptability: A Systematic Review*, 7 BMJ OPEN e015141(2017) (reviewing studies of physician burnout published in the United States, Germany Greece, Israel, Japan, China and Taiwan); Andrew Leung Luk & Adrian Fai To Yau, *Experiences of Public Doctors on Managing Work Difficulties and Maintaining Professional Enthusiasm in Acute General Hospitals: A Qualitative Study*, 6 FRONTIERS PUB. HEALTH. 19, 19 (2018) (“Overseas studies suggest that 10-20% of doctors are depressed, 30-45% have burnout, and many report dissatisfaction with work-life balance.”); West et al., *supra* note 12, at 516.

54. Lauren Vogel, *CMA Must Address Physician Burnout, Pharmacare, Say Doctors*, 189 CAN. MED. ASS'N J. e1171, e1171 (2017) (“Doctors called for urgent action on physician burnout and universal pharmacare at the Canadian Medical Association (CMA) General Council meeting in Quebec City.”).

55. Udemezue O. Imo, *Burnout and Psychiatric Morbidity Among Doctors in the UK: A Systematic Literature Review of Prevalence and Associated Factors*, 41 B.J. PSYCH. BULL. 197, 197, 201 (2017).

56. Alan H. Rosenstein, *Addressing Physician Stress, Burnout, and Compassion Fatigue: The Time Has Come*, 2 ISR. J. HEALTH POL'Y RES. 32, 32 (2013) (discussing a study that “highlights the growing problem of stress, burnout, and loss of compassion in our physician population”).

57. Tarja Heponiemi et al., *Finnish Physicians' Stress Related to Information Systems Keeps Increasing: A Longitudinal Three-Wave Survey Study*, 17 BMC MED. INFO. DECISION MAKING. 147, 148 (2017); Tarja Heponiemi et al., *Predictors of Physicians' Stress Related to Information Systems: A Nine-Year Follow-Up Survey Study*, 18 BMC HEALTH SERVS. RES. 284, 284 (2018).

Although the scope of the problem is global, this Article is limited to addressing professional burnout in the United States. While I do not wish to minimize the severity of the phenomenon among other health care professionals, I focus primarily on physicians in this piece.

B. The Consequences of Burnout

Burnout has far-reaching effects on physicians and patients. These fall generally into three categories: diminished physician well-being, poor quality of care, and workforce attrition.

1. Physician Well-Being

Burnout takes a heavy toll on physicians' mental health. As noted above, it is characterized by emotional exhaustion, negativity, cynicism, and a sense of lack of accomplishment and job fulfillment.⁵⁸ Not surprisingly, therefore, assuming that it is distinct from depression,⁵⁹ it can lead to depression.⁶⁰ In addition, physicians with high burnout scores suffer from insomnia and poor sleep quality at significantly higher rates than colleagues with lower levels of burnout.⁶¹ Burnout victims are also vulnerable to marital problems, substance abuse, and even suicide.⁶² Approximately four hundred physicians commit suicide each year in the United States.⁶³ Experts have noted that “[o]f all occupations and professions, the medical profession consistently hovers near the top of occupations with the highest risk of death by suicide.”⁶⁴

An even larger number experience suicidal ideation, that is, thoughts of suicide with or without a plan to end one's life.⁶⁵ In a study of 7905 surgeons, 501

58. See *supra* note 22 and accompanying text.

59. See *supra* notes 29-30 and accompanying text.

60. DeCaporale-Ryan et al., *supra* note 8, at 454 (noting that burnout is “a condition that is widely believed to lead and contribute to depression”); Bruce Sigsbee & James L. Bernat, *Physician Burnout: A Neurologic Crisis*, 83 *NEUROLOGY* 2302 (2014); Walter Wurm et al., *Depression-Burnout Overlap in Physicians*, 11 *PLOS ONE* e0149913 (2016) (demonstrating “the overlap of burnout and major depression in terms of symptoms” and questioning the traditional, “three-dimensional concept of burnout”).

61. Antonio Vela-Bueno et al., *Insomnia and Sleep Quality among Primary Care Physicians with Low and High Burnout Levels*, 64 *J. PSYCHOSOMATIC RES.* 435, 439 (2008)

62. DeCaporale-Ryan et al., *supra* note 8, at 454.

63. *Id.*; see also Louise B. Andrew, *Physician Suicide*, *MEDSCAPE* (June 17, 2017), <https://emedicine.medscape.com/article/806779-overview> (estimating that every day a physician commits suicide in the United States).

64. See Andrew, *supra* note 63; see also Pauline Anderson, *Physicians Experience Highest Suicide Rate of Any Profession*, *MEDSCAPE* (May 7, 2018), <https://www.medscape.com/viewarticle/896257>.

65. Robert I. Simon, *Passive Suicidal Ideation: Still a High-Risk Clinical Scenario*, 13

or 6.4% reported suicidal ideation during the prior twelve months. Suicidal ideation was 1.5 to 3.0 times more common among surgeons who were forty-five and older than among their counterparts in the general population.⁶⁶

2. *Quality of Care*

There is substantial agreement that physician burnout adversely affects care quality and patient safety.⁶⁷ In a variety of studies, physicians self-reported that burnout caused them to make treatment mistakes.⁶⁸ One national study of surgeons involved 7905 participants.⁶⁹ Seven hundred of them (8.9%) reported that they had made what they consider to be a major medical error in the last three months.⁷⁰ The researchers noted that “each one point increase in depersonalization, emotional exhaustion, and mental QOL [quality of life] score was associated with a 5% to 11% higher likelihood of reporting a recent major medical error.”⁷¹ Medical residents who identify as suffering from burnout similarly perceive that they provide a lower quality of care to patients.⁷² A study of emergency physicians, who work in one of the most stressful environments, also assessed themselves as providing “suboptimal care” when suffering from burnout.⁷³ Researchers acknowledge, however, the possibility that the causal relationship is reversed and that making medical mistakes is what causes physicians to feel burned-out rather

CURRENT PSYCHIATRY 13, 13 (2014).

66. Tait Shanafelt et al., *Special Report: Suicidal Ideation among American Surgeons*, 146 AMA ARCHIVES SURGERY 54, 55 (2011).

67. See, e.g., Tait Shanafelt & Lotte Dyrbye, *Oncologist Burnout: Causes, Consequences, and Responses*, 30 J. CLINICAL ONCOLOGY 1235, 1237 (2012) (asserting that a “strong association between burnout and medical errors among practicing physicians has . . . been documented.”); Shanafelt & Noseworthy, *supra* note 14, at 130; Jean E. Wallace, Jane B. Lemaire & William A. Ghali, *Physician Wellness: A Missing Quality Indicator*, 374 LANCET 1714, 1716-18 (2009). But see Joseph Rabatin et al., *Predictors and Outcomes of Burnout in Primary Care Physicians*, 7 J. PRIMARY CARE & COMMUNITY HEALTH 41, 41-42 (2016) (using 2002-03 data and concluding that “[p]hysicians reporting burnout at baseline and 12 months were not more likely to err or to provide lower-quality care than physicians who reported burnout once or never”).

68. See, e.g., Tait D. Shanafelt et al., *Burnout and Medical Errors among American Surgeons*, 251 ANNALS SURGERY 995, 997 (2010); Eric S. Williams et al., *The Relationship of Organizational Culture, Stress, Satisfaction, and Burnout with Physician-Reported Error and Suboptimal Patient Care: Results from the MEMO Study*, 32 HEALTH CARE MGMT. REV. 203, 206 (2007).

69. Shanafelt et al., *supra* note 68, at 997.

70. *Id.* at 995 (defining medical error as “a commission or omission with potentially negative consequences for the patient that would have been judged wrong by skilled and knowledgeable peers at the time it occurred, independent of whether there were any negative consequences”).

71. *Id.* at 997.

72. Tait D. Shanafelt et al., *Burnout and Self-Reported Patient Care in an Internal Medicine Residency Program*, 136 ANNALS INTERNAL MED. 358, 358 (2002); Colin P. West et al., *Association of Perceived Medical Errors with Resident Distress and Empathy*, 296 JAMA 1071, 1071 (2006).

73. Dave W. Lu et al., *Impact of Burnout on Self-Reported Patient Care Among Emergency Physicians*, 16 W. J. EMERGENCY MED. 996, 999 (2015).

than vice versa.⁷⁴

Several studies have attempted to develop objective evidence of a link between burnout and adverse health care outcomes. For example, one investigation focused on 178 pairs of patients who had been hospitalized in the prior year and their physicians.⁷⁵ It concluded that the depersonalization aspect of physician burnout was associated with lower patient satisfaction and longer recovery time after hospital discharge.⁷⁶ A meta-analysis of eighty-two studies including 210,669 health care providers found “small to medium-sized relationships between burnout and both decreased quality of care and decreased [patient] safety.”⁷⁷

A few studies have found that errors are associated with depression but not with burnout that has not progressed to depression. One study focused on 123 residents in three U.S. children’s hospitals, twenty-four of whom met the criteria for depression and ninety-two of whom met the criteria for burnout.⁷⁸ It found that residents with depression made 6.2 times as many drug errors per resident month as those without depression.⁷⁹ However, burnout alone did not appear to be associated with a higher rate of medication errors.⁸⁰ Likewise, a study of thirty-one intensive care units in France found that medical errors were associated with clinicians’ depression but not burnout.⁸¹

3. *Workforce Attrition*

Physician burnout endangers patients not only through possible medical errors but also by contributing to already significant deficits in the physician workforce. By some accounts, physician shortages may reach crisis proportions in the near future.⁸² According to the Association of American Medical Colleges, by 2030,

74. Shanafelt et al., *supra* note 68, at 997 (conceding that the authors were “unable to determine whether distress causes errors or errors cause distress”).

75. Jonathon R. B. Halbesleben & Cheryl Rathert, *Linking Physician Burnout and Patient Outcomes: Exploring the Dyadic Relationship Between Physicians and Patients*, 33 HEALTH CARE MGMT. REV. 29, 29 (2008).

76. *Id.* at 33-34. See also Renée A. Scheepers et al., *A Systematic Review of the Impact of Physicians’ Occupational Well-Being on the Quality of Patient Care*, 22 INT’L J. BEHAV. MED. 683, 696 (2015) (finding “that physicians’ occupational well-being could positively contribute to patient satisfaction and the quality of interpersonal aspects of care”).

77. Michelle P. Salyers et al., *The Relationship Between Professional Burnout and Quality and Safety in Healthcare: A Meta-Analysis*, 32 J. GEN. INTERNAL MED. 475, 479 (2017).

78. Amy M. Fahrenkopf et al., *Rates of Medication Errors Among Depressed and Burnt out Residents: Prospective Cohort Study*, 336 BMJ 488, 488 (2008).

79. *Id.*

80. *Id.*

81. Maite Garrouste-Orgeas et al., *The Iatref Study: Medical Errors Are Associated with Symptoms of Depression in ICU Staff but Not Burnout or Safety Culture*, 41 INTENSIVE CARE MED. 273, 273 (2015).

82. See Aaron E. Carroll, *A Doctor Shortage? Let’s Take a Closer Look*, N.Y. TIMES, Nov. 7,

the United States will experience a shortage of between 42,600 and 121,300 doctors.⁸³ In the area of primary care, it predicts a shortfall of between 14,800 and 49,300 by 2030.⁸⁴

It is already difficult to recruit medical students to the fields of internal medicine and primary care because students perceive these to be high-stress jobs.⁸⁵ Students observe physicians who are burned-out and opt for other specialties.⁸⁶

This trend is extremely troubling because competent primary care is often vital to maintaining good health.⁸⁷ Primary care physicians practice general medicine and are able to diagnose and treat a multitude of conditions as well as prevent illnesses through vaccinations, screening, consistent monitoring, and other preventive interventions.⁸⁸ Ideally, primary care physicians maintain thorough familiarity with their patients' health conditions and oversee all of their care.⁸⁹ While specialists treat particular conditions in isolation, primary care physicians can ensure that a patient's care does not become fragmented and is well-coordinated.⁹⁰

Furthermore, because of the growing pressures of medical practice, some physicians are reducing their work hours or retiring early.⁹¹ For example, a study

2016, <https://www.nytimes.com/2016/11/08/upshot/a-doctor-shortage-lets-take-a-closer-look.html> (explaining both the view that the country will soon experience a dire physician shortage and the argument that "there's no shortage at all—just a poor distribution of the doctors we have").

83. Association of American Medical Colleges, *New Research Shows Increasing Physician Shortages in Both Primary and Specialty Care*, AAMC NEWS PRESS RELEASE (April 11, 2018), https://news.aamc.org/press-releases/article/workforce_report_shortage_04112018/; TIM DALL ET AL., THE COMPLEXITIES OF PHYSICIAN SUPPLY AND DEMAND: PROJECTIONS FROM 2016 TO 2030, 3 (2018).

84. Association of American Medical Colleges, *supra* note 83.

85. Mark Linzer et al., *10 Bold Steps to Prevent Burnout in General Internal Medicine*, 29 J. GEN. INTERNAL MED. 18, 18 (2014) ("Recruitment of medical students into general internal medicine is worrisomely low, and may relate in part to the perceived stressfulness of a primary care career."); Linzer et al., *supra* note 16, at 1584.

86. Linzer et al., *supra* note 16, at 1584 ("Students observe harried primary care providers and choose alternative career paths."); Colin P. West & Karen E. Hauer, *Reducing Burnout in Primary Care: A Step toward Solutions*, 30 J. GEN. INTERNAL MED. 1056, 1056 (2015) ("Students demonstrate little interest in primary care careers, and even those who choose primary care training programs often depart for other specialty areas along the way.")

87. West & Hauer, *supra* note 86, at 1056 (asserting that "[p]rimary care is the cornerstone of high-quality health care systems across the world").

88. *The Importance of a Primary Care Provider*, MAYO CLINIC HEALTH SYS. (April 7, 2015), <https://mayoclinichealthsystem.org/hometown-health/speaking-of-health/the-importance-of-a-primary-care-provider>.

89. *Id.*

90. See SHARONA HOFFMAN, AGING WITH A PLAN: HOW A LITTLE THOUGHT TODAY CAN VASTLY IMPROVE YOUR TOMORROW 73-5 (2015).

91. Thomas Bodenheimer et al., *Continuity and Access in the Era of Part-Time Practice*, 16 ANNALS FAM. MED. 359, 359 (2018) ("In 2011, 22% of male physicians and 44% of female physicians worked less than full time, up from 7% and 29% in 2005."); Miyasaki et al., *supra* note

at the Mayo Clinic found that the percentage of its physicians working less than full-time increased from 13.5 to 16.0 between 2008 and 2014.⁹² These numbers correlated with burnout rates.⁹³ Women in particular often choose to work part-time.⁹⁴

Many who have not already taken action to alleviate burnout assert that they plan to do so in the future. A 2008 study involving 7615 surgeons who were members of the American College of Surgeons found that approximately forty percent of participants experienced burnout and thirty-two percent reported “at least a moderate likelihood” that they would leave their current practice within the next two years.⁹⁵ Among the latter, 58.5% indicated they planned to stop being surgeons and pursue other work.⁹⁶ An analysis of data from the 2016 Physicians Foundation Survey revealed that only fifty-two percent of respondents planned to continue as they are in the next one to three years, and all others planned to take steps to improve their quality of life, such as reducing their hours, seeking a non-clinical health care job, or retiring.⁹⁷

As the American population ages, the demand for physicians will only grow.⁹⁸ Professional burnout may be a significant hindrance to meeting this critical need.

C. The Causes of Burnout

What are the primary reasons for burnout among physicians in the United States? The literature identifies many causes.

In 2015, Medscape conducted a survey of physicians and inquired about burnout causes.⁹⁹ Physicians were asked to rank the causes on a scale of one to seven.¹⁰⁰ In order of importance, along with their average scores, they were as follows:

- Too many bureaucratic tasks (4.74)
- Too many hours at work (3.99)

16, at 1736.

92. Tait D. Shanafelt et al., *Longitudinal Study Evaluating the Association Between Physician Burnout and Changes in Professional Work Effort*, 91 MAYO CLINIC PROC. 422, 426 (2016).

93. *Id.* at 422, 426-27.

94. *Id.* at 426; Linzer & Harwood, *supra* note 44, at 963.

95. Tait D. Shanafelt et al., *Why Do Surgeons Consider Leaving Practice?*, 212 J. AM. C. SURGEONS 421, 421 (2011).

96. *Id.*

97. *2016 Survey of America's Physicians: Practice Patterns and Perspectives*, *supra* note 38, at 7.

98. Dyrbye et al., *supra* note 7 (discussing the need to provide “care for an aging population with high rates of chronic disease and co-morbidities”).

99. Peckham, *supra* note 35.

100. *Id.*

- Insufficient income (3.71)
- Increasing computerization (3.68)
- The impact of the Affordable Care Act (3.65)
- Feeling like just a cog in a wheel (3.54)
- Too many difficult patients (3.37)
- Too many patient appointments in a day (3.34)
- Inability to provide patients with a high level of quality care (3.22)
- Lack of professional fulfillment (3.05)
- Difficult colleagues or staff (2.90)
- Inability to keep up with current research (2.85)
- Compassion fatigue (2.80)
- Difficult employer (2.80)¹⁰¹

The MSSNY 2016 survey found the following drivers of burnout, listed in order of prevalence.¹⁰² The percentage of respondents who identified the stressor as a factor in burnout is indicated in parentheses.

- Length and degree of documentation requirements (65.99%)
- Extension of work into home life (e-mail, record completion, phone calls) (58.27%)
- Prior authorizations for medications/procedures/admissions (54.74%)
- Dealing with difficult patients (51.89%)
- EMR functionality problems (51.05%)
- CMS/State/Federal laws and regulations (44.33%)
- Lack of voice in being able to decide what good care is (40.39%)
- Hospital/Insurer imposed Quality Metrics (38.87%)
- Dealing with difficult colleagues (31.49%)
- Requirement for increased CME [Continuing Medical Education]/maintenance of certification (31.49%)¹⁰³

A 2014 survey conducted by the Wisconsin Medical Society listed three factors as the primary causes of dissatisfaction and burnout among physicians: decrease in direct patient care, EHRs, and poor work-life balance.¹⁰⁴ Other experts emphasize that the cumbersome and time-consuming administrative tasks that contemporary physicians face are a root cause of burnout.¹⁰⁵

101. *Id.*

102. Taskforce on Physician Stress and Burnout, *supra* note 18.

103. *Id.*

104. Michele Coleman et al., *Factors Affecting Physician Satisfaction and Wisconsin Medical Society Strategies to Drive Change*, 114 WMJ 135, 137-39 (2015).

105. Tait D. Shanafelt et al., *Addressing Physician Burnout: The Way Forward*, 317 JAMA 901, 901 (2017) (“Unlike many industries in which advances in technology have improved efficiency,

Two interrelated sources of burnout emerge as repeated themes in the literature. First is the transition to EHRs and associated clerical burdens, and second is inadequate time for face-to-face interactions with patients. Each of these could potentially be addressed through regulation, and thus, the remainder of this Article will focus on these two drivers of physician burnout.

II. ELECTRONIC HEALTH RECORD SYSTEMS AND PHYSICIAN BURNOUT

The EHR system has become the “virtual patient” that many believe demands more time than human patients.¹⁰⁶ This Part explains what EHR systems are and describes their benefits and shortcomings. It also analyzes the link between EHR systems and physician burnout. Finally, it describes and critiques the web of EHR-related regulations that are arguably key contributors to burnout. These include the Meaningful Use regulations, the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015,¹⁰⁷ and EHR certification requirements.

A. *Electronic Health Record Systems*

In 2004, President George W. Bush identified the transition from traditional paper records to EHRs as a priority for the federal government.¹⁰⁸ President Bush set a goal of having all Americans’ health records computerized within ten years and established the Office of the National Coordinator for Health Information Technology (ONC) within the U.S. Department of Health and Human Services to promote and oversee this process.¹⁰⁹ The transition accelerated under the Obama administration. The Health Information Technology for Economic and Clinical Health (HITECH) Act,¹¹⁰ part of the Obama stimulus plan, provided financial incentives for meaningful use of certified EHRs.¹¹¹ Today the vast majority of

EHRs appear to have increased clerical burden for physicians and can distract some physicians from meaningful interactions with patients.”); Squiers et al., *supra* note 43, at 1120 (stating that the authors “believe that one important mismatch is obvious to most practicing physicians—the increasing demands of medical bureaucracy that is at odds with and distracts from their primary passions of medical practice (e.g. patient care, research, and teaching)”).

106. Miyasaki et al., *supra* note 16, at 1736.

107. Pub. L. No. 114-10, 129 Stat. 87 (2015) (codified as amended in scattered sections of 16, 26, and 42 U.S.C.).

108. Joseph Conn, *10 Years after the Revolution: Health IT Coordinators Look Back at the Nation’s Progress*, MODERN HEALTHCARE (Apr. 5, 2014), <http://www.modernhealthcare.com/article/20140405/MAGAZINE/304059980>.

109. *Id.*

110. Pub. L. No. 111-5, 123 Stat. 226 (2009) (codified as amended in scattered sections of 42 U.S.C.).

111. David Blumenthal & Marilyn Tavenner, *The ‘Meaningful Use’ Regulation for Electronic Health Records*, 363 NEW ENG. J. MED. 501, 501 (2010); Sharona Hoffman & Andy Podgurski, *Meaningful Use and Certification of Health Information Technology: What About Safety?*, 39 J.L.

practices have adopted EHR systems.¹¹² As of 2016, over ninety-five percent of hospitals eligible to participate in the HITECH incentive program and over sixty percent of all office-based physicians are using EHR systems in compliance with the program.¹¹³ Many more physicians have EHRs but have not fulfilled all of the incentive program's requirements.¹¹⁴

The Institute of Medicine, the Robert Wood Johnson Foundation, and other experts¹¹⁵ identified eight "core EHR functionalities" that could make them more useful and versatile than paper records:

Clinical documentation and health information display: EHR systems record and display a wealth of information such as diagnostic test results, allergies, medication lists, diagnoses, demographics, clinicians' notes, advance directives, and more.

Results management: EHRs enable clinicians to search the record for details such as a patient's laboratory test results and prior treatments, thus enhancing their access to needed information.

Computerized provider order entry and management (CPOE): Health care providers can order prescriptions, diagnostic tests, treatments, and referrals to other physicians electronically.

Clinical decision support: This is a potentially life-saving feature that generates alerts and reminders for clinicians. Examples are warnings about drug interactions or side effects, guidance regarding appropriate medication dosage, and prompts relating to preventive and wellness care.

MED. & ETHICS (SUPP. ISSUE 1), 77, 77 (2011).

112. *Hospital Progress to Meaningful Use*, OFF. NAT'L COORDINATOR FOR HEALTH INFO. TECH. (2016) <https://dashboard.healthit.gov/quickstats/pages/FIG-Hospital-Progress-to-Meaningful-Use-by-size-practice-setting-area-type.php>; *Office-based Health Care Professional Participation in the CMS EHR Incentive Programs*, OFF. NAT'L COORDINATOR FOR HEALTH INFO. TECH. (2016), <https://dashboard.healthit.gov/quickstats/pages/FIG-Health-Care-Professionals-EHR-Incentive-Programs.php>.

113. See *supra* note 112.

114. National Center for Health Statistics, *Electronic Medical Records/Electronic Health Records (EMRs/EHRs)*, CTRS. FOR DISEASE CONTROL & PREVENTION (Mar. 31, 2017), <https://www.cdc.gov/nchs/fastats/electronic-medical-records.htm> (indicating that 86.9% of office-based physicians use some type of EHR system).

115. INSTITUTE OF MEDICINE, KEY CAPABILITIES OF AN ELECTRONIC HEALTH RECORD SYSTEM 7-11 (2003); Timothy G. Ferris, et al., *A Framework for Measuring the Effects of Health Information Technology on Health Care Quality*, in HEALTH INFORMATION TECHNOLOGY IN THE UNITED STATES: WHERE WE STAND 178-79 (David Blumenthal et al. eds., Robert Wood Johnson Foundation, 2008).

Electronic communication and connectivity: EHR systems enable medical team members to communicate online with each other, with other providers whom they might consult, and with patients. More communication can enhance the patient's treatment experience and results.

Patient support: EHR systems can facilitate patient education and access to health records. Some systems offer patients a personal health record, which is "[a]n electronic application through which individuals can access, manage and share their health information . . . in a private, secure, and confidential environment."¹¹⁶ The systems also may remind patients to pursue preventive and follow-up care.

Administrative processes: Additional components include electronic scheduling systems, insurance eligibility verification, billing, and claims processing. Clinicians can further use computerized tools to identify individuals who are potential candidates for clinical trials, who are taking drugs subject to recalls, or who are eligible for chronic disease management programs. EHR systems can also facilitate quality assessment, quality improvement, public health, and other initiatives.

Reporting and population health management: Health care providers can collect clinical data to meet government, private, and institutional reporting requirements.¹¹⁷

EHR systems advocates have touted the many benefits that they can yield. These include enhancing the quality of care, improving patient safety, saving costs, and facilitating medical research and public health initiatives.¹¹⁸ A key advantage is that EHRs eliminate the problem of illegible handwriting in physician notes and prescriptions.¹¹⁹

Nevertheless, many physicians complain bitterly that contemporary EHR systems and the regulations that govern them generate cumbersome and time-

116. Paul C. Tang et al., *Personal Health Records: Definitions, Benefits, and Strategies for Overcoming Barriers to Adoption*, 13 J. AM. MED. INFORMATICS ASS'N 121, 122 (2006).

117. INSTITUTE OF MEDICINE, *supra* note 115, at 7-11; INSTITUTE OF MEDICINE, HEALTH IT AND PATIENT SAFETY: BUILDING SAFER SYSTEMS FOR BETTER CARE 38-44 (2012); Ferris, et al., *supra* note 115, at 78-79.

118. SHARONA HOFFMAN, ELECTRONIC HEALTH RECORDS AND MEDICAL BIG DATA: LAW AND POLICY 15-23 (2016).

119. George A. Gellert et al., *Should US Doctors Embrace Electronic Health Records?*, 356 BMJ j242, j242 (2017).

consuming work. Consequently, many believe that EHR systems are a significant cause of burnout.¹²⁰

B. The Link between EHR Systems and Burnout

Contemporary physicians spend as much as fifty percent of their total work time on documentation.¹²¹ According to one study, for each hour that doctors spend face-to-face with patients, they spend up to two hours on documentation.¹²² Moreover, physicians spend one to two hours outside the office each day on computer work.¹²³ This phenomenon has spawned a new term popular among health care providers: “pajama time.”¹²⁴ A leading expert, Dr. Robert Wachter, has explained that “EHRs contribute to burnout by turning physicians into unhappy data-entry clerks.”¹²⁵

A study of EHR system use at a community hospital concluded that even in the emergency room, physicians spent forty-four percent of their time on EHR work, which far exceeded the amount of time they devoted to direct patient care (twenty-eight percent).¹²⁶ The EHR work required an average of four hundred mouse clicks per hour and thus 4000 clicks in a ten-hour shift.¹²⁷

Of course, before the advent of EHR systems, physicians were also required

120. N. Lance Downing et al., *Physician Burnout in the Electronic Health Record Era: Are We Ignoring the Real Cause?*, 169 ANNALS INTERNAL MED. 50, 50 (2018) (arguing that “there is a growing sense within the medical community that the EHR is driving professional dissatisfaction and burnout”); Jesse Ehrenfeld & Jonathan Wanderer, *Technology as Friend or Foe? Do Electronic Health Records Increase Burnout?*, 31 CURRENT OP. ANAESTHESIOLOGY. 357, 357 (2018) (asserting that “there is growing concern about the adverse consequences of [EHR] use on physician satisfaction and burnout”).

121. Alexander K. Ommaya et al., *Care-Centered Clinical Documentation in the Digital Environment: Solutions to Alleviate Burnout*, NAT’L ACAD. MED. DISCUSSION PAPER, (Jan. 29, 2018), <https://nam.edu/care-centered-clinical-documentation-digital-environment-solutions-alleviate-burnout/> (“Recent studies have shown that physicians spend as much as 50 percent of their time completing clinical documentation.”); Christine Sinsky et al., *Allocation of Physician Time in Ambulatory Practice: A Time and Motion Study in 4 Specialties*, 165 ANNALS INTERNAL MED. 753, 755 (2016) (finding that “[d]uring the office day, physicians spent 27.0% of their total time on direct clinical face time with patients and 49.2% of their time on EHR and desk work”).

122. Sinsky et al., *supra* note 121, at 757. *But see* Ming Tai-Seale et al., *Electronic Health Record Logs Indicate That Physicians Split Time Evenly Between Seeing Patients and Desktop Medicine*, 36 HEALTH AFFS. 655, 655 (2017) (studying 471 primary care physicians and finding that “the physicians logged an average of 3.08 hours on office visits and 3.17 hours on desktop medicine each day”).

123. Sinsky et al., *supra* note 121, at 756-57.

124. Ommaya et al., *supra* note 121.

125. Roger Collier, *Electronic Health Records Contributing to Physician Burnout*, 189 CMAJ E1405, E1405 (2017).

126. Robert G. Hill Jr. et al., *4000 Clicks: A Productivity Analysis of Electronic Medical Records in a Community Hospital ED*, 31 AM. J. EMERGENCY MED. 1591, 1592 (2013).

127. *Id.*

to document their diagnoses and treatments thoroughly and to comply with health care regulatory requirements.¹²⁸ However, by many accounts, computerization has exacerbated rather than alleviated the onus of these tasks.¹²⁹

The explanation for this perplexing change lies in the design and functionality of contemporary EHR systems. EHR products often have user interfaces¹³⁰ that are not intuitive and are difficult to navigate.¹³¹ Fixed templates restrict physicians' ability to enter information in sensible and natural ways, and patient charts are plagued by information overload.¹³² In the era of paper records, physicians could dictate notes or jot down notes at their own discretion, but now they spend up to six times longer on computer tasks.¹³³

Another inefficiency arises from excessive alerts and reminders, also called clinical decision support.¹³⁴ Electronic alerts and reminders can save lives, and they are a welcome addition to the health care toolkit. However, in practice, they

128. See Ommaya et al., *supra* note 121 (discussing clinical documentation and coding requirements).

129. Tait D. Shanafelt et al., *Relationship Between Clerical Burden and Characteristics of the Electronic Environment with Physician Burnout and Professional Satisfaction*, 91 MAYO CLINIC PROC. 836, 846 (2016) (noting that in their current form, EHRs have “a variety of unintended negative consequences that reduce efficiency, increase clerical burden, and increase the risk of burnout for physicians”).

130. The user interface is the “application that allows users to enter data into a computer and that presents data to the user.” EDWARD H. SHORTLIFFE & JAMES J. CIMINO, BIOMEDICAL INFORMATICS: COMPUTER APPLICATIONS IN HEALTH CARE AND BIOMEDICINE 997 (2006).

131. *Id.* See also, Saif Khairat et al., *Focus Section on Health IT Usability: Perceived Burden of EHRs on Physicians at Different Stages of Their Career*, 9 APPLIED CLINICAL INFORMATICS 336, 344 (2018) (observing fourteen emergency physicians and concluding that “the factors causing high EHR frustrations are: (1) remembering menu and button names and commands use; (2) performing tasks that are not straightforward; (3) system speed; and (4) system reliability” and that more senior physicians experience more frustrations than younger doctors).

132. HOFFMAN, *supra* note 118, at 29-32.

133. Paul Dechant, *How Does the EHR Drive Burnout? Let's Count the Ways*, KEVINMD.COM (August 13, 2017), <https://www.kevinmd.com/blog/2017/08/ehr-drive-burnout-lets-count-ways.html>; Sun Young Park et al., *The Effects of EMR Deployment on Doctors' Work Practices: A Qualitative Study in the Emergency Department of a Teaching Hospital*, 81 INT'L J. MED. INFORMATICS 204, 204 (2012) (concluding that implementation of an EHR system increased “documentation time four to five fold”); Lise Poissant et al., *The Impact of Electronic Health Records on Time Efficiency of Physicians and Nurses: A Systematic Review*, 12 J. AM. MED. INFORMATICS ASS'N 505, 508 (2005) (finding that CPOE increased physicians' work time between 98.1% and 328.6%).

134. Megan E. Gregory et al., *Electronic Health Record Alert-Related Workload as a Predictor of Burnout in Primary Care Providers*, 8 APPLIED CLINICAL INFORMATICS 686, 688, 693 (2017) (finding that primary care physicians' subjective perception that they had inadequate time to manage EHR alerts contributed to burnout); Tina Shah et al., *Impact of a National QI Programme on Reducing Electronic Health Record Notifications to Clinicians*, BMJ QUALITY & SAFETY 1, 1 (2018).

can exacerbate burnout. A study of the primary care physicians working for the Department of Veteran Affairs revealed that seventy percent felt they could not effectively manage the number of alerts they received.¹³⁵ Moreover, thirty percent indicated that during the prior year, they had missed patient test results because of alert burden and consequently delayed patient care.¹³⁶ Another research project concluded that primary care physicians received a mean of 56.4 alerts with new information per day and spent an average of forty-nine minutes per day processing these alerts.¹³⁷ All too many alerts are boilerplate notifications that relate to trivial drug risks that are not of clinical significance or matters that do not apply to the patient in question.¹³⁸ According to one study, it takes over 331 alerts to prevent one adverse drug event, and just ten percent of notifications account for seventy-eight percent of cost savings from preventable errors.¹³⁹ While alerts are worthwhile if they avert even one critical medical mistake and expense reduction is always appreciated, physicians commonly complain of “alert fatigue” and long for improved clinical decision support that would issue only serious warnings that could meaningfully enhance care.¹⁴⁰

Yet another source of information overload is the EHR’s copy and paste feature.¹⁴¹ The ability to copy narrative from a prior visit and paste it into new visit notes is designed to save clinicians time.¹⁴² Ironically, however, this feature may waste a great deal of time because it can make the medical record repetitive and excessively voluminous.¹⁴³ Because of such “note bloat,” reviewing a patient’s record prior to a visit or locating particular details within it can become a slow and arduous task.¹⁴⁴ Moreover, if the copied information is not carefully edited and updated, the new visit notes could be erroneous and mislead or confuse physicians.¹⁴⁵ For example, in one reported case, the EHR of a patient who suffered

135. Hardeep Singh et al., *Primary Care Practitioners’ Views on Test Result Management in EHR-Enabled Health Systems: A National Survey*, 20 J. AM. MED. INFORMATICS ASS’N 727, 731 (2013).

136. *Id.*

137. Daniel R. Murphy et al., *Notifications Received by Primary Care Practitioners in Electronic Health Records: A Taxonomy and Time Analysis*, 125 AM. J. MED. 209.e1, 209.e5 (2012).

138. HOFFMAN, *supra* note 118, at 28-29.

139. Saul N. Weingart et al., *An Empirical Model to Estimate the Potential Impact of Medication Safety Alerts on Patient Safety, Health Care Utilization, and Cost in Ambulatory Care*, 169 ARCHIVES INTERNAL MED. 1465, 1465 (2009).

140. NICK ZAGORSKI, *ARE TODAY’S EHR ALERTS PUTTING CLINICIANS, PATIENTS AT RISK?*, PSYCH. NEWS, July 19, 2017, <https://psychnews.psychiatryonline.org/doi/full/10.1176/appi.pn.2017.5b23>.

141. Ommaya et al., *supra* note 121.

142. HOFFMAN, *supra* note 118, at 25.

143. Ommaya et al., *supra* note 121 (indicating that because of the practice of copying and pasting, “the EHR has become a bloated repository of repetitive and redundant information”).

144. *Id.* (stating that “clinical notes have become bloated and difficult to read,” which forces clinicians “to go through a process of foraging to uncover important elements” of the record).

145. Sue Bowman, *Impact of Electronic Health Record Systems on Information Integrity*:

surgical complications and was hospitalized for many weeks indicated each day that this was “post-op day No. 2” because the note was repeatedly copied but never edited.¹⁴⁶

Many clinicians have also complained generally about EHR system usability. Usability is a term that refers to “the extent to which a product can be used by specified users to achieve specified goals with *effectiveness, efficiency, and satisfaction* in a specified context of use.”¹⁴⁷ Contemporary EHR systems suffer from a number of inadequacies that make them difficult to operate. For example, physicians find that they are difficult to navigate, display information poorly, do not enable users to search easily for data, disrupt the natural workflow of health care operations, and do not enable clinicians to use language effectively to tell the patient’s story.¹⁴⁸ Experimentation with different user interface configurations has confirmed that optimized configuration can reduce physicians’ task load, shorten the time it takes to complete tasks, and even lower error rates.¹⁴⁹ A few suggestions concerning features that enhance EHR usability are offered in Part V.B below.

EHR systems contribute to physician burnout not only because of the technology itself, but also because of the regulations that govern them. EHR regulations are analyzed in the next section.

C. The Regulatory Burden: Meaningful Use, MACRA, and Certification

In 2009, in an effort to dramatically advance EHR systems’ adoption, Congress enacted the HITECH Act.¹⁵⁰ The law established an incentive program by which qualified health care providers could receive incentive payments for becoming meaningful users of certified EHR systems.¹⁵¹ Health care providers could receive incentive payments from Medicare through 2016 and from Medicaid

Quality and Safety Implications, 10 PERSP. HEALTH INFO. MGMT. 1, 4 (2013).

146. Kevin B. O’Reilly, *EHRs: ‘Sloppy and Paste’ Endures Despite Patient Safety Risk*, AM. MED. NEWS, Feb. 4, 2013, <http://www.amednews.com/article/20130204/profession/130209993/2/>.

147. TOM TULLIS & BILL ALBERT, *MEASURING THE USER EXPERIENCE: COLLECTING, ANALYZING, AND PRESENTING USABILITY METRICS* 4 (2008).

148. *Id.* at 808-11; HOFFMAN, *supra* note 118, at 29-30 (discussing EHR systems’ inflexibility and lack of customization); Ommaya et al., *supra* note 121, at 4 (“The patient’s story is . . . lost in the fog of self-populated content that adds pages but little purpose to the notes.”).

149. Adil Ahmed et al., *The Effect of Two Different Electronic Health Record User Interfaces on Intensive Care Provider Task Load, Errors of Cognition, and Performance*, 39 CRITICAL CARE MED. 1626, 1627, 1633 (2011) (reporting on the design of a novel user interface that displayed “a subset of high-value data”).

150. Pub. L. No. 111-5, 123 Stat. 226 (2009) (codified as amended in scattered sections of 42 U.S.C.).

151. Blumenthal & Tavenner, *supra* note 111, at 501; Hoffman & Podgurski, *supra* note 111, at 77. Providers could receive up to \$44,000 through Medicare or \$63,750 through Medicaid, depending on eligibility.

until 2021.¹⁵² The program is now named the Promoting Interoperability (PI) Program.¹⁵³ In order to implement the HITECH Act, the Centers for Medicare and Medicaid Services (CMS) issued a series of regulations that establish the standards for meaningful use and EHR system certification. Meaningful Use standards have also been incorporated into a second law, MACRA.¹⁵⁴ This section addresses the regulations that are relevant to physician burnout and analyzes their pitfalls.

1. *The Meaningful Use Regulations and MACRA*

The Meaningful Use regulations and MACRA require physicians to perform a variety of functions using their EHR systems. Both have been criticized by commentators as overly burdensome and needlessly causing physicians distress. Both are analyzed below.

a. The Meaningful Use Regulations

The Meaningful Use regulations aim to ensure that clinicians put EHR systems to good use and employ them to improve health outcomes.¹⁵⁵ They were rolled out in three stages, with the intention of allowing health care providers to adjust their practices gradually in order to fully utilize EHR systems.¹⁵⁶ Stage 3 Meaningful Use regulations became effective in 2017.¹⁵⁷ They establish eight objectives for professionals and hospitals that are eligible for incentives:

- 1) Protect patient health information
- 2) Generate and transmit prescriptions electronically
- 3) Implement clinical decision support
- 4) Use computerized provider order entry
- 5) Provide patients with electronic access to health information
- 6) Coordinate care through patient engagement
- 7) Engage in health information exchange

152. HOFFMAN, *supra* note 118, at 39-40. Eligible professionals had to select participation in either the Medicare or Medicaid program, but eligible hospitals could participate in both simultaneously. 42 C.F.R. §§ 495.60(e), 495.310(c), 495.310(g) (2018).

153. *Medicare and Medicaid Promoting Interoperability Program Basics*, CTRS. FOR MEDICARE & MEDICAID SERVS. (May 9, 2018), <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Basics.html>.

154. Pub. L. No. 114-10, 129 Stat. 87 (2015) (codified as amended in scattered sections of 16, 26, and 42 U.S.C.).

155. Centers for Disease Control and Prevention, *Meaningful Use* (Jan. 18, 2017), <https://www.cdc.gov/ehrmeaningfuluse/introduction.html>.

156. HOFFMAN, *supra* note 118, at 42.

157. *Id.*

8) Report data to public health authorities or clinical data registries¹⁵⁸

Health care providers participating in the PI program must also submit clinical quality measure (CQM) data to the Centers for Medicare and Medicaid Services.¹⁵⁹ CQMs focus on six primary domains:

- Patient and Family Engagement
- Patient Safety
- Care Coordination
- Population/Public Health
- Efficient Use of Healthcare Resources
- Clinical Process/Effectiveness¹⁶⁰

Examples of CQMs are the “[p]ercentage of women 50-74 years of age who had a mammogram to screen for breast cancer”¹⁶¹ and the “[p]ercentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.”¹⁶² In 2018, eligible professionals receiving Medicaid EHR incentive payments must report six out of fifty-three CQMs.¹⁶³

b. MACRA

Physicians seeking Medicare payments must learn to comply with a new law

158. 42 C.F.R. § 495.22(e) (2018); *Eligible Hospital and Critical Access Hospital Medicaid EHR Incentive Program Stage 3 Objectives and Measures Table of Contents*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Aug. 2017), https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/TableofContents_EH_Medicaid_Stage3.pdf; *Eligible Professional Medicaid EHR Incentive Program Stage 3 Objectives and Measures Table of Contents*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Aug. 2017), https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/TableofContents_EP_Medicaid_Stage3.pdf; *Stage 3 Program Requirements for Providers Attesting to their State’s Medicaid Promoting Interoperability (PI) Programs*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Apr. 25, 2018), https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Stage3Medicaid_Require.html.

159. *Clinical Quality Measures Basics*, CTRS. FOR MEDICARE & MEDICAID SERVS. (May 8, 2018), <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/ClinicalQualityMeasures.html>.

160. *Id.*

161. *Breast Cancer Screening*, CTRS. FOR MEDICARE & MEDICAID SERVS. (May 14, 2018), <https://ecqi.healthit.gov/ecqm/measures/cms125v7>.

162. *Pneumococcal Vaccination Status for Older Adults*, CTRS. FOR MEDICARE & MEDICAID SERVS. (May 14, 2018), <https://ecqi.healthit.gov/ecqm/measures/cms127v7>.

163. *Program for 2018 Reporting*, CTRS. FOR MEDICARE & MEDICAID SERVS. (March 26, 2018), <https://ecqi.healthit.gov/ecqms/ecqm-news/cms-clarifies-ecqm-requirements-eligible-professionals-eps-under-medicare-electronic>.

as well, MACRA, which went into effect in 2017.¹⁶⁴ MACRA, in relevant part, aims to decrease clinicians' administrative burdens by consolidating three quality reporting programs for Medicare purposes: 1) the Physician Quality Reporting System, 2) the Value-based Payment Modifier, and 3) Meaningful Use. It also adds a new performance category, however, called improvement activities.¹⁶⁵ MACRA does not apply to hospitals and does not affect the Medicaid Promoting Interoperability program.¹⁶⁶

Under MACRA, physicians who wish to be paid by Medicare must participate in either the Merit-Based Incentive Payment System (MIPS) or an Advanced Alternative Payment Model (AAPM).¹⁶⁷ MIPS creates a scoring system with a range from zero to one hundred and adjusts payment based on performance in four categories: quality, cost of care, promoting interoperability, and improvement activities.¹⁶⁸ Based on their scores, physicians will receive positive, negative, or no Medicare payment adjustments.¹⁶⁹ Thus, clinicians must scrupulously track and report the required data in compliance with complex and sometimes abstruse instructions in order to maximize Medicare payments and avoid penalties.¹⁷⁰

While most health care providers are subject to MIPS, some participate in an

164. Pub. L. No. 114-10, 129 Stat. 87 (2015) (codified as amended in scattered sections of 16, 26, and 42 U.S.C.); Virgil Dickson, *Physician Offices, Hospitals Still Trying to Prepare for MACRA's Reimbursement Changes*, MODERN HEALTHCARE (Aug. 26, 2017), <http://www.modernhealthcare.com/article/20170826/NEWS/170829947>.

165. *Frequently Asked Questions: Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)*, AM. ACAD. FAM. PHYSICIANS (Jan. 2018), <https://www.aafp.org/practice-management/payment/medicare-payment/macra-101/faq.html>.

166. 42 U.S.C. § 1395w-4(q) (Supp. 2016); 42 C.F.R. § 414.1310 (2018); HOFFMAN, *supra* note 118, at 46.

167. *MACRA Basics Merit-based Incentive Payment System (MIPS)*, AM. ACAD. FAM. PHYSICIANS (Jan. 25, 2018), <https://www.aafp.org/practice-management/payment/medicare-payment/mips.html>. The regulations establish an exclusion for those meeting the "low volume threshold" of two hundred or fewer Medicare Part B beneficiaries or \$90,000 or less in billing for Part B covered services. See 42 C.F.R. §§ 414.1305, 414.1310(b) (2018).

168. In 2018 the categories were weighted as follows: quality – 50%, cost – 10%, promoting interoperability – 25%, and improvement activities – 15%. 42 U.S.C. § 1395w-4(q)(2)(A), (5) (Supp. 2016); 42 C.F.R. § 414.1380(c) (2018); *MACRA Basics Merit-based Incentive Payment System (MIPS)*, *supra* note 167. In 2018 there were 275 available quality measures, and participants had to submit six that were relevant to their practice. See *Quality Payment Program*, CTRS. FOR MEDICARE & MEDICAID SERVS. (2018), <https://qpp.cms.gov/mips/explore-measures/quality-measures?py=2018#measures>.

169. 42 U.S.C. § 1395w-4(q)(6) (Supp. 2016); 42 C.F.R. § 414.1405 (2018); *MACRA Basics Merit-based Incentive Payment System (MIPS)*, *supra* note 167.

170. 42 U.S.C. § 1395w-4(q)(4)(B) (Supp. 2016); 42 C.F.R. § 414.1325 (2018); *MACRA Basics Merit-based Incentive Payment System (MIPS)*, *supra* note 167.

AAPM¹⁷¹ and are exempt from MIPS.¹⁷² Nevertheless, AAPM participants must still measure cost and quality and use certified EHR technology.¹⁷³

c. Critique

If the foregoing sections were difficult for readers to follow, the regulations are all the more overwhelming for physicians who must comply with them. Undoubtedly, it is prudent to regulate EHR systems and track quality of care, and doing so should in principle promote improved health outcomes.¹⁷⁴ However, critics posit that the current reporting requirements are excessively arduous, repetitive, and inflexible and thus exacerbate burnout.¹⁷⁵

John D. Halamka and Micky Tripathi, both renowned EHR experts, co-authored a commentary on the HITECH era in the *New England Journal of Medicine* in 2017.¹⁷⁶ They lamented that “confusing layers of regulations” caused the loss of the “hearts and minds of clinicians.”¹⁷⁷ To illustrate, they argued that “quality measurement added data collection requirements that had a substantial

171. The Centers for Medicare and Medicaid Services define an alternative payment model (APM) as “a payment approach, developed in partnership with the clinician community, that provides added incentives to clinicians to provide high-quality and cost-efficient care. APMs can apply to a specific clinical condition, a care episode, or a population.” *Quality Payment Program 8*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Oct. 26, 2016), <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Quality-Payment-Program-webinar-slides-10-26-16.pdf>.

172. 42 C.F.R. § 414.1310(b)(1)(ii) (2018); *Answering Your FAQs about MIPS, MACRA AND APMS: The New Quality Payment Program Explained*, MINGLE ANALYTICS (2018), <https://mingleanalytics.com/confused-macra-mips-apms-explained-plain-english/>; *Quality Payment Program*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Oct. 26, 2016), <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Quality-Payment-Program-webinar-slides-10-26-16.pdf>. A subset of APMs are Advanced APMs.

173. 42 U.S.C. § 1395l(z) (Supp. 2016); 42 C.F.R. § 414.1415 (2018).

174. See Sharona Hoffman & Andy Podgurski, *Finding a Cure: The Case for Regulation and Oversight of Electronic Health Record Systems*, 22 HARV. J.L. & TECH. 103 (2008); *Quality Measure and Quality Improvement*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Aug. 24, 2017), <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Quality-Measure-and-Quality-Improvement.html> (explaining that the aim of quality measures “is to optimize health outcomes by improving quality and transforming the health care system”).

175. Shari M. Erickson et al., *Putting Patients First by Reducing Administrative Tasks in Health Care: A Position Paper of the American College of Physicians*, 166 ANNALS INTERNAL MED. 659, app. (2017); Richard A. Young et al., *The Challenges of Measuring, Improving, and Reporting Quality in Primary Care*, 15 ANNALS FAM. MED. 175, 175 (2017); Sara Health, *What Clinical Quality Measures Mean to Healthcare Providers*, EHR INTELLIGENCE (July 1, 2016), <https://ehrintelligence.com/features/what-clinical-quality-measures-mean-to-healthcare-providers>.

176. John D. Halamka & Micky Tripathi, *The HITECH Era in Retrospect*, 377 NEW ENG. J. MED 907 (2017).

177. *Id.* at 907.

negative effect on usability with little return.”¹⁷⁸ Another author complained that the Meaningful Use regulations disrupt workflow because they require doctors to perform EHR tasks that non-physicians could otherwise handle.¹⁷⁹ Likewise, the Medicare Payment Advisory Commission has asserted that MIPS is very complex and burdensome.¹⁸⁰

In his well-regarded book, *The Digital Doctor: Hope, Hype, and Harm at the Dawn of Medicine's Computer Age*,¹⁸¹ Professor Robert Wachter critiqued the Stage 2 Meaningful Use regulations that preceded Stage 3. He posited that many of the mandates “depended on a clinical ecosystem and health care culture that did not yet exist.”¹⁸² For example, they required that more than five percent of patients “view, download, and transmit” their electronic health information to third parties.¹⁸³ Thus, physicians had to invest time in encouraging patients to engage in activities in which they may have no interest and from which they may not benefit.

In addition, the regulations required hospitals to transmit discharge summaries electronically to other facilities,¹⁸⁴ but they did not mandate that these summaries be useful to recipients. Consequently, some hospitals were spending time arbitrarily sending discharge summaries to other facilities for no good reason other than to “check a box on . . . [their] Stage 2 scorecard.”¹⁸⁵

As a third example, Dr. Wachter cited the requirement that doctors be prompted by their EHRs to provide educational materials to ten percent of their patients.¹⁸⁶ Doctors who routinely gave their patients information sheets about

178. *Id.*

179. See *supra* note **Error! Bookmark not defined.** and accompanying text.

180. Shannon Firth, *MIPS Takes a Beating at MedPAC—Medicare Advisory Panel Says It Needs to Go*, MEDPAGE TODAY (Oct. 5, 2017), <https://www.medpagetoday.com/publichealthpolicy/medicare/68362>.

181. ROBERT WACHTER, *THE DIGITAL DOCTOR: HOPE, HYPE, AND HARM AT THE DAWN OF MEDICINE'S COMPUTER AGE* (McGraw Hill Education, 2015).

182. *Id.* at 209.

183. 42 C.F.R. § 495.20(j)(10)(ii)(B) (2018). Stage 3 retains this requirement. See 42 C.F.R. § 495.22(e)(8)(i)(A)(2)(ii) (2018). MIPS has a similar requirement. See *Quality Payment Program, CTRS. FOR MEDICARE & MEDICAID SERVS.* (2018), <https://app.cms.gov/mips/explore-measures/quality-measures?py=2018#measures> (requiring that at least one patient be “provided timely access to view online, download, and transmit his or her health information”).

184. 42 C.F.R. § 495.20(l)(11) (2018). Stage 3 retains this requirement. See 42 C.F.R. § 495.22(e)(5) (2018). MIPS has a related requirement. See *Quality Payment Program, supra* note 183 (requiring that “[f]or at least one transition of care or referral received or . . . [encounter with a new patient], the MIPS eligible clinician receives or retrieves and incorporates into the patient’s record an electronic summary of care document”).

185. WACHTER, *supra* note 181, at 209.

186. 42 C.F.R. § 495.20(j)(12)(ii) (2018). Stage 3 retains this requirement. See 42 C.F.R. § 495.22(e)(6) (2018). MIPS has a similar requirement. See *Quality Payment Program, supra* note 183 (requiring that clinicians “use clinically relevant information from certified EHR technology to identify patient-specific educational resources and provide electronic access to those materials to at least one unique patient”).

their conditions were not deemed in compliance. They had to find a way to have their EHR system *prompt* them to do so. According to the author, the regulations were so problematic that some clinicians referred to them as “Meaningless Abuse.”¹⁸⁷

2. EHR Certification

EHR certification regulations are designed to establish oversight and quality control for EHR products.¹⁸⁸ Unfortunately, they fall short of ensuring optimal usability of EHR systems. Consequently, many clinicians feel that rather than diminishing their administrative burdens, computerization has caused these burdens to become even heavier.¹⁸⁹

a. Regulatory Requirements

Health care providers that wish to participate in the incentive program must operate certified EHR systems.¹⁹⁰ ONC, a division of the U.S. Department of Health and Human Services, oversees the Health IT Certification Program.¹⁹¹ Ideally, certification should ensure that a product is safe and user-friendly and that it facilitates clinicians’ clerical tasks to the extent possible. However, that is not the primary focus of this certification process.¹⁹²

The certification regulations focus on enabling EHR system users to fulfill the Meaningful Use objectives.¹⁹³ To illustrate, one certification criterion is that the EHR system enable users to “electronically record, change, and access” medication, laboratory, and radiology or imaging orders.¹⁹⁴

Another regulatory provision requires that “[u]ser-centered design processes must be applied to each capability an EHR technology includes.”¹⁹⁵ User-centered design (UCD) prioritizes the cognitive and information needs of users.¹⁹⁶ Although UCD evaluates the design and development process and focuses on the product’s

187. WACHTER, *supra* note 181, at 209-210. *See also*, G. Talley Holman et al., *Meaningful Use’s Benefits and Burdens for US Family Physicians*, 25 J. AM. MED. INFORMATICS ASS’N 694, 694 (2018) (stating that MACRA adopted the Meaningful Use (MU) criteria and that “[f]or many physicians, MU created a significant practice burden without clear benefits to patient care”).

188. 45 C.F.R. § 170.300, .314–.315, .545–.550, .555–.557 (2018).

189. *See supra* Part II.B.

190. 42 U.S.C. § 1395w-4(o)(2) (Supp. 2016).

191. *About the ONC Health IT Certification Program*, HEALTHIT.GOV (Feb. 21, 2018), <https://www.healthit.gov/topic/certification-ehrs/about-onc-health-it-certification-program>.

192. HOFFMAN, *supra* note 118, at 46-49, 50-54.

193. 45 C.F.R. § 170.315 (2018).

194. 45 C.F.R. § 170.315(a)(1) (2018).

195. 45 C.F.R. § 170.315(g)(3) (2018).

196. Raj M. Ratwani et al., *Electronic Health Record Vendor Adherence to Usability Certification Requirements and Testing Standards*, 314 JAMA 1070, 1070 (2015).

anticipated users,¹⁹⁷ it does not specify precise methods for the design process and does not evaluate the product itself.

Vendors who wish to obtain certification must attest to implementing a UCD process and must conduct and report the results of usability testing on eight specified EHR functions.¹⁹⁸ Vendors can develop their own UCD process or adopt well-respected processes, such as those published by the International Organization for Standardization or the National Institute of Standards and Technology.¹⁹⁹

In order to conduct usability testing, vendors recruit participants to engage in representative tasks relating to the eight EHR capabilities.²⁰⁰ Vendors then measure the amount of time it takes to complete the task, the number and types of errors found, and subjective user satisfaction with the way the EHR system operated.²⁰¹ According to ONC, vendors should include at least fifteen participants, and reports are made public once the EHR product is certified.²⁰²

b. Usability Testing Critique

The certification process focuses only on a narrow set of technical meaningful use requirements in a controlled laboratory setting, and vendors are given testing scenarios in advance.²⁰³ Thus, testing does not examine the product's capabilities in wide-ranging and diverse circumstances, such as those that exist in the real world.²⁰⁴

Moreover, vendors maintain a great deal of discretion with respect to usability

197. *User-Centered Design Basics*, USABILITY.GOV (Apr. 3, 2017), <https://www.usability.gov/what-and-why/user-centered-design.html>.

198. Raj M. Ratwani et al., *Electronic Health Record Usability: Analysis of the User-Centered Design Processes of Eleven Electronic Health Record Vendors*, 22 J. AM. MED. INFORMATICS ASS'N 1179, 1179 (2015). See also 45 C.F.R. § 170.314-.315 (2018); *Understanding Certified Health IT*, OFF. NAT'L COORDINATOR FOR HEALTH INFO. TECH. (2015), <https://www.healthit.gov/sites/default/files/understanding-certified-health-it-2.pdf>. The eight capabilities encompass clinical processes, care coordination, clinical quality measurement, privacy and security, patient engagement public health, health IT design and performance, and electronic exchange of information.

199. Ratwani et al., *supra* note 196, at 1070.

200. *Id.* at 1181; ROBERT M. SCHUMACHER & SVETLANA Z. LOWRY, NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY, CUSTOMIZED COMMON INDUSTRY FORMAT TEMPLATE FOR ELECTRONIC HEALTH RECORD USABILITY TESTING 10 (2010), http://www.nist.gov/itl/hit/upload/LowryNISTIR-7742Customized_CIF_Template_for_EHR_Usability_Testing_Publication1_Version-doc.pdf.

201. SCHUMACHER & LOWRY, *supra* note 200, at 18-19.

202. Ratwani, et al., *supra* note 196, at 1070.

203. A. Jay Holmgren et al., *Are All Certified EHRs Created Equal? Assessing the Relationship Between EHR Vendor and Hospital Meaningful Use Performance*, 25 J. AM. MED. INFORMATICS ASS'N 654, 659 (2018).

204. *Id.*

and invest varying amounts of resources in it.²⁰⁵ According to one study, the quality of vendors' UCD processes ranges from well-developed to basic to misconceived.²⁰⁶ A second study led by the same investigator found "a lack of adherence to ONC certification requirements and usability testing standards among several widely used EHR products that were certified as having met these requirements."²⁰⁷

The American Medical Association and MedStar Health's National Center for Human Factors in Healthcare have criticized the usability process for its "narrow focus on only eight capabilities among the dozens required by the ONC for the Meaningful Use (MU) program and to the absence of best practices in the certification process."²⁰⁸ They assert that many vendors do not implement best practices and are nevertheless certified by ONC.²⁰⁹

Consequently, researchers cite persistent problems in the areas of data entry, alerts, interoperability of different systems, visual displays, availability of information, automation, default settings, workflow disruptions, electronic ordering, test results management, and more.²¹⁰ EHR systems remain plagued by poor usability and excessive "click burden."²¹¹ These deficiencies not only contribute to physician burnout, but also may lead to medical errors and endanger patients.²¹²

III. INABILITY TO SPEND ADEQUATE TIME WITH PATIENTS

One of the consequences of the very heavy administrative burdens with which physicians are saddled is that they spend relatively little time interacting face-to-face with patients. Thus, many lament that they cannot do what they love to do most as members of the healing profession.²¹³ Physicians are forced to rush through examining patients, listening to them, thoughtfully considering the reasons

205. *Id.* at 655 ("Vendors . . . make different decisions about system architecture, user interface design, and functionality, which carry important implications for how they are implemented and used.").

206. Ratwani et al., *supra* note 198, at 1180.

207. Ratwani et al., *supra* note 196, at 1071.

208. National Center for Human Factors in Healthcare, *EHR User-Centered Design Evaluation Framework*, MEDSTAR HEALTH, <https://www.medicalhumanfactors.net/ehr-vendor-framework/>.

209. *Id.*

210. Jessica L. Howe et al., *Electronic Health Record Usability Issues and Potential Contribution to Patient Harm*, 319 JAMA 1276, 1277 (2018); Zahabi et al., *supra* note 147, at 808-811.

211. Guo et al., *supra* note 8, at 140.

212. Howe et al., *supra* note 210, at 1277; Kathryn M. Kellogg et al., *EHR Usability: Get It Right from the Start*, 51 BIOMEDICAL INSTRUMENTATION & TECH. 197, 197 (2017).

213. Larissa R. Thomas et al., *Charter on Physician Well-being*, 319 JAMA 1541, 1541 (2018) (asserting that "[a]uthentic, humanistic interactions with patients and colleagues enhance physician well-being").

for their concerns, explaining diagnoses and treatments, and answering questions.²¹⁴ These time pressures contribute to physicians' dissatisfaction and burnout.²¹⁵ This section analyzes the length of time allotted for patient visits, the causes of short patient visits, and two self-help measures that physicians are using to increase the time they have with patients.

A. Time Allotted for Patient Visits

The average primary care visit is fifteen to twenty minutes.²¹⁶ While relatively simple medical problems can be addressed in a few minutes, many cannot.²¹⁷ Experts note that because of our aging population, an increasing number of patients have multiple chronic ailments and complex needs.²¹⁸ The time allotted, therefore, is frequently inadequate to the task. Some experts posit that effective primary care visits often require thirty minutes or more.²¹⁹

Medscape conducted its 2018 Physician Compensation Report by electronically surveying 20,329 physicians in twenty-nine specialties.²²⁰ The survey included a question about the number of minutes doctors generally spent with patients during visits.²²¹ They responded as follows:

- Five percent spent fewer than five minutes per visit;
- Twenty-two percent spent between nine and twelve minutes per visit;
- Twenty-nine percent spent between thirteen and sixteen minutes per visit;
- Thirty-three percent spent between seventeen and twenty-four minutes per visit;

214. Thomas L. Schwenk, *Physician Well-being and the Regenerative Power of Caring*, 319 JAMA 1543, 1543 (2018) (bemoaning "the loss of the opportunity and ability for physicians to care in the current health care system").

215. Virginia Adams O'Connell et al., *Physician Burnout: The Effect of Time Allotted for a Patient Visit on Physician Burnout Among OB/GYN Physicians*, 24 J. MED. PRAC. MGMT. 300, 300 (2009) ("A factor associated with the likelihood of reporting burnout is lack of control over the pace of work, and one aspect of pace of work is the length of patient visits.").

216. Linzer et al., *supra* note 1617, at 1584; Peter Pronovost, *How the 15-Minute Doctor's Appointment Hurts Health Care*, WALL ST. J. (Apr. 15, 2016), <https://blogs.wsj.com/experts/2016/04/15/how-the-15-minute-doctors-appointment-hurts-health-care/>.

217. Pronovost, *supra* note 216.

218. Linzer et al., *supra* note 16, at 1584; Michael Stein, *When Medical Care is Delivered in 15-Minute Doses, There's Not Much Time for Caring*, WASH. POST, Nov. 13, 2015, https://www.washingtonpost.com/opinions/when-medical-care-is-delivered-in-15-minute-doses-theres-not-much-time-for-caring/2015/11/13/85ddba3a-818f-11e5-a7ca-6ab6ec20f839_story.html.

219. Linzer et al., *supra* note 1616, at 1585.

220. Leslie Kane, *Medscape Physician Compensation Report 2018*, MEDSCAPE, <https://www.medscape.com/slideshow/2018-compensation-overview-6009667>.

221. *Id.* at 32.

- Eleven percent spent twenty-five minutes or longer per visit.²²²

The 2016 Physicians Foundation survey revealed that only fourteen percent of doctors felt they have the time necessary to provide the highest quality of care.²²³ Furthermore, eighty percent reported being overextended or at capacity and lacking time to see any additional patients.²²⁴

Even highly specialized physicians who care for complex patients are rushed for time. A study of neurologists found that they suffered burnout partly because of reduced time with patients and consequently diminished enjoyment of their work.²²⁵

It is important to recognize that patient visits that are too short have adverse consequences not only for physicians who are more likely to suffer burnout, but also for patients. Time pressures can lead to poor patient care.²²⁶ Providers may take abbreviated patient histories, conduct superficial physical exams, and order unnecessary tests because they do not have time to be more thoughtful about what course to pursue.²²⁷ Thus, spending more time with patients could not only increase physicians' career satisfaction but could also enhance patient welfare, improve treatment outcomes, and save the health care system money.²²⁸

B. Reasons for Short Visit Times

Physicians face an accumulation of demands and responsibilities that take time away from patient appointments. This section will focus on two areas: administrative work and financial pressures.

1. Administrative Work

The work of operating EHR systems and complying with associated regulations, discussed extensively above, is no small factor in limiting the time that

222. *Id.*

223. *2016 Survey of America's Physicians: Practice Patterns and Perspectives*, *supra* note 38, at 7.

224. *Id.*

225. Miyasaki et al., *supra* note 16, at 1736.

226. Linzer et al., *supra* note 16, at 1584.

227. *Id.* (positing that physicians do not have time to develop a deep understanding of patients' conditions or to consider psychosocial determinants of health, and these shortcomings can "translate to decreased patient satisfaction, excess emergency room usage and non-adherence to treatment plans").

228. See Kim Tingley, *Trying to Put a Value on the Doctor-Patient Relationship*, N.Y. TIMES MAG. May 16, 2018, at 43, <https://www.nytimes.com/interactive/2018/05/16/magazine/health-issue-reinvention-of-primary-care-delivery.html> (recounting that a primary care practice that spent more time with patients was able to reduce hospitalizations by twenty percent).

doctors can devote to face-to-face patient care.²²⁹ However, it is not the only culprit.

Physicians grapple with a myriad of additional administrative demands arising from regulatory mandates and other obligations. For example, as noted above, MACRA includes numerous reporting requirements, many of which are unrelated to EHR systems.²³⁰ Physicians must also interact with public health authorities and submit certain data to them, such as information about communicable diseases.²³¹

Health care payers and regulators require clinicians to report a multitude of quality and performance measures. The National Quality Measures Clearinghouse lists over 2500 performance measures.²³² CMS alone uses as many as 1700 measures with which providers may have to be familiar.²³³ Performance measures have faced increasing criticism in recent years. One survey found that only twenty-seven percent of physicians felt that contemporary measures were “moderately or very representative of the quality of care” they provide.²³⁴ Another assessed the validity of eighty-six of the 271 measures in MIPS’s Quality Payment Program and determined that only thirty-two were valid, whereas thirty were invalid, and twenty-four were of uncertain validity.²³⁵

Obtaining insurance payments from either private or public insurance payers is a work-intensive and time-consuming endeavor.²³⁶ In addition to reporting quality measures, health care providers must be prepared to handle eligibility verification, billing, prior authorization, appeals of coverage denials, referrals, and much more.²³⁷ Billing requires expertise with respect to Evaluation/Management Codes, International Classification of Diseases Tenth Revision (ICD-10), Relative Value Units, and the Geographic Practice Cost Index, among other matters.²³⁸

229. See *supra* Part II.

230. See *supra* notes 164-170 and accompanying text.

231. *Communicable Disease Reporting*, N.Y. STATE DEP’T HEALTH (Feb. 2015), <https://www.health.ny.gov/professionals/diseases/reporting/communicable/> (“Reporting of suspected or confirmed communicable diseases is mandated under the New York State Sanitary Code.”).

232. Catherine H. MacLean et al., *Time Out—Charting a Path for Improving Performance Measurement*, 378 NEW ENG. J. MED. 1757, 1757 (2018).

233. Gail Wilensky, *The Need to Simplify Measuring Quality in Health Care*, 319 JAMA 2369, 2370 (2018) (stating that MIPS is very burdensome and “would cost about \$1.3 billion to implement”).

234. Lawrence P. Casalino et al., *US Physician Practices Spend More than \$15.4 Billion Annually to Report Quality Measures*, 35 HEALTH AFFS. 401, 402 (2016).

235. MacLean et al., *supra* note 232, at 1757-58.

236. Erickson et al., *supra* note 175, at app.

237. *Id.*

238. CENTERS FOR MEDICARE AND MEDICAID SERVICES, HOW TO USE THE SEARCHABLE MEDICARE PHYSICIAN FEE SCHEDULE (MPFS) 4, 8 (2017), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/How_to_MPFS_Booklet_ICN901344.pdf; What Is ICD-10?, AM.

Another source of administrative tasks is board certification, evaluation, and accreditation by professional entities such as the American Board of Internal Medicine,²³⁹ the Joint Commission,²⁴⁰ the National Committee for Quality Assurance,²⁴¹ and others. Interacting with vendors and suppliers and ordering medical equipment likewise can entail considerable administrative hassles.²⁴²

2. *Financial Pressures*

Financial pressures abound as well. Medicare established the relative value unit (RVU) payment model in the early 1990s.²⁴³ RVUs are calculated based on the physician's work, the expenses of the medical practice, and the cost of medical malpractice insurance.²⁴⁴ To illustrate, in 2014, an intermediate office visit was assigned 3.01 RVUs, a diagnostic colonoscopy 11.03 RVUs, and a total hip replacement 38.94 RVUs.²⁴⁵

In order to enhance their total RVUs, health systems began to pressure physicians to increase the number of patients they saw and meet daily visit targets.²⁴⁶ The reimbursement system incentivizes all clinicians "to do more in order to be paid more."²⁴⁷ Even salaried physicians working for well-established medical centers face powerful financial inducements. The majority receive "productivity bonuses."²⁴⁸ In some cases, their salaries are directly tied to RVUs, or they suffer wage deductions if their RVUs are too low.²⁴⁹

ACAD. PROF. CODERS (2018), <https://www.aapc.com/icd-10/icd-10.aspx>.

239. *Certification by the American Board of Internal Medicine (ABIM)*, AM. BD. INTERNAL MED., <https://www.abim.org/about/mission.aspx> ("Certification by the American Board of Internal Medicine (ABIM) has stood for the highest standard in internal medicine and its 20 subspecialties.").

240. *What is Certification?*, JOINT COMM'N, https://www.jointcommission.org/certification/certification_main.aspx ("Certification is earned by programs or services that may be based within or associated with a health care organization.").

241. *About NCQA*, NAT'L COMM. FOR QUALITY ASSURANCE, <https://www.ncqa.org/about-ncqa/> ("Since 2008, our mission has brought us closer to where care is delivered: We've grown to measure the quality of medical providers and practices.").

242. Erickson et al., *supra* note 175, at app.

243. Linzer et al., *supra* note 16, at 1584.

244. *The Basics: Relative Value Units (RVUs)*, NAT'L HEALTH POL'Y F. (Jan. 12, 2015), at 1, https://www.nhpf.org/library/the-basics/Basics_RVUs_01-12-15.pdf.

245. *Id.* at 2.

246. Linzer et al. *supra* note 16, at 1584-85.

247. Robert Fifer, *Health Care Economics: The Real Source of Reimbursement Problems*, AM. SPEECH-LANGUAGE-HEARING ASS'N (July 2016), <https://www.asha.org/Articles/Health-Care-Economics-The-Real-Source-of-Reimbursement-Problems/>.

248. ELISABETH ROSENTHAL, AN AMERICAN SICKNESS: HOW HEALTHCARE BECAME BIG BUSINESS AND HOW YOU CAN TAKE IT BACK 37 (2017); Dhruv Khullar et al., *How 10 Leading Health Systems Pay Their Doctors*, 3 HEALTHCARE 60, (2015) (finding that of ten leading health systems, five "use productivity-adjusted salaries").

249. ROSENTHAL, *supra* note 248, at 37.

Medical employers routinely hire consultants and health care advisory firms in an effort to increase revenues.²⁵⁰ Today, few physicians work independently. Over seventy-five percent of doctors were employed by large health care organizations in 2014,²⁵¹ and forty-two percent were employed by hospitals as of 2016.²⁵² A majority of physicians thus work in environments that are likely influenced by fiscal consultants and the income-maximizing pressures they create.

3. *Loss of Clinical Autonomy*

A related concern is that physicians employed by large organizations often feel that they are deprived of clinical autonomy. The 2016 Physicians Foundation survey found that loss of autonomy was the second most commonly cited reason for job dissatisfaction, behind only regulatory and paperwork burdens (listed by 58.3% and 31.8% of respondents, respectively).²⁵³ Remarkably, a 2018 study concluded that physicians in practices with five or fewer doctors in New York City had only a 13.5% burnout rate.²⁵⁴ The researchers attributed the very low burnout rate to the independence that physicians in small practices enjoy.²⁵⁵ Among other benefits, such autonomy allows doctors to spend more time with patients and form deeper relationships with them.²⁵⁶

Because of administrative and financial pressures, most contemporary physicians are said to “have one eye on the patient and one eye on the clock.”²⁵⁷ This phenomenon takes a toll both on patients and doctors who often feel profoundly disappointed with a career that they assumed would enable them to focus first and foremost on caring for their patients.

250. *Id.* at 35 (stating that Deloitte is ranked the top health care consulting firm and enjoyed record revenues of \$34.2 billion in 2014).

251. Shanafelt et al., *supra* note 32, at 1608.

252. *Updated Physician Practice Acquisition Study: National and Regional Changes in Physician Employment 2012-2016*, PHYSICIAN ADVOC. INST., (Mar. 2018), <http://www.physiciansadvocacyinstitute.org/Portals/0/assets/docs/2016-PAI-Physician-Employment-Study-Final.pdf>.

253. *2016 Survey of America's Physicians: Practice Patterns and Perspectives*, *supra* note 38, at 13.

254. Batel Blechter et al., *Correlates of Burnout in Small Independent Primary Care Practices in an Urban Setting*, 31 J. AM. BD. FAM. MED. 529, 529 (2018) (involving “235 providers practicing in 174 small independent primary care practices in New York City”).

255. *Id.* at 531-32.

256. *Id.* at 532.

257. Roni Caryn Rabin, *15-Minute Doctor Visits Take a Toll on Patient-Physician Relationships*, PBS NEWS HOUR (Apr. 21, 2014, 10:52 AM), <https://www.pbs.org/newshour/health/need-15-minutes-doctors-time>.

C. Physicians' Efforts to Increase Time with Patients

Some doctors have taken matters into their own hands. They have crafted partial solutions to alleviate some of the burdens contributing to physician burnout. This section will analyze two approaches: 1) scribes and 2) direct primary care.

1. Scribes

Scribes are professionals who shadow physicians and do the work of EHR data entry while the doctors interact with patients.²⁵⁸ Employing a scribe can significantly reduce the time the doctor must spend on documentation.²⁵⁹ Doctors employed close to 17,000 scribes in 2016,²⁶⁰ and the number is expected to grow to 100,000 by 2020.²⁶¹ At least twenty-two companies supply scribes and provide them with pre-employment training.²⁶² Scribes are often pre-medical college students or graduates.²⁶³

Not all physicians are equally enthusiastic about scribes.²⁶⁴ Some doctors and patients may be concerned about privacy because scribes learn sensitive information about patients and must be trusted to maintain confidentiality.²⁶⁵ In addition, incompetent or careless scribes could introduce errors into EHRs.²⁶⁶ Perhaps most importantly, scribes require salaries and thus could reduce the income of medical practices.²⁶⁷ According to Salary.com, medical scribe salaries

258. Katie Hafner, *A Busy Doctor's Right Hand, Ever Ready to Type*, N.Y. TIMES, Jan. 12, 2014, <https://www.nytimes.com/2014/01/14/health/a-busy-doctors-right-hand-ever-ready-to-type.html>.

259. *Id.*; Vinod E. Nambudiri et al., *Medical Scribes in an Academic Dermatology Practice*, 154 JAMA DERMATOLOGY 101, 103 (2018).

260. Melissa Bailey, *The Pay is Low, the Typing Nonstop, but the Medical Scribe Business is Booming*, STAT (April 25, 2016), <https://www.statnews.com/2016/04/25/scribes-emergency-room/>.

261. Meg Bryant, *Why More Providers Are Seeing Value in Medical Scribes*, HEALTHCARE DIVE (Apr. 13, 2017), <https://www.healthcaredive.com/news/why-more-providers-are-seeing-value-in-medical-scribes/440472/>; Derek Klein, *Medical Scribes: A Physician's Secret Weapon*, MERRITT HAWKINS (Mar. 6, 2018), <https://www.merrithawkins.com/news-and-insights/blog/healthcare-news-and-trends/medical-scribes-a-physicians-secret-weapon/>.

262. George A. Gellert et al., *The Rise of the Medical Scribe Industry: Implications for the Advancement of Electronic Health Records*, 313 JAMA 1315, 1315 (2015). *See, e.g., Who We Are*, SCRIBEAMERICA (Aug. 2018), https://www.scribeamerica.com/who_we_are.html (stating that ScribeAmerica is "the nation's most frequently used medical scribe company with more than 15,000 employees in 50 states providing professional services for over 2,000 clients").

263. Bailey, *supra* note 260; *Scribe Resources FAQ*, SCRIBEAMERICA, <https://www.scribeamerica.com/faqs.html#a15>.

264. Gellert et al., *supra* note 262, at 1316.

265. HOFFMAN, *supra* note 118, at 102.

266. Robert Pranaat et al., *Use of Simulation Based on an Electronic Health Records Environment to Evaluate the Structure and Accuracy of Notes Generated by Medical Scribes: Proof-of-Concept Study*, 5 JMIR MED. INFORMATICS e30 (2017) (finding that "there was a wide inter- and intrascribe variation in accuracy for each section of the notes with ranges from 50% to 76%").

267. *Id.*

ranged from \$27,637 to \$36,498 in 2018, with an average of \$33,162.²⁶⁸

Scribe advocates have responses to all of these objections. Studies show that patients are generally comfortable with scribes in the examination room.²⁶⁹ Moreover, when data is entered by time-strapped clinicians in often chaotic circumstances, EHRs can easily become replete with errors.²⁷⁰ Scribes whose sole or primary job is to enter data may actually increase EHR accuracy.²⁷¹ Finally, according to some experts, scribes enhance rather than diminish income for medical practices. When physicians are freed of some of their documentation duties, they have time to see more patients. The added income can compensate for scribes' modest wages or even exceed them.²⁷² To illustrate, one study of a cardiology clinic in Minnesota found that physicians who used scribes were ten percent more productive than those without scribes.²⁷³ As a result, use of scribes increased the clinic's annual revenue by \$1,372,694 at a cost of only \$98,588.²⁷⁴ A second study concluded that two full-time scribes would increase the earnings of a small office of seven family physicians by \$168,600 per year at an annual cost of only \$79,500.²⁷⁵ Overall, many physicians have found that scribes significantly improve their work quality and, consequently, job satisfaction.²⁷⁶ Note, however, that if hiring scribes translates into pressure to schedule a larger number of patient appointments and does not create opportunities to devote more time to each patient,

268. *Salary for Medical Scribe in the United States*, SALARY.COM, <https://www1.salary.com/Medical-Scribe-Salary.html>.

269. Nambudiri et al., *supra* note 259, at 103 ("Scribes were well received by patients, with few refusals and unchanged overall patient satisfaction scores."); Chen Yan et al., *Physician, Scribe, and Patient Perspectives on Clinical Scribes in Primary Care*, 31 J. GEN. INTERNAL MED. 990, 990 (2016) ("Most patients were comfortable with the scribe's presence and perceived increased attention from their physicians.").

270. HOFFMAN, *supra* note 118, at 23-27.

271. Risha Gidwani et al., *Impact of Scribes on Physician Satisfaction, Patient Satisfaction, and Charting Efficiency: A Randomized Controlled Trial*, 15 ANNALS FAM. MED. 427, 430 (2017) (finding that "[s]cribes improved physician-perceived chart quality and chart accuracy"); Yan et al., *supra* note 269, at 994 (stating that "clinical scribe notes were more up-to-date, thorough, useful, and comprehensible").

272. Nambudiri et al., *supra* note 259, at 103 (finding that revenue increases "more than off-set the cost of the scribes").

273. Alan J. Bank & Ryan M. Gage, *Annual Impact of Scribes on Physician Productivity and Revenue in a Cardiology Clinic*, 7 CLINICOECONOMICS & OUTCOMES RES. 489, 489 (2015).

274. *Id.*

275. Stephen T. Earls et al., *Can Scribes Boost FPs' Efficiency and Job Satisfaction?*, 66 J. FAMILY PRAC. 206, 206 (2017). *See also* Heather A. Heaton et al., *Effect of Scribes on Patient Throughput, Revenue, and Patient and Provider Satisfaction: A Systematic Review and Meta-Analysis*, 34 AM. J. EMERGENCY MED. 2018, 2027 (2016) (concluding that "[t]here might be a benefit on increase revenue value units" and that "[t]here is a small increase in the number of patients per hour seen when using scribes").

276. Gidwani, *supra* note 271, at 430 ("When working with a scribe, physicians were much more satisfied with how their clinic went, the length of time they spent face-to-face with patients, and the time they spent charting."); Hafner, *supra* note 258.

burnout rates are unlikely to improve.

Some physicians delegate clerical tasks to others without using professional scribes.²⁷⁷ Various organizations have health coaches, medical assistants, or nurses that help with documentation and other tasks.²⁷⁸ Others have “flow managers” that guide physicians’ activities with the aim of improving efficiency and saving time.²⁷⁹ Many experts emphasize the importance of teamwork and its potential to improve physician well-being.²⁸⁰ In a team model, certain work can be delegated to non-physicians such as nurse practitioners so that doctors can spend more time with patients, doing the work they enjoy most and do best.²⁸¹ However, expanding staff to include new team members can also complicate the work environment and require additional coordination, and thus may generate stress and even costs. This section has focused on scribes because their job in particular is to alleviate the burdens of EHR data entry.

2. *Direct Primary Care and Concierge Medicine*

A more radical approach to freeing up time for patient care is to devise new medical practice settings that remove some of the shackles that encumber contemporary physicians. Direct primary care (DPC) is a model that is being adopted by a growing number of clinicians.²⁸² As of early 2018, there were at least 770 DPC offices operating in forty-eight states.²⁸³

DPC physicians provide all of their patients’ primary care for a monthly fee that commonly ranges between twenty-five and eighty-five dollars.²⁸⁴ Consequently, DPC has been described as a “subscription” or “retainer” form of

277. Scott A. Shipman & Christine A. Sinsky, *Expanding Primary Care Capacity by Reducing Waste and Improving the Efficiency of Care*, 32 HEALTH AFFS. 1990, 1993 (2013).

278. *Id.*

279. *Id.*

280. Annalena Welp & Tanja Manser, *Integrating Teamwork, Clinician Occupational Well-being and Patient Safety – Development of a Conceptual Framework Based on a Systematic Review*, 16 BMC HEALTH SERVS. RES. 281, 319 (2016); Wright & Katz, *supra* note 18, at 311.

281. Sophia Arabadjis & Erin E. Sullivan, *How One California Medical Group Is Decreasing Physician Burnout*, HARV. BUS. REV. June 7, 2017, <https://hbr.org/2017/06/how-one-medical-group-is-decreasing-physician-burnout>; Rachel Willard-Grace et al., *Panel Management, Team Culture, and Worklife Experience*, 33 FAM., SYS. & HEALTH 231, 232, 237 (2015).

282. Philip Eskew, *In Defense of Direct Primary Care*, 23 FAM. PRAC. MGMT., 12, 12 (2016).

283. Rita Rubin, *Is Direct Primary Care a Game Changer?*, 319 JAMA 2064, 2064 (2018) (stating that the Direct Primary Care Coalition, a lobbying group, has 770 members in 48 states). See also Lydia Ramsey, *A New Kind of Doctor’s Office that Doesn’t Take Insurance and Charges a Monthly Fee Is ‘Popping up Everywhere’—and that Could Change How We Think about Healthcare*, BUS. INSIDER, Mar. 18, 2018, <http://www.businessinsider.com/direct-primary-care-no-insurance-healthcare-2018-3> (stating that there are 790 DPC practices).

284. Charlotte Huff, *Direct Primary Care: Concierge Care for the Masses*, 34 HEALTH AFFS. 2016, 2016 (2015).

practice.²⁸⁵ A key advantage from the physicians' perspective is that DPC practices generally do not bill insurers and rely instead on the income they receive directly from patients.²⁸⁶ Thus, DPC doctors are liberated from the considerable hassles of billing private insurers, Medicare, or Medicaid and are spared the expense of hiring staff to do this administrative work. Note, however, that DPC patients still need health insurance to cover non-primary care services, such as visits to specialists or treatment in hospitals.²⁸⁷

Because they have low overhead costs and a predictable income that is not dependent on the vicissitudes of insurance coverage, DPC physicians feel they can afford to treat fewer patients and spend much more time with them.²⁸⁸ DPC physicians generally accept six hundred to eight hundred patients rather than the typical patient panel of 2000 to 2500 that family physicians ordinarily have.²⁸⁹ Consequently, DPC doctors pride themselves on their availability and responsiveness to patients.²⁹⁰ As a result, they often derive greater career satisfaction than those in traditional practice settings.²⁹¹

A well-known DPC practice is Atlas MD, located in Wichita, Kansas.²⁹² On its website, Atlas MD states that each of its physicians attends to only five-hundred patients and that the practice offers “[s]ame-day scheduling with little to no waits and extended visits of an hour or more, if you’d like.”²⁹³ Among the benefits it furnishes are house calls, when needed, and round-the-clock accessibility to physicians.²⁹⁴ Atlas MD has a tiered fee schedule as follows:

- Adults 20-44 years old, \$50/month;
- Adults 45-64 years old, \$75/month;

285. Glenn E. Chappell, *Health Care's Other "Big Deal": Direct Primary Care Regulation in Contemporary American Health Law*, 66 DUKE L.J. 1331, 1331 (2017); Robert Doherty, *Assessing the Patient Care Implications of "Concierge" and Other Direct Patient Contracting Practices: A Policy Position Paper from the American College of Physicians*, 163 ANNALS INTERNAL MED. 949, 950 (2015).

286. Eskew *supra* note 282, at 12; Kyle Rowe et al., *Direct Primary Care in 2015: A Survey with Selected Comparisons to 2005 Survey Data*, 10 KAN. J. MED. 3, 6 (2017) (finding that between 2005 and 2015 the rate of insurance billing significantly diminished).

287. Eli Y. Adashi et al., *Direct Primary Care: One Step Forward, Two Steps Back*, 320 JAMA 637, 637 (2018); Edmond S. Weisbart, *Is Direct Primary Care the Solution to Our Health Care Crisis?*, 23 FAM. PRAC. MGMT. 10, 10-11 (2016); Ramsey, *supra* note 283.

288. *FAQ on Direct Primary Care*, AM. ACAD. FAM. PHYSICIANS, <https://www.aafp.org/practice-management/payment/dpc/faq.html>.

289. *Id.*

290. *Id.*

291. *Id.*

292. *About Us*, ATLAS MD, <https://atlas.md/wichita/about-us/>.

293. *Id.*

294. *Benefits*, ATLAS MD, <https://atlas.md/wichita/benefits/>.

- Adults 65+ years old, \$100/month.²⁹⁵

Atlas MD has also developed a “Direct Care Curriculum,” offering advice to physicians interested in establishing their own DPC practices.²⁹⁶

An alternative to DPC is concierge medicine. Concierge practices are more common than DPC offices, numbering as high as 12,000 in 2014.²⁹⁷ Like doctors with DPC practices, concierge physicians charge patients monthly fees and maintain a relatively small patient panel, which enhances their job satisfaction.²⁹⁸ However, concierge practices generally continue to bill insurers for their services and thus must grapple with the regulatory and administrative burdens associated with that activity.²⁹⁹ They also charge much higher monthly fees—according to one source \$183 per month on average in 2015.³⁰⁰ Consequently DPC has been called “concierge care for the masses.”³⁰¹

The DPC/concierge medicine model is not without critics. For the sake of clarity and brevity, I will address only DPC in the remainder of this section, but many of the arguments apply to the higher-end concierge practices as well.

One concern relates to DPC practices’ lack of participation in Medicare and Medicaid. Because they need not comply with Medicare and Medicaid regulations and their associated reporting requirements, these practices may be less accountable than other providers.³⁰²

Because DPC physicians see fewer patients per day than others, some are concerned that a proliferation of these practices will reduce overall access to care and worsen physician shortages.³⁰³ Potentially, the DPC phenomenon could exacerbate health disparities. This is because it might be unavailable to disadvantaged individuals who cannot pay monthly fees or do not live near a DPC

295. *Monthly Membership Fees*, ATLAS MD, <https://atlas.md/wichita/our-fees/>.

296. *Atlas.md Direct Care Curriculum*, ATLAS MD, <https://atlas.md/dpc-curriculum/topics/view/140/>.

297. James E. Dalen & Joseph S. Alpert, *Concierge Medicine Is Here and Growing!*, 130 AM. J. MED. 880, 880 (2017).

298. HOFFMAN, *supra* note 90, at 75.

299. Huff, *supra* note 284, at 2016; *Direct Primary Care vs. Concierge Medicine: Which is Right for You?*, AM. ACAD. FAM. PHYSICIANS INS. PROGRAM (Mar. 21, 2016), <http://www.aafpins.com/2016/03/direct-primary-care-vs-concierge-medicine-which-is-right-for-you/>; Nick Hernandez, *Concierge Medicine vs. Direct Primary Care*, PHYSICIANS PRAC. (Jan. 28, 2015), <http://www.physicianspractice.com/fee-schedule-survey/concierge-medicine-vs-direct-primary-care>.

300. Michael Laff, *Researchers Study What ‘Direct Primary Care’ Really Means*, AM. ACAD. FAM. PHYSICIANS (Nov. 10, 2015, 8:43 AM), <https://www.aafp.org/news/practice-professional-issues/20151110dpceterms.html>.

301. Huff, *supra* note 284, at 2016.

302. Eli Y. Adashi et al., *supra* note 287, at 637-38.

303. Doherty, *supra* note 285, at 950 (noting concerns that DPC may impede access for patients who cannot afford the monthly fees); Weisbart, *supra* note 287, at 10.

office, and the trend could absorb many doctors who would otherwise see larger numbers of patients in traditional practices.³⁰⁴ DPC practices may also be tempted to turn away sicker patients who would require frequent appointments and complex care.³⁰⁵

On the other hand, for those without insurance, paying modest monthly fees for comprehensive primary care may be an affordable and prudent approach.³⁰⁶ The alternative for uninsured patients is paying out-of-pocket for treatment, often after having neglected their health problems and facing a medical crisis that requires a costly visit to a hospital emergency room.³⁰⁷ Some practices have made particular efforts to be accessible to lower-income patients.³⁰⁸ For example, they may offer financially stressed patients discounted fees or even fee waivers.³⁰⁹

In addition, advocates argue that concern that the DPC phenomenon will contribute to physician shortages is misplaced.³¹⁰ The growing availability of urgent care centers and retail clinics means that patients can receive medical attention for certain conditions when they need it even if they cannot immediately see their primary care physician, and some prefer the convenience of such facilities.³¹¹ Thus, some patients may seek appointments with primary care physicians less frequently. In fact, the emergence of DPC practices could arguably diminish shortages if it keeps some doctors in practice when they would otherwise leave the profession.³¹²

According to the Direct Primary Care Coalition, twenty-five states have passed legislation addressing DPC.³¹³ The laws generally define DPC as a medical

304. Doherty, *supra* note 285, at 950 (noting that DPC physicians have been found to have a disproportionately low number of Hispanic and African American patients and that this may be because the practices often choose to be located in wealthier communities).

305. Eli Y. Adashi et al., *supra* note 287, at 637.

306. Doherty, *supra* note 285, at 950.

307. Robin M. Weinick et al., *Many Emergency Department Visits Could Be Managed at Urgent Care Centers and Retail Clinics*, 29 HEALTH AFFS. 1630, 1632 (2010) (“[A]pproximately 17 percent of visits to emergency departments were made by patients who were uninsured, compared with approximately 26 percent of visits to retail clinics.”).

308. Doherty, *supra* note 285, at 950.

309. Charlotte Huff, *New Practice Model Evolves: ‘Direct Care’*, APC INTERNIST, Jan. 2015, <https://acpinternist.org/archives/2015/01/practice.htm> (“One option is to carve out a portion of each panel for low-income scholarship or charity care patients who can’t afford the fee”).

310. Reed Abelson & Julie Creswell, *The Disappearing Doctor: How Mega-Mergers Are Changing the Business of Medical Care*, N.Y. TIMES, Apr. 7, 2018, <https://www.nytimes.com/2018/04/07/health/health-care-mergers-doctors.html> (noting that visits to primary care physicians declined by eighteen percent during the years 2012-2016, though visits to specialists increased in number).

311. *Id.* (stating that patients are “flocking to retail clinics and urgent care centers,” of which approximately 12,000 exist in the United States).

312. David Von Drehle, *Medicine Gets Personal*, TIME, Dec. 29, 2014–Jan. 5, 2015, p. 49, 54.

313. *2018 DPC Laws Passed in 25 States*, DIRECT PRIMARY CARE COALITION, <https://www.dpcare.org/state-level-progress-and-issues>.

service that is not governed by state insurance regulations, and some establish certain patient protections.³¹⁴ For example, the Oregon statute prohibits discrimination based on “race, religion, gender, sexual identity, sexual preference or health status” and requires DPC practices to make various disclosures to patients.³¹⁵

At the federal level, the Primary Care Enhancement Act was introduced in Congress in 2017.³¹⁶ It would allow patients to use health savings accounts³¹⁷ to pay DPC retainer fees, a practice that is currently illegal under Internal Revenue Service rules.³¹⁸ If passed, such a law would make DPC practices more appealing to patients with such accounts and likely would promote DPC growth.

IV. WHY BURNOUT IS A LEGAL ISSUE

Physician burnout is a serious problem for the medical community.³¹⁹ However, it is also a threat to the welfare of the public at large. Demoralized physicians who are prone to error or who reduce their hours or abandon the profession altogether will leave considerable medical needs unmet.³²⁰

Physician wellness is an area that is ripe for legal intervention. The health and safety of workers, including health care providers, is traditionally a matter that is subject to government regulation.³²¹ The Fair Labor Standards Act,³²² the Occupational Safety and Health Act,³²³ a variety of anti-discrimination laws, and many other statutes protect American employees.³²⁴

Safety-critical jobs are of particular concern to regulators. Federal regulations recognize that professionals who are responsible for public safety, such as transportation workers, must be well-rested when they are fulfilling job duties. Thus, regulations limit the work hours of air traffic controllers,³²⁵ pilots,³²⁶ flight

314. *Id.*

315. OR. REV. STAT. § 735.500 (2017).

316. H.R. 365, 115th Congress (2017).

317. A health savings account (HSA) is an account available to consumers with high deductible health plans that allows them to save pre-tax money to pay for qualified medical expenses such as deductibles, copayments, and coinsurance. Because individuals are not taxed on these funds, the HSA can lower their overall health costs. *Health Savings Account (HSA)*, HEALTHCARE.GOV, <https://www.healthcare.gov/glossary/health-savings-account-hsa/>.

318. H.R. 365, 115th Congress (2017); Ramsey, *supra* note 283.

319. *See supra* Part I.

320. *Id.*

321. *See Workplace Safety and Health*, U.S. DEP'T LAB., <https://www.dol.gov/general/topic/safety-health>.

322. 29 U.S.C. §§ 201-219 (2010).

323. 29 U.S.C. §§ 651-78 (2010).

324. *Laws and Guidance*, EEOC, <https://www.eeoc.gov/laws/index.cfm>.

325. *See* 14 C.F.R. § 65.47 (2018).

326. *See* 14 C.F.R. § 121.503 (2018).

attendants,³²⁷ train employees,³²⁸ merchant marine officers,³²⁹ nuclear power reactor employees,³³⁰ and others.³³¹ Likewise, the states have enacted legislation to ensure adequate rest for transportation workers, police officers, and firefighters, among others.³³²

It is no stretch to posit that physicians are safety-critical workers as well. Missed diagnoses and careless treatments can surely injure or even kill patients. Thus, the mental health and well-being of doctors should be within reach of the law.

Regulators have already recognized the need to limit the fatigue and stress of some health care providers. For example, state regulations limit the nurse to patient ratios in hospitals and other health care facilities.³³³ Congress has also considered a federal bill entitled “The Nurse Staffing Standards for Hospital Patient Safety and Quality Care Act of 2017.”³³⁴ The bill would mandate specific minimum nurse-to-patient ratios, depending on the hospital unit, and would require hospitals to post notices regarding ratios and record actual ratios for each shift and unit.³³⁵

To the relief of many young doctors, the Accreditation Council for Graduate Medical Education³³⁶ capped the number of hours that medical residents can work at eighty per week, with limited exceptions.³³⁷ Moreover, residents are restricted to twenty-four consecutive hours per shift, with an additional four hours allowed to manage care transitions.³³⁸ Yet, no law, regulation, or certification standard is

327. See 14 C.F.R. § 91.1062 (2018).

328. See 49 C.F.R. § 228.405 (2018).

329. 46 C.F.R. § 15.1111 (2018).

330. 10 C.F.R. § 26.205 (2018).

331. See, e.g., 49 U.S.C. § 21104 (2010) (railroad signal employees); 49 U.S.C. § 21105 (2010) (railroad dispatching service employees).

332. See, e.g., ALA. CODE § 32-9A-6 (1975) (limiting hours for commercial vehicle drivers); ARK. CODE ANN. § 14-53-105 (1973) (relating to municipal firefighters); N.J. REV. STAT. § 34:10-3 (2018) (establishing 12-hour maximum days for employees operating street railroads and elevated railroads); WIS. STAT. § 62.13(2e), (7M), (7n), (11), (11a) (2018) (limiting hours and mandating rest periods for police and fire department employees).

333. *Nurse Staffing*, AM. NURSES ASS'N (Dec. 2015), <https://www.nursingworld.org/practice-policy/advocacy/state/nurse-staffing/>. See, e.g., CAL. CODE REGS. tit. 22, § 70217 (2018) (addressing nurse to patient ratios in general acute care hospitals); DEL. CODE ANN. tit. 16, § 1162 (2018) (establishing minimum staffing levels for residential health facilities); ILL. ADMIN. CODE tit. 77, § 1110.220(b)(5)(a)(ii) (2018) (establishing minimum nurse to patient ratios for open heart surgery patients in intensive care units).

334. H.R. 2392, 115th Cong. (2017); S. 1063, 115th Cong. (2017).

335. See *supra* note 334.

336. This is an independent, not-for-profit organization. *About Us*, ACCREDITATION COUNCIL FOR GRADUATE MED. EDUC., <http://www.acgme.org/About-Us/Overview>.

337. ACCREDITATION COUNCIL FOR GRADUATE MEDICAL EDUCATION, *THE ACGME 2011 DUTY HOUR STANDARD: ENHANCING QUALITY OF CARE, SUPERVISION AND RESIDENT PROFESSIONAL DEVELOPMENT 29-30* (2011), [https://www.acgme.org/Portals/0/PDFs/jgme-monograph\[1\].pdf](https://www.acgme.org/Portals/0/PDFs/jgme-monograph[1].pdf).

338. *Id.* at 31-35; Luke Gale, *ACGME Approves 24-Hour Shifts for First-Year Residents*,

designed to curb the demands placed on physicians who have completed their training and to ensure that their workload is manageable.

A second justification for legal intervention is that cumbersome regulations are partly responsible for physician burnout. As discussed extensively above, these regulations relate to EHR systems, insurance, quality measures, and other matters, and physicians complain bitterly about the regulations' impact on their workdays and job satisfaction.³³⁹ Consequently, it would be reasonable to focus on the maze of regulations that govern physicians to identify possible modifications that would alleviate physician burnout.

V. RECOMMENDATIONS

There is no sweeping reform that will constitute a panacea for physician burnout. At best, a number of modifications can be made that will incrementally yield improvement. This Part recommends the following changes: streamlining EHR-related regulations, expanding usability testing, measuring and reporting physician wellness, promoting mechanisms that are proven to ease burnout, and engaging in further study of the problem.

A. Streamlining EHR-related Regulations

As they modify and develop the regulatory landscape, health care regulators should concentrate on relieving physicians' workload pressures. Contemporary physicians must navigate a thicket of regulatory requirements and dedicate a vast amount of time to responding to the demands of Meaningful Use regulations, quality measures, MACRA, and more.³⁴⁰

Legislators have not turned a blind eye to this problem. As noted above, MACRA consolidated three separate quality programs with the hope of diminishing clinicians' administrative workload, though some argue that it is doomed to fail in this regard.³⁴¹

Section 4001 of the 21st Century Cures Act requires the Department of Health and Human Services to develop a strategy and recommendations for reducing administrative burdens related to EHR use.³⁴² ONC and CMS, which are units within the Department, have stated that they are committed to fulfilling this

HEALTHCARE DIVE, March 10, 2017, <https://www.healthcarediver.com/news/acgme-approves-24-hour-shifts-for-first-year-residents/437891/>.

339. See *supra* Parts II.C. & III.B.1.

340. See *supra* Parts II.C. & III.B.1.

341. Wilensky, *supra* note 233, at 2369. See also *supra* notes 164-166 and accompanying text.

342. Pub. L. No. 114-255, 130 Stat. 1033 (2016) (codified as amended at 42 U.S.C. § 300jj note (Supp. 2016) (Assisting Doctors and Hospitals in Improving Quality of Care for Patients)).

mandate.³⁴³ To that end, they plan to revise evaluation and management (E&M) codes, which are used to document the nature and severity of patients' ailments for insurance billing purposes.³⁴⁴ The current E&M coding guidelines were created in 1995 and 1997, and many physicians consider them to be outdated and vexing.³⁴⁵

ONC and CMS further hope to implement a "meaningful use overhaul," with three specific goals:

- Making the program more flexible and less burdensome;
- Emphasizing measures that require the exchange of health information between providers and patients;
- Incentivizing providers to make it easier for patients to obtain their medical records electronically.³⁴⁶

The first objective, which is responsive to burnout concerns, is consistent with suggestions formulated by well-regarded experts. John Halamka and Micky Tripathy have suggested that the Meaningful Use regulations and MIPS be "dramatically simplified to focus on interoperability and a streamlined set of outcome-oriented quality measures."³⁴⁷ Interoperability refers to EHR systems' capacity to communicate with one another, exchange information, and operate seamlessly and in a coordinated fashion across organizations.³⁴⁸ While the architects of the EHR incentive program envisioned a fully interoperable National Health Information Network, current technology has fallen far short of enabling widespread interoperability.³⁴⁹

Health economist Gail Wilensky has asserted that health care quality measures must be dramatically revised and simplified.³⁵⁰ Likewise, the American College of Physicians issued a position paper in which it made several recommendations for reducing clinicians' administrative tasks.³⁵¹ It emphasized the need for all stakeholders, including public and private payers, professional societies, health

343. Greg Slabodkin, *ONC, CMS Set Their Sights on Reducing EHR Clinical Burden*, HEALTH DATA MGMT. (Mar. 8, 2018, 6:11 AM), <https://www.healthdatamanagement.com/news/onc-cms-set-their-sights-on-reducing-ehr-clinical-burden>.

344. *Id.*

345. *Id.*; Richard A. Young et al., *Family Physicians' Opinions on the Primary Care Documentation, Coding, and Billing System: A Qualitative Study from the Residency Research Network of Texas*, 46 FAM. MED. 378, 382-83 (2014).

346. Mary Butler, *CMS Announces Overhauls to Meaningful Use in Proposed Rule*, J. AHIMA (Apr. 25, 2018), <http://journal.ahima.org/2018/04/25/cms-announces-overhauls-to-meaningful-use-in-proposed-rule/>.

347. Halamka & Tripathy, *supra* note 176, at 908.

348. SHORTLIFFE & CIMINO, *supra* note 130, at 952.

349. HOFFMAN, *supra* note 118, at 36-37.

350. Wilensky, *supra* note 233, at 2369-70.

351. Erickson et al., *supra* note 175, at 660-61.

care providers, patients, and EHR vendors to collaborate to determine how best to streamline administrative tasks.³⁵²

CMS has recently proposed removal of some quality measures, a step that is welcomed by many health care providers.³⁵³ As of this writing, the government has not detailed its plans or made final decisions about how it will simplify and trim its regulatory requirements.³⁵⁴

Developing a comprehensive blueprint for regulatory reform is beyond the scope of this Article. Instead, I offer a limited set of recommendations below. At the same time, it is essential that HHS remain steadfast in its commitment to the task of reducing administrative burdens and seek extensive input from all stakeholders.³⁵⁵ HHS must eliminate regulatory duplication and require only measures that will appreciably yield benefits to patients or public health. Doing so is vital for the well-being of the American health care workforce and therefore of the public at large.

B. Expanding Usability Testing in the EHR Certification Process and Requiring Acceptance Testing

Despite the general plea for streamlining articulated above, a few regulatory gaps must be filled in order to combat physician burnout. The first is in the area of certification and thus would target vendors rather than clinicians. EHR certification regulations should emphasize usability to a much greater extent.³⁵⁶ As noted above, current product testing prior to certification is minimal and is executed with varying degrees of thoroughness.³⁵⁷

Thus, pre-certification usability testing should be significantly expanded. To the extent possible, it is important to assess how EHR products perform in real-world settings. What difficulties do users encounter? How can EHR systems be made more efficient and user-friendly? The certification regulations should specify the methodology by which products will be evaluated, including the types of system failures and adverse events that clinician-testers will consider, how testers will detect, report, and confirm those failures, and what failure and adverse event

352. *Id.*

353. *CMS Proposes Changes to Empower Patients and Reduce Administrative Burden*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Apr. 24, 2018), <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2018-Press-releases-items/2018-04-24.html>; Erin Dietsche, *Goodbye, Meaningful Use. CMS Renames Program "Promoting Interoperability"*, MEDCITY NEWS (Apr. 25, 2018, 3:46 PM), <https://medcitynews.com/2018/04/meaningful-use-cms/>;

354. *CMS Proposes Changes to Empower Patient and Reduce Administrative Burden*, *supra* note 353; Dietsche, *supra* note 353.

355. See Shanafelt et al., *supra* note 105, at 901.

356. See *supra* Part II.C.2.

357. See *supra* Part II.C.2.b.

rates are acceptable (since rates of zero are not realistic).³⁵⁸

To that end, certification should include much more extensive EHR system usability testing through simulated clinical workloads. Testing should employ real-world scenarios that vendors do not receive in advance.³⁵⁹ Such simulations do not require a product's installation in a medical facility, but rather, they test various functions using fictional patient data.³⁶⁰ Authorized Certification Bodies³⁶¹ should recruit clinician-testers and pay them, perhaps from a fund to which vendors seeking product approval contribute. Clinician-testers would be assigned to authorized testing laboratories³⁶² and then to individual products' testing processes.

Testing should be based on national usability standards developed by well-respected professional organizations such as the National Institute for Standards and Technology.³⁶³ Usability should be measured using appropriate usability metrics.³⁶⁴ Usability metrics measure user experience in an observable, quantifiable way, assessing a product's effectiveness or efficiency, or the user's satisfaction with respect to particular tasks.³⁶⁵

Experts have noted that a variety of features can improve EHR system usability. As John Glaser, Senior Vice President, Population Health of Cerner Corporation, explains:

Context-aware software can whittle down choices to a manageable number so that users don't have to scroll through dozens of options every time they need to enter an order. Advanced data visualization can help users focus on the most important information and correctly interpret that information.

Natural language processing is already making amazing progress at interpreting free text and pulling out individual data elements. It can potentially liberate clinicians from clicks and pull-down menus entirely. Combined with advanced voice recognition, it could even save them from typing.³⁶⁶

358. HOFFMAN, *supra* note 118, at 50-52.

359. *Id.*, at 51; WACHTER, *supra* note 181, at 269; Holmgren, *supra* note 203, at 659.

360. HOFFMAN, *supra* note 118, at 51.

361. See HOFFMAN, *supra* note 118, 47-49 (explaining the certification process); *Certification Process*, HEALTHIT.GOV (June 27, 2018), <https://www.healthit.gov/topic/certification-ehrs/certification-process>.

362. See HOFFMAN, *supra* note 118, 47-49; *ONC – Authorized Testing Laboratories (ONC-ATLs)*, HEALTHIT.GOV (Sept. 25, 2017), <https://www.healthit.gov/topic/certification/onc-authorized-testing-laboratories-onc-atls>.

363. John Glaser, *Cerner's John Glaser: How to Finally Fix the EHR Usability Problem*, HEALTHCAREITNEWS (Aug. 9, 2017, 11:09 AM), <https://www.healthcareitnews.com/blog/cerners-john-glaser-how-finally-fix-ehr-usability-problem>; NAT'L INST. FOR STANDARDS & TECH., <https://www.nist.gov/>.

364. TULLIS & ALBERT, *supra* note 147, at 7-8.

365. *Id.*

366. Glaser, *supra* note 363.

Other features that have been found to improve usability include color-coding abnormal test results and physician alerts in the EHR to reduce inappropriate test ordering.³⁶⁷ Certification must ensure that vendors are incorporating updated, proven technology to reduce physicians' clerical burdens.³⁶⁸

However, simulated EHR usage is by nature based on specific assumptions about users and their environments. A limited number of simulations cannot take into account the very diverse population of EHR system users that have very different levels of computer skills and capabilities.³⁶⁹ Thus, they cannot anticipate all of the difficulties, obstacles, and mistakes that could arise in real health care facilities. As the American Medical Association and other experts observed, EHR systems "deployed in dynamic clinical settings do not always mirror the laboratory testing environment of the ONC Certification Program."³⁷⁰

Not all usability problems are attributable to flawed design or production. Some are caused by health care organizations' attempts to customize products to fit their own needs.³⁷¹ Customization can be a serious contributor to usability problems, and health care organizations should be sure to employ highly skilled information technology specialists to prevent glitches and resolve them when they arise. But many problems are inherent to products as they are originally configured.³⁷²

In an ideal world, effective usability testing would include clinical safety testing of EHR systems in their natural environments.³⁷³ Facilities would be asked to volunteer to be testing sites and have staff members use new EHR products over time in order to identify usability defects. Facilities could choose this undertaking if they are interested in the product and then would be rewarded with discounts if the EHR system is approved and they decide to purchase it. In addition, they could adopt the EHR system only to a limited extent and have just some clinicians use it in order to minimize disruption to the practice.

Admittedly, however, such clinical testing would pose significant challenges. First, it would require greater government oversight and more testing personnel.

367. Guo et al., *supra* note 8, at 140-41.

368. Kellogg et al., *supra* note 212, at 197 (stating that user-centered design must put "the cognitive needs of the clinician at the forefront of development, with a better understanding of the cognitive support that clinicians will need").

369. HOFFMAN, *supra* note 118, at 51.

370. Letter from American Medical Association et al., to Karen B. DeSalvo, Nat'l Coordinator for Health Info. Tech., U.S. Dep't Health & Human Servs. (Jan. 21, 2015) at 3, http://www.aafp.org/dam/AAFP/documents/advocacy/health_it/emr/LT-ONC-EHRCertification-012115.pdf.

371. Sharona Hoffman & Andy Podgurski, *Meaningful Use and Certification of Health Information Technology: What about Safety?* 39 J.L. MED. & ETHICS 77, 79 (2011).

372. HOFFMAN, *supra* note 118, at 23-35 (discussing EHR system shortcomings).

373. *See id.* at 50-52 (recommending clinical safety testing).

Second, it would place demands on health care providers. For testing purposes, some would have to implement EHR systems that are not yet certified and that they may find to be a poor fit. Usability assessments, therefore, could exacerbate burnout at testing facilities in the short-term. Third, any incentive, such as price discounts, could create conflicts of interest. Facilities that find a new EHR system to be satisfactory may be motivated to report data that are excessively positive in order to ensure product certification and obtain discounts. Consequently, it is unrealistic to expect that the proposed clinical usability testing would be mandated in the near future.

In the alternative, CMS regulations should require that vendors allow customers to engage in acceptance testing. Acceptance testing is common in the software arena and is the final phase of testing, performed after a product is delivered and installed.³⁷⁴ It is designed to verify that users can accomplish their work using the system and that all of the customer's requirements have been met.³⁷⁵ It often reveals flaws that were not apparent from simulated test data.³⁷⁶ Vendor contracts specify the terms of acceptance testing.³⁷⁷ If the customer does not accept the product pursuant to the contract terms, it may provide the vendor additional time to remedy defects or may reject the product and obtain specified remedies such as refunds of any money already paid.³⁷⁸ Contracts thus should provide that final payment is not due until the buyer has performed acceptance testing and accepted the product.³⁷⁹

Acceptance testing would place little if any burden on health care providers. It is performed after a health care organization has selected an EHR system and signed a contract for its purchase.³⁸⁰ Without it, clinicians would simply have to adopt the system and begin using it despite any flaws. Acceptance testing will furnish an opportunity to demand that the vendor eliminate defects or to reject

374. IAN SOMMERVILLE, *SOFTWARE ENGINEERING* 80 (8th ed. 2007); Linda Ray, *The Difference Between Acceptance Testing & Qualification Testing*, CHRON (Nov. 21, 2017), <https://smallbusiness.chron.com/difference-between-acceptance-testing-qualification-testing-39049.html>.

375. ROB CIMPERMAN, *UAT DEFINED: A GUIDE TO PRACTICAL USER ACCEPTANCE TESTING* 8 (2006), <http://proquest.safaribooksonline.com/book/software-engineering-and-development/software-testing/0321498143>.

376. SOMMERVILLE, *supra* note 374, at 80.

377. Jon L. Roberts, *Work Made for Hire: The Fiction, the Reality and the Impact Upon Software Development*, 1 HARV. J.L. & TECH. 97, 123 (1988). For more information about software contracts, see generally AMERICAN LAW INSTITUTE, *PRINCIPLES OF THE LAW OF SOFTWARE CONTRACTS* (2015).

378. Michael J. Dunne, *Eight Significant Points in Technology Outsourcing and Remote Hosting Contracts*, 255 N.J. LAW., Dec. 2008, at 19, 21.

379. Stephen M. Goldberg, *What the Customer Can Do About Software Disabling Devices (with Sample Clauses)*, 45 PRAC. LAW., Apr. 1999, at 71, 77.

380. See *supra* note 356 and accompanying text.

severely problematic products before they are fully implemented and all members of the workforce undergo training to use them.

Finalizing EHR system implementation without thorough usability testing is akin to selling drugs that have not been responsibly tested in clinical trials involving actual patients.³⁸¹ After investing substantial money, time, and effort in purchasing and implementing an EHR system, providers may be very reluctant to switch to a different product even if their existing system has significant flaws.³⁸² Yet, EHR systems manage many aspects of patient care and have the potential to cause clinicians great misery.³⁸³ EHR systems also have serious safety implications for patients because documentation mistakes, inappropriate prompts, defective CPOE, and other aspects of the technology can lead to serious treatment errors.³⁸⁴ Consequently, it is critical that every certification process include comprehensive usability testing. In addition, it is important to allow buyers to conduct acceptance testing before finalizing their purchases. Ensuring that EHR systems rate highly in the usability area and facilitate rather than hinder clinicians' administrative work could go far towards alleviating physician burnout.

C. *Measuring and Reporting Physician Wellness*

In addition to expanded usability testing, federal regulations should require the inclusion of physician wellness among the quality measures that are reported to CMS.³⁸⁵ Thus, MACRA and the Meaningful Use regulations should be revised to incorporate a physician wellness measure. Physicians should be required to complete the MBI or an equivalent assessment tool annually.³⁸⁶ This would not be an excessively burdensome task because it takes only ten to fifteen minutes to complete the MBI.³⁸⁷ Clinicians should then upload the results directly to a website

381. See *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, U.S. FOOD & DRUG ADMIN. (Nov. 24, 2017), <https://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm>.

382. *The Challenges of Switching EHRs*, MED. ECON. (Oct. 25, 2016), <http://www.medicaleconomics.com/medical-economics-blog/challenges-switching-ehrs> (stating that "while 60% of ambulatory EHR system users either dislike their system or are neutral about it, and nearly half say they wouldn't recommend it to a colleague, only 15% of respondents say they're considering switching to another system in the next year"). But see, *Switching EHRs Becoming Norm in Healthcare*, MED. ECON., (Oct. 25, 2017), <http://www.medicaleconomics.com/med-ec-blog/switching-ehrs-becoming-norm-healthcare> (stating that 62% of respondents indicated they had switched EHR systems during their career and that while half did so because of a change in employment, the other half did so because of dissatisfaction with the system they were using).

383. See *supra* Part II.B.

384. HOFFMAN, *supra* note 118, at 23-35 (discussing EHR system shortcomings); *supra* note 117 and accompanying text (discussing EHR system features).

385. See *supra* Part II.C.1.

386. See *supra* notes 23-25 and accompanying text.

387. Vibeke Hansen & Afaf Girgis, *Can a Single Question Effectively Screen for Burnout in*

provided by CMS. Direct submission will prevent health care employers from having an opportunity to manipulate outcomes in order to avoid negative financial consequences. Health care organizations should receive summary reports from CMS regarding burnout in their workforces. If CMS becomes concerned that clinicians are manipulating their MBI responses in order to protect their employers, it could require employers to submit annual data regarding the number of workers who left, switched to a part-time schedule, or retired early. Such data may serve as an additional indicator of the level of burnout in the workplace and be used to determine whether testing outcomes appear reliable.

CMS could then include physician burnout in its reimbursement calculus so that organizations with a burnout rate that exceeds a stated level would be subject to pay adjustments.³⁸⁸ CMS may need to adjust the allowable burnout rate for particular practice settings, such as high-stress specialties³⁸⁹ or resource-poor facilities in underserved areas. Small practices (to be defined by CMS) would be exempt from the reporting requirement because every physician would have an outside influence on the overall burnout rate. Nonetheless, they should be encouraged to measure physician wellness and act to mitigate burnout.

Experts have noted that health care systems traditionally embrace the triple aim of enhancing patient experience, improving population health, and reducing costs, but they posit that a fourth aim should be added: cultivating providers' wellness.³⁹⁰ Without workforce wellness, it is impossible to achieve the first three goals.³⁹¹

The adverse consequences of physician burnout are well-recognized.³⁹² It can erode physicians' mental health, reduce productivity, diminish the quality of care, and lead to workforce attrition.³⁹³ Burnout should be of concern to all health care providers because it can be associated with outcomes such as lower patient satisfaction, longer recovery time after hospital discharge, and even malpractice suits arising from medical errors.³⁹⁴

Furthermore, promoting physician wellness is a professional ethical

Australian Cancer Care Workers?, 10 BMC HEALTH SERVICES RES. 341, 341 (2010)

388. See *supra* notes 168-169 and accompanying text.

389. See *supra* note 43 and accompanying text (discussing high-stress and lower-stress specialties).

390. Thomas Bodenheimer & Christine Sinsky, *From Triple to Quadruple Aim: Care of the Patient Requires Care of the Provider*, 12 ANNALS FAM. MED. 573, 575 (2014); Christine A. Sinsky, *Dissatisfaction Among Wisconsin Physicians Is Part of Serious National Trend*, 114 WMJ 132, 133 (2015).

391. Bodenheimer & Sinsky, *supra* note 390, at 575.

392. See *supra* Part I.B.

393. Tait Shanafelt et al., *The Business Case for Investing in Physician Well-being*, 177 JAMA INT'L MED. 1826, 1827-28 (2017); Wallace et al., *supra* note 67, at 1714-19; *supra* Part I.B.

394. See Dzau et al., *supra* note 7, at 312; Halbesleben and Rathert, *supra* note 75, at 34.

obligation.³⁹⁵ The American Medical Association Code of Medical Ethics Opinion 9.3.1 establishes that “physicians have a responsibility to maintain their health and wellness” and “an obligation to ensure that colleagues are able to provide safe and effective care, which includes promoting health and wellness among physicians.”³⁹⁶

CMS pay adjustments would constitute a meaningful incentive for health care organizations to attend to clinician wellness. Concern for patient welfare and business interests should do so as well. Reporting and tracking of physician wellness is worthwhile because entities can implement a variety of interventions.³⁹⁷ Educational programs regarding mindfulness and stress management and small group discussions have proven useful.³⁹⁸ Likewise, support through teamwork or the hiring of scribes is helpful.³⁹⁹ Professional organizations have begun to develop additional tools to help health care providers combat burnout.⁴⁰⁰ Indeed, Dr. Tate Shanafelt credits such initiatives with helping to reduce burnout rates between 2014 and 2017.⁴⁰¹ Collecting and storing burnout data from across the nation would also enable researchers to study the phenomenon in greater depth and better evaluate the efficacy of different interventions.

This Article proposes that CMS consider reported wellness measures in calculating reimbursement rates. However, these measures would be of even greater benefit to regulated health care entities themselves because they could use the information as a springboard for addressing the problem of burnout.⁴⁰² Without

395. Rosandra Walker & Harold Pine, *Physician Wellness Is an Ethical and Public Health Issue*, 158 OTOLARYNGOLOGY–HEAD & NECK SURGERY 970, 970 (2018).

396. COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, AMERICAN MEDICAL ASSOCIATION, CODE OF MEDICAL ETHICS: CURRENT OPINIONS WITH ANNOTATIONS 377-78 (2016), <https://www.ama-assn.org/sites/default/files/media-browser/code-of-medical-ethics-chapter-9.pdf>.

397. Noseworthy et al., *supra* note 8 (discussing the importance of measuring physician well-being and taking action to address it).

398. Shanafelt et al., *supra* note 105, at 902.

399. Bodenheimer & Sinsky, *supra* note 390, at 575; Wright & Katz, *supra* note 18, at 311. *See also supra* Part III.C.1.

400. *See* Dzau et al, *supra* note 7, at 313 (discussing a National Academy of Medicine collaborative that is creating an online “knowledge hub” that will serve as a “repository for available data, models, and toolkits”); Mark Linzer et al., *Preventing Physician Burnout*, STEPSFORWARD (June 2017), https://www.stepsforward.org/Static/images/modules/15/downloadable/Preventing_Physician_Burnout.pdf (presenting a module designed to help providers eliminate burnout and adopt wellness approaches in their practices); Stephen Swensen et al., *Physician-Organization Collaboration Reduces Physician Burnout and Promotes Engagement: The Mayo Clinic Experience*, 61 J. HEALTHCARE MGMT. 105, 108-20 (2016) (describing the Listen-Act-Develop model for reducing burnout).

401. Shanafelt et al., *supra* note 13, at 11.

402. Linzer et al., *supra* note 85, at 18 (“Any system that does not measure, monitor and optimize clinician well-being and sustainability is at risk.”); Shanafelt & Noseworthy *supra* note 14, at 133-42 (emphasizing the importance of measuring physician well-being and offering nine

specific data about burnout in their own work environment, health care organizations may not be motivated to implement interventions.

D. Promoting Measures Proven to Ease Burnout

Health care regulations and laws should support and promote approaches that have proven successful in mitigating physician burnout. These include employing scribes and shifting to a direct primary care model.⁴⁰³

For example, Medicare could provide bonus points for MIPS scoring purposes to practices that hire scribes.⁴⁰⁴ Medicare already provides bonus points in a variety of circumstances. It awards a five-point bonus for small practices with fewer than fifteen clinicians and up to five bonus points for treating complex patients.⁴⁰⁵ Such a bonus would encourage providers to implement this self-help measure and may ultimately help pay for scribes' wages. If other workplace interventions prove particularly successful, Medicare could provide bonus points for implementation of those as well.⁴⁰⁶

Congress should support direct primary care practices by passing the Primary Care Enhancement Act that would allow patients to use health savings accounts to pay DPC retainer fees.⁴⁰⁷ This benefit would help some patients cover the out-of-pocket costs of DPC and would thus provide important financial support for DPC practitioners. The law could include a sunset provision. Thus, if Congress determined that DPC was exacerbating physician shortages,⁴⁰⁸ it could choose not to renew the legislation at the end of the sunset period.

Policy-makers should use their considerable power to aid physicians in adopting mechanisms to combat burnout. If physicians feel empowered to promote their own wellness, they are much more likely to remain content and productive members of the clinical medicine profession.⁴⁰⁹

E. Addressing Patient Visit Length: A Need for Further Study

It is known that longer patient visits improve physicians' job satisfaction as well as treatment outcomes.⁴¹⁰ It is therefore tempting to propose legal limits on

institutional strategies to improve it).

403. See *supra* Parts III.C.1 & III.C.2.

404. See *supra* notes 167-169 and accompanying text (describing MIPS).

405. *MACRA Basics: Merit-based Incentive Payment System (MIPS)*, *supra* note 167.

406. See *supra* note 400 and accompanying text.

407. H.R. 365, 115th Cong. (2017); Ramsey, *supra* note 283; *supra* notes 316-318 and accompanying text.

408. See *supra* notes 303-305 and accompanying text.

409. See *supra* Part III.C.

410. Linzer et al., *supra* note 85, at 19 (urging that health care organizations lengthen patient visits in order to combat burnout); Tingley, *supra* note 228, at 43 (stating that having doctors spend

the number of patients physicians can see each day.

Other jurisdictions have considered or implemented such proposals. In 2015, the Alberta Medical Association suggested that general physicians see no more than six patients per hour (a number that seems alarmingly high).⁴¹¹ British Columbia doctors are subject to a fifty-patient daily cap, after which they get paid only half of their fee until they reach sixty-five patients, after which they are paid nothing (also very high limits).⁴¹² In June 2018, the British Medical Association passed a motion calling for a “sensible cap” on the workload of general practitioners.⁴¹³

American scholars have also suggested workload limitations. For example, one study of primary care physicians found that “visit rates above 3 to 4 per hour are associated with suboptimal visit content.”⁴¹⁴ Similarly, experts have urged that it is irresponsible for primary care physicians to see more than twenty-five to thirty patients per day.⁴¹⁵ For hospitalists, the suggested number has been lower, perhaps fifteen to eighteen per day.⁴¹⁶

Nevertheless, it would be inappropriate to formulate a legal mandate with absolute visit caps based on currently available evidence. The number of patients a physician can effectively treat in a day depends on a multitude of factors. These include the specialty, patients’ complexity, physician’s efficiency and work habits, the amount of work that is delegated to other team members, and more.⁴¹⁷ We do

more time with patients can reduce hospitalizations and save the health care system money); *supra* Part III.A.

411. Emily Mertz, *Alberta Medical Association Proposes Capping Number of Patients Doctors See*, GLOBAL NEWS, (Nov. 13, 2015, 4:51 PM) <https://globalnews.ca/news/2337609/alberta-medical-association-proposes-capping-number-of-patients-doctors-see/>.

412. *Get Rid of Daily Patient Cap, Says B.C. Walk-in Clinic Founder*, CBC NEWS (Jan. 20, 2017, 2:08 PM), <http://www.cbc.ca/news/canada/british-columbia/get-rid-of-daily-patient-cap-says-b-c-walk-in-clinic-founder-1.3945412>.

413. Jenny Cook, *BMA Demands GP Workload Cap to Protect Patients and Doctors*, GP (June 26, 2018), <https://www.gponline.com/bma-demands-gp-workload-cap-protect-patients-doctors/article/1486038>. See also, Laurence Buckman & Michael Griffiths, *Should GPs’ Daily Number of Consultations Be Capped?*, 361 *BMJ* k1947 (2018) (debating both sides of the argument).

414. David C. Dugdale et al., *Time and the Patient–Physician Relationship*, 14 *J. GEN. INTERNAL MED.* (Supp. 1) S34, S36 (1999). See also, Eric S. Williams & Asheley Cockrell Skinner, *Outcomes of Physician Job Satisfaction: A Narrative Review, Implications, and Directions for Future Research*, 28 *HEALTH CARE MGMT. REV.* 119, 134 (2003) (citing the Dugdale study and calling on managers to work with physicians to “develop realistic practice policies for physician productivity”).

415. See Luis Collar, *How Many Patients Can a Doctor Safely See a Day?*, KEVINMD (Dec. 31, 2013), <https://www.kevinmd.com/blog/2013/12/patients-doctor-safely-day.html>.

416. James Allen, *How Many Patients Should a Hospitalist See a Day?*, *HOSP. MED. DIR.* (Aug. 13, 2016), <https://hospitalmedicaldirector.com/how-many-patients-should-a-hospitalist-see-a-day/>; Steven M. Harris, *Appropriate Patient Census: Hospital Medicine’s Holy Grail*, *THE HOSPITALIST* (Jan. 2012), <https://www.the-hospitalist.org/hospitalist/article/125455/appropriate-patient-census-hospital-medicines-holy-grail>.

417. See Allen, *supra* note 416 (listing a large number of variables that should be considered in

not know what the workload tipping point is that causes physicians to suffer burnout. Nor have we verified the extent to which burnout or consequent depression causes medical errors. Many published studies have focused on physicians' own perception of performing sub-optimally rather than on objective measure of poor outcomes.⁴¹⁸ American physicians would likely find a cap objectionable because it would deprive them of discretion and could harm patients.⁴¹⁹ A patient who is seriously ill may not be able to access her doctor if the clinician has already scheduled the allotted number of appointments for the day.⁴²⁰

Thus, researchers should continue to study burnout to determine its consequences and identify effective preventive mechanisms. Such causal inference studies are complex and must adjust for numerous variables that can impact physicians' performance.⁴²¹ If researchers develop a sound rationale for capping the number of patients seen per day (or per hour or week) in particular specialties, those caps could be established by law. Caps would need to take into account the nature of the patient visit and allow for exceptions in emergency situations. For example, one British proposal suggested that family doctors have twenty-five to thirty-five appointments per day if they were for routine care (e.g. sore throats or blood pressure checks) but see only fifteen patients per day if the individuals had complex problems.⁴²²

In the meantime, other proposed interventions, such as streamlining regulatory requirements, improving EHR usability, and encouraging the use of scribes,⁴²³ should diminish the demands of clerical work and leave physicians with opportunities to lengthen patient visits. Health care organizations must refrain from requiring that doctors fill freed-up time with extra appointments. Regulatory improvements must enable physicians to enjoy greater job satisfaction by spending more time with patients. They should not generate even more crowded appointment schedules and thus fuel the fires of physician burnout.

determining hospitalists' patient loads).

418. See *supra* Part I.B.2.

419. See Buckman & Griffiths, *supra* note 413.

420. *Id.*

421. HOFFMAN, *supra* note 118, at 157-60 (discussing data analysis challenges); Sharon Hoffman & Andy Podgurski, *The Use and Misuse of Biomedical Data: Is Bigger Really Better?* 39 AM. J.L. & MED. 497, 521-25, 532-36 (2013) (discussing the challenges of bias and causal inference and causal inference techniques); *supra* note 417 and accompanying text.

422. Brian Goldman, *Should Number of Appointments by Family Doctors Be Capped? Medical Community Weighs in*, CBC RADIO (May 14, 2018), <http://www.cbc.ca/radio/whitecoat/blog/doctors-are-run-off-their-feet-1.4661676>.

423. See *supra* Parts V.A, V.B, and V.D.

VI. CONCLUSION

The American health care system suffers from numerous fractures and failures.⁴²⁴ Physician burnout is a core problem, which is as serious as any.⁴²⁵ Quality health care cannot be delivered without dedicated physicians who are happy with their work.⁴²⁶

Health care professionals widely bemoan their existing professional circumstances. Physician and author Siddhartha Mukherjee critiques “the form-filling, diagnosis-coding, button-pushing culture of modern medicine.”⁴²⁷ Dr. Thomas Schwenk writes in *JAMA* that the “caring relationship has been lost for many physicians in the current system of fragmented, rushed, dysfunctional, digitized, corporatized, and costly medical care – a system that prizes efficiency over relationships, profits over common good, and volume over value.”⁴²⁸ Philip Miller asks in *Health Affairs*: “The question is, Will medicine remain a calling with patient care at its heart or become a mere occupation, characterized by bureaucracy and a focus on the bottom line?”⁴²⁹

Physician well-being is a worthy cause that deserves the attention of both the medical community and policy-makers. Because public health is at stake, the law can no longer ignore the reality of physician burnout. Its power must be harnessed to launch a multi-faceted effort to combat the problem. Initiatives should include streamlining regulatory requirements, emphasizing usability in the process of EHR certification, measuring and reporting physician wellness indicators, supporting the use of scribes and direct primary care, and conducting further research to better understand burnout and identify additional solutions.⁴³⁰

Policy-makers must work to restore the appeal of the medical profession and retain the physician workforce. The health of the nation is at stake.

424. See, e.g., Jonathan Bush, *Four Ways to Heal Our Broken Healthcare System*, FORBES (June 14, 2016, 6:30 AM), <https://www.forbes.com/sites/realspin/2016/06/14/four-ways-heal-healthcare-system/>.

425. Bodenheimer & Sinsky, *supra* note 390, at 573-75; Wallace et al., *supra* note 67, at 1714.

426. See *supra* Part I.B.2.

427. Siddhartha Mukherjee, *For Doctors, Delving Deeper as a Way to Avoid Burnout*, N.Y. TIMES (Oct. 10, 2018), <https://www.nytimes.com/2018/10/10/magazine/for-doctors-delving-deeper-as-a-way-to-avoid-burnout.html>.

428. Schwenk, *supra* note 214, at 1543.

429. Phillip Miller, *The Medical Profession's Future: A Struggle between Caring for Patients and Bottom-Line Pressures*, 35 HEALTH AFFS. 407, 409 (2016).

430. See *supra* Part V.

Drug Injury Advertising

Jesse King & Elizabeth Tippett*

ABSTRACT

Drug injury advertising, which solicits consumers for lawsuits against drug and medical device manufacturers, is a \$114 million business. Yet little is known about how consumers respond to the medical information contained in these ads. This study applies insights from the field of marketing to the drug injury advertising context, and further tests those insights through two experiments. Results suggest that some consumers are deceived by drug injury ads, and that some types of advertising are more deceptive than others. We also find that deceptive drug injury ads have a stronger influence on consumer risk perceptions and behavioral intentions, such as intentions to use the medication or seek additional information. These effects can be mitigated somewhat through educational interventions or competing ads that promote the drug. Additionally, we find some evidence of a “spillover effect,” where groups unaffected by the risks described in the ad nevertheless perceive increased risk. We situate the study within the factual and legal background for drug injury advertising, as well as the extant scientific literature. We conclude with a discussion of the regulatory implications of the study.

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INTRODUCTION

On June 23, 2017, a subcommittee of the House Judiciary Committee held an oversight hearing on attorney ethics relating to drug injury advertising.¹ The term “drug injury advertising” refers to attorney advertisements soliciting viewers for potential lawsuits against drug companies and medical device makers.² The advertisers hope to recruit consumers that have suffered a particular adverse medical event after taking a prescription drug or using a medical device.³ To capture viewers’ attention, these advertisements sometimes include strong cautionary language about the dangers of a particular drug, through words like “medical alert” or “FDA Warning.”⁴

Drug injury advertisements disseminate drug safety information to consumers, which may help inform consumer decision making.⁵ At the same time, if they lead consumers to overestimate drug risks, the ads could distort consumer medical decisions.⁶ The hearing included testimony from two doctors, who described cajoling patients frightened by drug injury ads to stick to their prescribed drug regimen.⁷ Each reported that a patient had died after discontinuing medication in response to a drug injury ad.⁸ The hearing also included testimony from a legal ethics attorney, who complained about the picayune nature of existing attorney ethics rules for advertising and cautioned lawmakers against further regulation.⁹

One of the authors of this article (Tippett), also testified at the hearing,

1. *Examining Ethical Responsibilities Regarding Attorney Advertising: Hearing before the Subcomm. on the Constitution and Civil Justice of the H. Comm. on the Judiciary*, 115th Cong. (June 23, 2017) [hereinafter *Subcomm. Hearing*], <https://www.govinfo.gov/content/pkg/CHRG-115hhrg29776/html/CHRG-115hhrg29776.htm>.

2. Elizabeth Tippett, *Medical Advice from Lawyers: A Content Analysis of Advertising for Drug Injury Lawsuits*, 41 AM. J. L. & MED. 7, 8 (2015).

3. These adverse medical events are also known as “adverse drug reactions.” WORLD HEALTH ORG., INTERNATIONAL DRUG MONITORING: THE ROLE OF NATIONAL CENTERS, WORLD HEALTH ORG. TECH REP. NO. 498 (1972).

4. Tippett, *supra* note 2, at 26-28; see also Daniel Schaffzin, *Warning: Lawyer Advertising May Be Hazardous to Your Health! A Call to Fairly Balance Solicitation of Clients in Pharmaceutical Litigation*, 8 CHARLESTON L. REV. 319, 321-322 (2013).

5. Subcomm. Hearing, *supra* note 1 (testimony of Elizabeth Tippett).

6. Subcomm. Hearing, *supra* note 1 (testimony of Elizabeth Tippett, Dr. Shawn Fleming, Dr. Ilana Kutinsky).

7. See *Subcomm. Hearing* (testimony of Dr. Shawn Fleming); *Subcomm. Hearing* (testimony of Dr. Ilana Kutinsky).

8. Fleming, *supra* note 7; Kutinsky, *supra* note 7.

9. *Subcomm. Hearing*, *supra* note 1 (testimony of Lynda Shely). See also ASS’N OF PROFESSIONAL RESPONSIBILITY LAWYERS, 2015 REPORT OF THE REGULATION OF LAWYER ADVERTISING COMMITTEE (2015), https://www.americanbar.org/content/dam/aba/administrative/professional_responsibility/aprl_june_22_2015%20report.authcheckdam.pdf [hereinafter 2015 REPORT OF THE REGULATION OF LAWYER ADVERTISING COMMITTEE].

providing context about the drug injury advertising market, its regulation, and the limited scientific research to date. This Article draws upon and further elaborates upon that testimony. It also adds to the scientific literature through two experimental studies on how consumers respond to drug injury advertising. The study is modeled on theory and research from the marketing field, but designed to answer several legally relevant questions: (1) Are viewers misled by drug injury advertisements? (2) Are some drug injury advertisements more misleading than others? (3) Do drug injury advertisements influence consumer risk perceptions and behavioral intentions? (4) Can educational interventions reduce the extent to which viewers are misled by drug injury advertisements? and (5) Does competing content from other sources mitigate the influence of drug injury advertising?

Overall, results suggest that consumers are sometimes deceived by drug injury advertising. While consumers were almost always able to identify the sponsor of an ad for soap or a direct-to-consumer pharmaceutical ad (97%), some viewers were confused about the sponsor of the drug injury advertisement, ranging from 16% of participants (for a transparent ad) to 28% (for a deceptive ad). As we explain below, this failure may substantially impair their ability to contextualize the medical information in the advertisement.

In addition, the most deceptive advertisements had a greater influence on viewers' risk perceptions and behavioral intentions, suggesting that the questionable content ultimately influences how viewers feel and potentially even behave with respect to the drug. We also observed a so-called "spillover" effect — where perceptions of increased risk affected viewers outside the population affected by the risk. The presence of a spillover effect suggests that attorney ads could be distorting patient risk perception.

The results also offer some guidance for how to mitigate the effect of drug injury advertisements on risk perceptions. The presence of a competing pharmaceutical ad in some respects cancelled out the effect of the drug injury ad. Pharmaceutical companies thus may have the means to counteract some effects of drug injury ads, albeit at considerable expense. Educational interventions also reduced confusion about the sponsor of the ad, and the effect of this confusion on risk perceptions and behavioral intentions. This suggests that a disclaimer-based approach might help, although further research is warranted as to the size, prominence, sequence, and content of disclaimers.

This Article proceeds as follows: Part I describes the market for drug injury advertising and how it is regulated. Part II summarizes extant scientific literature on drug injury advertising, and Part III applies research from the field of marketing to help theorize how consumers respond to the ads. Part IV describes the methodology for the studies and Part V summarizes the results. Part VI discusses the regulatory implications.

I. FACTUAL AND LEGAL CONTEXT

A. *The Market for Drug Injury Advertising*

Drug injury advertisements recruit viewers for mass tort lawsuits against pharmaceutical companies and medical device manufacturers. These lawsuits are typically pled as “failure to warn” cases, alleging that the manufacturer knew or should have known about a particular risk associated with the drug and disclosed that risk on the drug’s label.¹⁰

Drug injury advertisers (and lawyers) learn about undisclosed drug risks from a number of sources. When a patient suffers an adverse medical event after taking a drug, that event may be reported to the Food and Drug Administration for inclusion in an adverse event database.¹¹ Researchers draw from that data, or other medical records, in their studies on adverse events.¹² Legal advertisers apparently monitor scientific publications regarding adverse events and then sponsor advertising asking viewers if they have suffered the adverse event described in the literature.¹³ Legal advertisers may also sponsor advertising following action by the FDA¹⁴ — for example, where the FDA demands that a pharmaceutical company add additional warnings to the drug label.¹⁵ When new adverse events come to light, it is very rare for the drug to be recalled from the market entirely.¹⁶ As a result, almost all drug injury ads involve drugs or medical devices that are still

10. STEVEN GARBER, RAND INST. FOR CIVIL JUSTICE, ECONOMIC EFFECTS OF PRODUCT LIABILITY AND OTHER LITIGATION INVOLVING THE SAFETY AND EFFECTIVENESS OF PHARMACEUTICALS 19 (2013). For cases deciding on failure to warn, see *Pliva v. Mensing*, 131 S. Ct. 2567, 2573-74, 2577 (2011); *Wyeth v. Levine*, 129 S. Ct. 1187 (2009).

11. Brian Chen, John Restaino & Elizabeth Tippett, *Key Elements in Adverse Drug Reactions Safety Signals: Application of Legal Strategies*, CANCER POLICY: PHARMACEUTICAL SAFETY 47 (June McKoy, Dennis West eds. (2019) (describing the adverse event reporting system). Because adverse event reporting is voluntary, the majority of adverse events are not reported to the FDA. See e.g. Mara McAdams, Judy Staffa, & Gerald Dal Pan, *Estimating the extent of reporting to FDA: a case study of statin-associated rhabdomyolysis*, 17 PHARMACOEPIDEMOLOGY AND DRUG SAFETY 229 (2008).

12. *Id.* at 4.

13. David N. Juurlink et al., *The Effect of Publication on Internet-Based Solicitation of Personal-Injury Litigants*, 177 CAN. MED. ASSOC. J. 1369, 1370 (2007).

14. See Brian K. Chen & Elizabeth C. Tippett, *Association of Attorney Advertising and FDA Action with Prescription Claims: A Time Series Segmented Regression Analysis*, 38 DRUG SAFETY 1169, 1172 (2015).

15. Brian K. Chen & Y. Tony Yang, *Post-Marketing Surveillance of Prescription Drug Safety: Past, Present & Future*, 34 J. LEGAL MED., 193, 204-05 (2013).

16. LEWIS GROSSMAN, PETER BARTON HUTT & RICHARD MERRILL, *FOOD & DRUG LAW: CASES AND MATERIALS* 1303-04 (3d ed. 2007) (explaining that most recalls are “voluntary” in the sense that the manufacturer will recall the drug at the FDA’s request); Michael T. Roberts, *Mandatory Recall Authority: A Sensible and Minimalist Approach to Improving Food Safety*, 59 FOOD & DRUG L.J. 563 (2004).

available on the market,¹⁷ and that could influence the medical decisions of some viewers.

Drug injury advertisements tend to conform to a genre, although they can vary somewhat in the way their content is framed. One of our prior studies examined the content of attorney advertising broadcast in 2009. Overall, the ads tended to focus heavily on the adverse medical event associated with the drug at issue.¹⁸ Ads devoted far more time, and content, to discussing adverse events, with a median of 20 seconds devoted to adverse events, compared to 2 seconds for benefits/use of the drug.¹⁹ While all of the ads included in the study discussed adverse events associated with the drug, only about half mentioned the benefit or use of the drug.²⁰ Only 39% of ads advised viewers to consult a doctor, which was often displayed in small print on the screen.²¹ Most of the ads tended to reveal themselves as attorney advertising within the first few seconds.²² However, a subset of the advertisements in the study—about 20%—appeared to mimic public service announcements, containing cautionary language such as “FDA warning” “consumer alert” or “medical alert.”²³ This subset of ads also tended to delay their disclosure that the ad was sponsored by an attorney.²⁴ In a few of the ads, the attorney sponsor of the ad was not disclosed at all.²⁵

The genre of drug injury advertising has not changed significantly since the original content analysis. For example, one advertisement involving the anti-coagulant, Xarelto included the following language:²⁶

Have you taken the blood thinner Xarelto? If so, please listen carefully. Xarelto, a new blood thinner on the market since 2011 has caused incidents of uncontrollable bleeding, hemorrhaging, and even death. The makers of Xarelto sold the drug knowing that it had no antidote to reverse its blood thinning effects. If you’ve suffered hemorrhaging, gastrointestinal bleeding, stroke or if a loved one has died after taking Xarelto, call 1-888-294-9999 now to see if your case qualifies for substantial cash compensation.

Likewise, the use of cautionary language and medical imagery remains

17. Tippett, *Medical Advice from Lawyers*, *supra* note 2, at 7.

18. *Id.* at 21.

19. *Id.* at 21.

20. *Id.*

21. *Id.* at 20.

22. *Id.* at 29.

23. *Id.* at 26.

24. *Id.* at 28.

25. *Id.* at 30.

26. *Subcomm. Hearing* (testimony of Elizabeth Tippett), *supra* note 1. The content is from a dataset obtained from Kantar media for advertising broadcast between 2015-2016.

common, although some ads do so without obscuring the identity of the advertiser. Figures 1-3, below, represent screenshots of advertising broadcast in 2015-2016 and illustrate the diversity of ways that advertisers use fear-based appeals, references to medical and government authorities, and stark imagery to capture viewer attention.

Figure 1²⁷

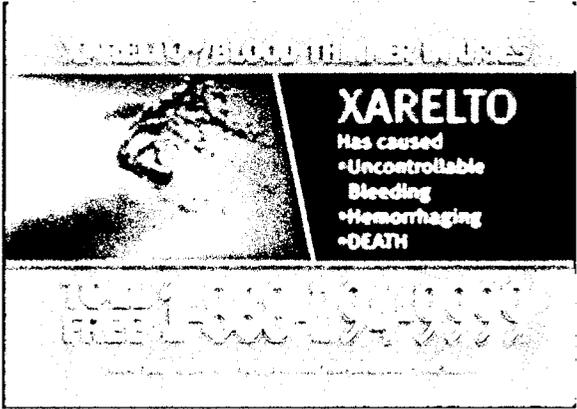
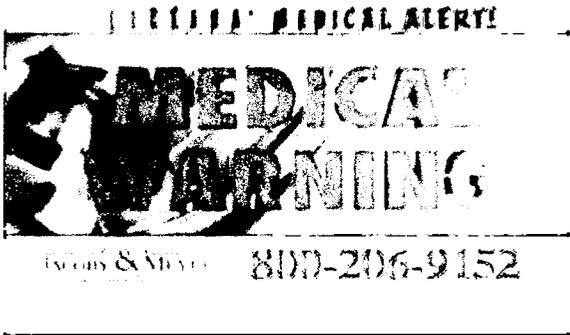
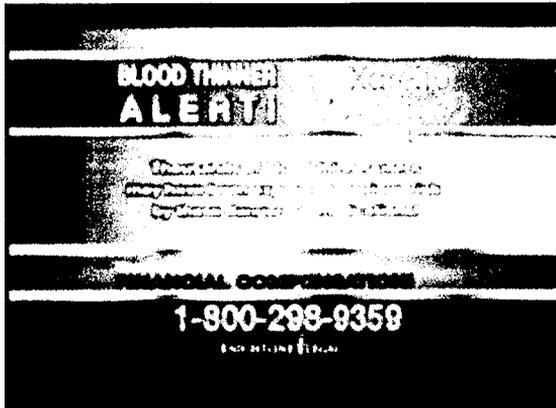


Figure 2²⁸



27. *Id.*

28. *Id.*

Figure 3²⁹

Unlike class action claims,³⁰ plaintiffs in a mass tort claim are not jointly represented by a single law firm. Instead, mass tort claims aggregate individual lawsuits, where each plaintiff has their own lawyer.³¹ Thus, a mass tort claim involving hundreds or thousands of plaintiffs may also involve scores of lawyers.³² Successful mass tort claims can be valuable for the attorneys involved because they are typically compensated on a contingency fee.³³ This financial incentive has produced a market in which advertisers compete to identify the most valuable plaintiffs for promising (or well-established) mass tort claims. Over the course of a year, about 53,000 drug injury advertisements are broadcast on national cable and broadcast networks.³⁴ This figure, which does not include local broadcast figures, amounts to about 145 ads per day. Kantar Media estimates the aggregate cost of those ads at around \$114 million.³⁵

29. *Id.*

30. Fed. R. Civ. P. 23(g).

31. See Paul D. Rheingold, *How Leadership Arises in MTL; Litigation Groups*, LITIGATING MASS TORT CASES § 7:5 (2017); see also Deborah R. Hensler & Mark A. Peterson, *Understanding Mass Personal Injury Litigation: A Socio-Legal Analysis*, 59 BROOK. L. REV. 961, 965 (1993); Charles Silver & Geoffrey P. Miller, *The Quasi-Class Action Method of Managing Multi-District Litigation: Problems and a Proposal*, 63 VAND. L. REV. 107, 115 (2010).

32. Rheingold, *supra* note 31, at § 7:5 (“Rare is the mass case in which there is only one law firm representing all plaintiffs. In some mass litigations, there may be thousands of law firms . . .”).

33. Task Force on Contingent Fees of the A.B.A.’s Tort Trial & Insurance Practice Section, *Contingent Fees in Mass Tort Litigation*, TORT TRIAL & INS. PRAC. L.J. 108 [hereinafter Task Force on Contingent Fees].

34. *Subcomm. Hearing* (testimony of Elizabeth Tippet), *supra* note 1.

35. *Id.*

Table 1. Most Prolific National Advertisers, 2015/2016³⁶

	Number of advertising spots aired	Percentage of national advertising volume
1. PULASKI LAW FIRM	11,491	21%
2. GOLDWATER LAW FIRM	10,298	19%
3. GOLD SHIELD GROUP	5,538	10%
4. KNIGHTLINE LEGAL	3,636	7%
5. FERRER, POIROT & WANSBROUGH	1,974	4%
6. AKIN MEARS LAW FIRM	1,828	3%
7. DRISCOLL FIRM	1,119	2%
8. GOZA & HONNOLD ATTORNEYS	1,049	2%
9. AVRAM BLAIR & ASSOCIATES	955	2%
10. RELION GROUP	948	2%

The advertising market is quite concentrated, with the top three advertisers representing about 50% of the overall advertising volume (Table 1). The top ten advertisers account for 72% of all advertising volume.³⁷ The top advertisers are not limited to law firms. In particular, the number 3 advertiser (Gold Shield Group), the number 4 advertiser (Knightline Legal), and the number 10 advertiser (Relion Group) are private companies. The Gold Shield Group is a trademark owned by MCM Services Group LLC,³⁸ a “lead management” company providing advertising services for lawyers.³⁹ Based on its marketing materials, it appears to produce advertising content and provide ad buying services for individual law firms.⁴⁰ Knightline Legal is a trademark owned by a California LLC.⁴¹ Its website claims that it is “not a law firm or referral service and does not provide legal representation to visitors of this site.”⁴² Relion Group is a Delaware Corporation with headquarters in California. Its disclaimer provides that it “is a consolidated

36. *Id.* (Tippett testimony).

37. *Id.*

38. *Id.* (Tippett testimony, citing GOLD SHIELD GRP. trademark Registration No. 4684241).

39. *Id.* (Tippett testimony, citing MCM SERVS. GRP., <http://mcmservicesgroup.com/>).

40. *Id.* (Tippett testimony, citing GOLD SHIELD GRP., <http://www.herniameshalert.com/disclaimer/>; *Notice, Disclaimers, and Terms of Use*, ICANN, <https://whois.icann.org/en/lookup?name=www.herniameshalert.com>; *Celebrating Fifteen Years of First-Class Law Firm Advertising*, MCM SERVS. GRP., <http://mcmservicesgroup.com/law-firm-advertising-portfolio/>).

41. *Id.* (Tippett testimony, citing KNIGHTLINE LEGAL, Registration No. 4643581).

42. *Id.* (Tippett testimony, citing *Disclaimer*, KNIGHTLINE LEGAL, <http://www.knightlinelegal.com/disclaimer>).

group of participatory attorneys”⁴³

The remaining top advertisers appear to be law firms. However, some of these top advertisers do not appear to litigate many cases that result from their advertising. For example, a search for the firm name in Bloomberg dockets produced few results for the Pulaski Law Firm, Goldwater Law Firm, and the Driscoll Firm. Others⁴⁴ in the top ten litigated with greater frequency — for example, Ferrer, Poirot & Wansbrough appeared in 331 cases in a 5-year period, and Goza & Honnold in 710 cases. Conversely, some of the less prolific advertisers were heavy litigators. For example, the Levin Papantonio Thomas Mitchell Rafferty & Proctor firm sponsored fewer than 300 advertising spots but appeared in more than 2,500 cases since 2012. The firm, Freese and Goss, sponsored only 7 advertising spots, but appeared in more than 1,900 cases.

The disconnect between litigation filings and advertising—as well as the presence of non-law firm advertisers—suggests that some law firms, and corporations, specialize in producing and financing advertising spots, while other law firms specialize in litigating.⁴⁵ This market will thus require some form of transaction between the advertiser that generated the lead and the litigator that files the claim. The nature of these transactions are not widely known, as they exist in an ambiguous regulatory space within attorney ethics rules.⁴⁶ Generally, the players appear to avoid ethics scrutiny by treating both the advertising firm and the litigating firm as jointly responsible for the case, in exchange for paying the advertising firm a percentage of the fee eventually recovered in the case.⁴⁷ These complex transactions are not apparent from the content of the ad, which, as discussed in greater detail below, may hinder consumers’ ability to infer the pecuniary motives of the advertiser and contextualize the medical information in the advertising.

B. Legal Rules

Attorney advertising is currently regulated at the state level, through attorney ethics rules. While state attorney ethics rules vary, all states regulate attorney

43. *Id.* (Tippett testimony, citing *Disclaimer*, RELION GROUP, <http://www.reliongroup.com/disclaimer>; Del. Dep’t of St., Div. of Corps., File No. 5378204, Relion Medial Group, Inc., incorporated Aug. 5, 2013; RELION MEDIA GROUP, Registration No. 3970426 (listed at same address)).

44. Dataset (on file with author).

45. *See* Tippett, *supra* note 2, at 8-9 (noting a similar disconnect between advertising volume and litigation frequency in a 2009 sample).

46. *See* discussion *infra* Part VI.

47. Task Force on Contingent Fees, *supra* note 33, at 108 (advertisers “will refer their cases in bulk to other lawyers who specialize in handling mass tort claims. The original [advertising] lawyers will make the referrals in return for a percentage of the new lawyer’s percentage and perhaps some reimbursement of costs.”).

advertising in some way. All states include some form of prohibition on false or misleading advertising.⁴⁸ Some states also impose specific requirements on advertisers, such as requiring them to list the firm name or address.⁴⁹ States have not adopted rules specific to drug injury advertising. We are also aware of no instance in which a state bar took action against an attorney for false or misleading content in a drug injury ad.

In recent decades, state bars have not aggressively enforced prohibitions on false or misleading advertising. A 2002 study by Frank Zacharias found high levels of non-compliant attorney advertising in the local phone book and virtually no efforts on the part of state bars to enforce them.⁵⁰ Consequently, the case law that has developed by state bars for assessing compliance with the prohibition on false or misleading advertising tends to be somewhat sparse. State ethics boards have found that content suggesting the advertisement has a public purpose—such as “legal helpline” or “public service”—is misleading because it suggests a charitable or government affiliation.⁵¹ Likewise, attorney advertising can be misleading where its format serves to obscure its purpose, such as a print ad labeled “public service announcement” advising drivers on behavior at drunk driving checkpoints.⁵² Similarly, a website offering to “match” consumers with attorneys after filling out a form was deemed misleading because it did not disclose that consumers would be matched with the attorney who purchased the exclusive right to receive referrals from a particular zip code.⁵³ Nevertheless, because drug injury advertisements have never been the subject of state ethics opinions, it is difficult to know how state bars would apply their rules to drug injury advertising.

Attorney advertising is protected under the First Amendment as commercial speech.⁵⁴ The First Amendment places an outer limit on states’ ability to regulate drug injury advertising. State regulation of attorney advertising must pass the *Central Hudson* test: the state must “assert a substantial interest” that is “directly advance[d]” by the speech restriction, which cannot be “served as well” through a

48. Tippet, *supra* note 2, at 3.

49. *Id.* at 32; see also 2015 Report of the Regulation of Lawyer Advertising Committee, *supra* note 9, at 21.

50. Fred C. Zacharias, *What Lawyers Do When Nobody’s Watching: Legal Advertising as a Case Study of the Impact of Underenforced Professional Rules*, 87 IOWA L. REV. 971, 985984-86 (2002).

51. Tippet, *supra* note 2, at 33-34 (citing S.C. Bar Ass’n Advisory Comm., Ethics Advisory Op. 13-05 (2013), 2013 WL 7196338, at *1; Conn. Bar Ass’n Comm. on Prof’l Ethics, Informal Op. 01-03 (2001), 2001 WL 694581, at *3; StateSt. Bar of Cal. Standing Comm. on Prof’l Responsibility & Conduct, Formal Op. 2004-167 (2004), 2004 WL 3079032, at *2).

52. Tippet, *supra* note 2, at 35; *Fla. Bar v. Doe*, 634 So. 2d 160, 161 (Fla. 1994).

53. Tippet, *supra* note 2, at 33-34; N.J. Comm. on Att’y Adver., *Internet Adver., Misleading Content, & Impermissible Referral Servs.*, N.J. CTS. (June 28, 2011), <https://www.njcourts.gov/notices/2011/n110629a.pdf>.

54. *Bates v. St. Bar of Ariz.*, 433 U.S. 350, 363 (1977).

“more limited restriction on commercial speech.”⁵⁵ However, false or misleading speech is not protected under the First Amendment.⁵⁶

In assessing state regulation of attorney advertising, the Supreme Court has on occasion opined as to whether it considered particular content misleading. In the 1985 *Zauderer* case, the Supreme Court did not require that a statement be overtly false to qualify as misleading.⁵⁷ Rather, a statement can be misleading through omission. The Court deemed the statement, “if there is no recovery, no legal fees are owed” misleading because it failed to disclose that the consumer would be liable for costs.⁵⁸ In doing so, the court looked past the literal content of the statement, which was truthful—in fact, no legal fees would be owed absent recovery. Instead, the Court considered the implication of the statement, and reasoned that consumers would infer from the statement that they would incur no out-of-pocket costs in connection with the litigation.⁵⁹ The Court reached this conclusion without extrinsic evidence that individuals were actually misled, reasoning: “When the possibility of deception is as self-evident as it is in this case, we need not require the State to ‘conduct a survey of the . . . public before it [may] determine that the [advertisement] had a tendency to mislead.’” However, if the misleading character of a statement is not apparent, it must be supported by some evidence of deception or harm.⁶⁰

The Federal Trade Commission (“FTC”) also has jurisdiction over attorney advertising.⁶¹ Its authority derives from the FTC Act, which provides that “unfair methods of competition in or affecting commerce and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful.”⁶² False advertising that is “misleading in a material respect” is included in the Act’s definitions of “unfair or deceptive acts or practices.”⁶³ The FTC’s broad purpose is not limited to protecting employees from purchases arising from deception, but

55. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of N.Y.*, 447 U.S. 557, 564 (1980).

56. *Id.* at 576.

57. *Zauderer v. Off. of Disciplinary Couns. of the Sup. Ct. of Ohio*, 471 U.S. 626, 652-53 (1985)

58. *Id.*

59. *Id.*

60. *Peel v. Att’y Registration & Disciplinary Comm’n of Ill.*, 496 U.S. 91, 106 (1990); *see also Ibanez v. Fla. Dep’t of Bus. & Prof’l Regulation, Bd. of Accountancy*, 512 U.S. 136, 145 (1994).

61. 15 U.S.C. § 52 (2012); 15 U.S.C. §45 (2012). In an interview with a Wall Street Journal reporter, an FTC official conceded that the agency has jurisdiction over drug injury ads and stated that the agency has “never pursued an investigation or action against mass tort attorney ads . . .” Sara Randazzo & Jonathan D. Rockoff, *Have You or Your Loved Ones Been Hurt by This Ad? Congressman Wants to Know*, WALL STREET JOURNAL (April 14, 2017, 5:30 AM), <https://www.wsj.com/articles/have-you-or-your-loved-ones-been-hurt-by-this-ad-congressman-wants-to-know-1492162205>.

62. 15 U.S.C. § 52.

63. 15 U.S.C. § 55 (2012). *See also* JOHN SPANOGLE ET AL., CONSUMER LAW: CASES AND MATERIALS 47 (2013).

rather to broadly safeguard “consumer sovereignty.”⁶⁴ Consequently, the FTC has broad jurisdiction over all forms of broadcast advertising, including advertising from lawyers. However, the FTC has generally declined to intervene regarding attorney advertising, consistent with its stated policy of deferring to state and local agencies.⁶⁵

The Food and Drug Administration (“FDA”) has not regulated drug injury advertising, although it regulates direct to consumer pharmaceutical advertising, which contains some of the same content. In fact, the FDA may not have jurisdiction over drug injury advertising because its authority only extends over advertising that is “issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug.”⁶⁶

Overall, state attorney ethics boards are most clearly responsible for regulating attorney advertising, which are subject to rules regarding false and misleading content. However, this regulation is somewhat theoretical in the sense that they have never been specifically applied to drug injury advertisers through disciplinary proceedings or opinion letters.

This study, in addition to filling gaps in the scientific literature, serves to answer two questions relevant to legal policy making. In particular, are consumers actually misled by drug injury advertising, and are some advertisements more misleading than others? If the answer to either question is no, it would suggest a poor case for regulatory action. If consumers are not misled, there is no harm for regulators to address. Conversely, if consumers are misled regardless of the content, regulation would in some sense be futile, as no improvements to the content of the ads would be beneficial for consumers. But if consumers are misled, and the deception can be attributed to the content of the ad, nudging advertisers toward less deceptive content might ultimately benefit consumers.

II. LITERATURE REVIEW

Research on drug injury advertisements is quite limited. A handful of studies have been conducted on the influence of drug injury advertisements involving pelvic mesh, which has been the subject of considerable advertising volume. A survey-based study by Koski et al. asked urology patients how they first learned

64. *In re Int'l Harvester Co.*, 104 F.T.C. 949 (1984).

65. Tippet, *supra* note 2, at 13, 40 (“[T]he FTC has not inserted itself into the regulation of attorney advertising beyond commenting on proposed attorney advertising rules that it deems overly restrictive”); FED. TRADE COMM’N, FREQUENTLY ASKED QUESTIONS: A GUIDE FOR SMALL BUSINESS, GENERAL ADVERTISING POLICIES (2008), <https://www.ftc.gov/tips-advice/business-center/guidance/advertising-faqs-guide-small-business> (“The FTC concentrates on national advertising and usually refers local matters to state, county, or city agencies”); Randazzo & Rockoff, *supra* note 61.

66. Federal Food, Drug & Cosmetics Act, § 502(n) (codified in 21 U.S.C. § 352(n) (2018)).

about pelvic mesh.⁶⁷ Those who recalled first learning about the mesh through drug injury ads expressed more doubts about its safety.⁶⁸ Patients in Koski's study also indicated that drug injury ads were more influential than other sources of information, including medical professionals.⁶⁹ A study by Tenggardjaja et al. suggested that drug injury ads may both inform and misinform viewers.⁷⁰ Patients that reported getting their information primarily from television (and were presumably exposed to drug injury advertising) were more likely to remember FDA announcements regarding pelvic mesh.⁷¹ However, they were also more likely to incorrectly believe that pelvic mesh had been subject to a product recall by the FDA.⁷²

In a study co-authored with several physicians, we examined the relationship between patient exposure to drug injury ads and perceptions of pelvic mesh.⁷³ We also asked patients about whether they previously had surgery involving pelvic mesh and previous visits to a urologist.⁷⁴ We found that exposure to drug injury advertising was quite high—88% of respondents reported having seen a drug injury advertisement involving pelvic mesh over the past six months.⁷⁵ The frequency of exposure was also quite high, with 75% of respondents reporting having seen such ads at least once per week.⁷⁶ Respondents had ambivalent attitudes towards drug injury advertising, rating them roughly in the middle of the scale we provided on credibility, reliability and truthfulness.⁷⁷

Personal experience with pelvic mesh surgery was the best predictor of a patient's perceptions — those who had undergone surgery reported that surgery was less risky and more beneficial than other patients.⁷⁸ Results suggested that greater exposure to drug injury advertising predicted higher risk perceptions, but did not reliably predict perceptions about the benefits of surgery.⁷⁹ By contrast, a past visit with a urologist did not reliably predict patient risk perceptions. However,

67. Michelle Elaine Koski et al., *Patient Perception of Transvaginal Mesh and the Media*, 84 FEMALE UROLOGY 572, 576 (2014).

68. *Id.*

69. *Id.*

70. Christopher F. Tenggardjaja et al., *Evaluation of Patients' Perceptions of Mesh Usage in Female Pelvic Medicine and Reconstructive Surgery*, 85 FEMALE UROLOGY 326, 327 (2015).

71. *Id.*

72. *Id.*

73. Elizabeth Tippet, Jesse King, Vincent Lucente, Sonia Ephraim, Miles Murphy & Eileen Taff, *Does Attorney Advertising Influence Patient Perceptions of Pelvic Mesh?*, 111 UROLOGY 65, 70 (2018).

74. *Id.* at 66.

75. *Id.* at 65.

76. *Id.* at 67.

77. *Id.* at 67.

78. *Id.* at 67.

79. *Id.* at 68.

such patients tended to view mesh surgery as more beneficial.⁸⁰ The study provides some insight into how patients process different sources of information relating to medical risks. Patients appear to trust their own experience and knowledge above all. However, when assessing information from third parties (doctors and drug injury ads) they appear to be retaining the primary message conveyed by each information source — in the case of doctors, the potential benefits of surgery, and in the case of drug injury ads, the risks. It may also be that patients retain the information that is novel from each source. Given the near universal exposure to the ads, they may first learn about risks from drug injury ads, which they retain, and which is reinforced through each viewing. Through a doctor's visit, they may first learn about the benefits of treatment, which are largely omitted from drug injury ads.⁸¹

Other studies have taken different methodological approaches. A study sponsored by Janssen Pharmaceuticals examined adverse event reports from the FDA to identify cases in which patients appear to have stopped taking medication in response to drug injury advertising.⁸² They identified thirty one patients that suffered serious adverse events, including a stroke, blood clot, and paralysis.⁸³ They also identified two patients that died.⁸⁴ A study by Tippet and Chen examined one year of Medicare reimbursement data to assess whether prescription rates changed following drug injury advertising.⁸⁵ The study found that drug injury advertising was strongly correlated with FDA regulatory action involving the drug at issue, such as a drug relabeling.⁸⁶ Results found that FDA action was associated with a reduction in the level or trend of the prescription rate.⁸⁷ However, no such reduction in the level or trend was observed in connection with high rates of attorney advertising.⁸⁸

Overall, extant research suggests that drug injury advertising might have an influence on patient attitudes, and possibly behaviors. However, the observational nature of the studies limits causal inferences to be drawn from them. The closest study to establish a causal inference was perhaps the Janssen Pharmaceuticals

80. *Id.* at 68.

81. Tippet, *Medical Advice from Lawyers*, *supra* note 2, at 21.

82. PAUL BURTON & W. FRANK PEACOCK, A MEDWATCH REVIEW OF REPORTED EVENTS IN PATIENTS WHO DISCONTINUED RIVAROXABAN (XARELTO) THERAPY IN RESPONSE TO LEGAL ADVERTISING 248 (Heart Rhythm Soc'y, vol. 2, 2016).

83. *Id.* It was unclear in the subcommittee hearings whether the doctors were describing the same patients referenced in the Janssen Pharmaceuticals study or whether they represented additional cases. See *Subcomm. Hearing*, *supra* note 7 (testimony of Dr. Shawn Fleming); *Subcomm. Hearing*, *supra* note 7 (testimony of Dr. Ilana Kutinsky).

84. Burton & Peacock, *supra* note 82 at 248.

85. Chen & Tippet, *supra* note 14, at 1170.

86. *Id.* at 1172.

87. *Id.* at 1172.

88. *Id.* at 1173.

study of adverse event reports, which originated from a biased source, but apparently traced the patient's decision making to attorney advertising. Observational research is also limited in its ability to disentangle the effect of different sources of information. Consumers receive drug information from multiple sources beyond drug injury ads—the media, the internet, medical professionals, the FDA, as well as family and friends.⁸⁹ Without experimental research, it is difficult to measure the influence of each source on consumer decision making. Lastly, extant research cannot measure the differential effects of advertisements, which vary in content. For example, the previously discussed content analysis of ads suggests that some ads are more misleading than others—where many are transparent, others obscure their sources and purpose.⁹⁰ It may be that the misleading ads influence consumer behavior to a greater extent than those that are more transparent.

III. THEORETICAL MODEL

Although few studies have examined drug injury advertising specifically, the field of marketing has developed sophisticated theory, supported by a body of research, around how consumers process marketing messages and the various ways in which consumers can be misled. We summarize the relevant theory from the marketing field below and then describe how we apply that theory to the drug injury context in our study design.

A. Insights from the Field of Marketing

The prevailing marketing theory for understanding consumer persuasion and deception was articulated in a 1994 article by Marian Friestad and Peter Wright.⁹¹ Friestad and Wright presented a “Persuasion Knowledge Model” (“PKM”), where the advertiser engages in a “persuasion attempt” with respect to a consumer.⁹² In their model, consumers do not approach these interactions with a blank slate. Rather, consumers bring to bear their substantive knowledge about the topic, their knowledge about the advertiser, as well as their knowledge about persuasion tactics.⁹³ Consumers develop knowledge about persuasion tactics, the “how, when and why marketers try to influence them,” through folk knowledge and personal experience.⁹⁴ This knowledge enables them to “cope” with persuasion attempts

89. *Id.* at 1171.

90. Tippet, *Medical Advice from Lawyers*, *supra* note 2, at 26.

91. Marian Friestad & Peter Wright, *The Persuasion Knowledge Model: How People Cope with Persuasion Attempts*, 21 J. CONSUMER RESEARCH 1, 1 (1994).

92. *Id.* at 2.

93. *Id.* at 2-4.

94. *Id.* at 1.

with greater sophistication over time.⁹⁵ Consumers “access persuasion knowledge . . . whenever they want to understand what is going on as they observe advertisements, sales presentation, or the behaviors of service providers.”⁹⁶

Consumers use their knowledge to “maintain control over the outcome[s] and thereby achieve whatever mix of goals is salient to them.”⁹⁷ They identify a persuasive attempt as such, and interpret and evaluate it based on what they know about past persuasive attempts, the motives of the advertiser, and facts or experiences that are inconsistent with what the agent is telling them.⁹⁸ Consumers then apply various coping tactics in response, such as ignoring the message, discounting it, or weighing it against counterarguments.⁹⁹ A coping attempt may also occur prior to,¹⁰⁰ or following the message—such as conducting research to investigate a marketer’s claim.¹⁰¹ Consumers also develop “tactic recognition heuristics” through which they use “one or two features of a persuasion attempt” to identify a particular tactic—for example, “the presence of . . . a celebrity, someone in a business suit, or someone shown in a laboratory - signals that the advertiser is trying to get me to trust what they say.”¹⁰²

Friestad and Wright also introduce a concept known as the “change of meaning” principle, referring to the moment a consumer recognizes the persuasive intent of an interaction or identifies the tactic used in a persuasive attempt.¹⁰³ This flash of recognition changes the meaning of the message consumers receive and how they respond. A consumer might process a message naively until the consumer recognizes a persuasive tactic, which then colors the consumer’s interpretation of the whole encounter (the “change of meaning”).¹⁰⁴ Once the change of meaning occurs, the consumer might apply a coping mechanism, such as ignoring or dismissing the message. Following the change of meaning, the consumer might

95. *Id.* at 3.

96. *Id.*

97. *Id.*

98. *Id.* at 3-4.

99. *Id.* at 5. Margaret Campbell, *When Attention-Getting Advertising Tactics Elicit Consumer Inferences of Manipulative Intent: The Importance of Balancing Benefits and Investments*, 4 J. CONSUMER PSYCHOL. 225, 248 (1995) (inferences of manipulative intent lowers persuasiveness of the advertisement).

100. A consumer’s “preexposure mindset” will also influence how they process the message. DAVID BOUSH, MARIAN FRIESTAD & PETER WRIGHT, *DECEPTION IN THE MARKETPLACE: THE PSYCHOLOGY OF DECEPTIVE PERSUASION AND CONSUMER SELF PROTECTION* 107 (2009). For example, a consumer will interpret an advertisement differently when primed to watch for persuasion-related contents versus other content. Amna Kirmani & Rui Zhu, *Vigilant Against Manipulation: The Effect of Regulatory Focus on the Use of Persuasion Knowledge*, 44 J. MARKETING RES. 688, 695-96 (2007).

101. Friestad & Wright, *supra* note 91, at 11.

102. *Id.* at 11.

103. *Id.* at 12-13.

104. *Id.* at 13.

also change his/her opinion of the advertiser, similar advertisements, and the product at issue.¹⁰⁵ As Schul later theorized, a change of meaning tends to color the consumer's assessment of the entire persuasive attempt, not just the portion of the message¹⁰⁶ that may be deceptive. The degree to which a consumer will discount a message following a change of meaning will depend on how much the consumer believes he has been influenced by the message and the extent to which that influence is consistent with the consumer's goals.¹⁰⁷ A consumer that believes he or she has been strongly influenced by a message inconsistent with the consumer's goals will discount that message to a much greater extent than if they believes that they were not influenced or that the direction of influence was helpful for achieving his or her goals.

The "change of meaning" principle explains why consumers vary in how they respond to a given marketing message and also why even small changes in marketing messages result in different responses. For example, a recommendation from a friend may be perceived as helpful suggestion, but this perception may change if you know your friend is receiving money for generating referrals. Friestad and Wright explain, "[s]omeone who is deflected from using their tactic knowledge will behave differently than they do when they can actively use that knowledge. When an [advertiser]'s general persuasive intent . . . is successfully obscured by the [advertiser], a [consumer's] thinking and behavior may differ from their thinking and behavior in situations in which the same feature is used but the [advertiser's] intent is apparent."¹⁰⁸

The PKM also explains why consumer responses may differ following repeat exposure to the message—a consumer sensitized to the persuasive intent in a particular ad incorporates that into their knowledge about the advertiser, and applies the same level of skepticism to future advertisements from that source.¹⁰⁹ However, consumers are also vulnerable to a countervailing psychological principle known as the "truth effect," where they tend to infer that a statement is more truthful following repeated exposure to it.¹¹⁰

105. *Id.*

106. BOUSH ET AL., *supra* note 100, at 97; Yaacov Schul et al., *How People Cope With Uncertainty Due to Chance or Deception*, 43 J. EXPERIMENTAL SOC. PSYCHOL., 91, 101 (2007) (when study participants instructed that the some of the results of the game they were playing may have been the result of deception, participants essentially ignored other information that otherwise would have been helpful in winning the game).

107. BOUSH ET AL., *supra* note 100, at 97. By contrast, consumers have difficulty discounting messages they believe were not very effective. *Id.* at 98.

108. Friestad & Wright, *supra* note 91, at 14.

109. Peter R. Darke & Robin J.B. Ritchie, *The Defensive Consumer: Advertising Deception, Defensive Processing, and Distrust*, 44 J. MARK. RES. 114, 114 (2007) ("deceptive advertising engenders distrust, which negatively affects people's responses to subsequent advertising from both the same source and second-party sources.").

110. Hal Arkes, Lawrence Boehm & Gang Xu, *Determinants of Judged Validity*, J.

Following the PKM, marketing researchers have sought to identify “the situational factors that suppress otherwise accessible persuasion knowledge” as well as advertising “behavior[s] that disguise a tactic.”¹¹¹ Marketing theory further elaborates upon different types of deceptive tactics, intended to impede a consumer’s ability to apply appropriate coping strategies. The following deception tactics are particularly relevant to the drug injury advertising context:

- “Misrepresentations of bad things that might happen if the consumer does [not] buy the marketed product.”¹¹² This decoying tactic works by creating “mental simulations of future events”—consumers then consider how these imagined futures might be avoided or obtained through their actions.¹¹³ These simulations tend to rely heavily on fear-based and threatening messaging,¹¹⁴ “lay[ing] out an oversimplified, inaccurate, and often downright dangerous set of actions” that could have been avoided by heeding the advertiser’s message.¹¹⁵
- Fear appeals. Fear appeals encompass advertising that features some form of threat. The “threat is an appeal to fear, a communication stimulus that attempts to evoke fear response by showing some type of outcome that audience (it is hoped) wants to avoid.”¹¹⁶ Existing research suggests that fear appeals increase interest in the advertisement and are persuasive.¹¹⁷ The use of emotional content focuses and holds consumers’ attention.¹¹⁸
- “Mimicking: showing the false through imitation[.]”¹¹⁹ For example, imitating language or design elements used by a trusted source in order to mislead customers.
- The “Omega strategy”—reducing consumer resistance to the message. One means of doing so is to “redefine the sales interaction,” for example, “an insurance agent [that] calls not to sell you insurance, but to help you

EXPERIMENTAL SOC. PSYCHOL., 576, 587 (1991); Alice Dechene et al., *The Truth about the Truth: A Meta-Analytic Review of the Truth Effect*, 14 *Personality & Soc. Psychol. Rev.*, 238, 238 (2010).

111. Friestad & Wright, *supra* note 91, at 14.

112. BOUSH ET AL., *supra* note 100, at 43.

113. *Id.* at 60.

114. *Id.* at 61.

115. *Id.* at 61.

116. Sara J. Bliss, Robin L. Snipes & Michael S. LaTour, *Don’t be Afraid to Use Fear Appeals: An Experimental Study*, 36 (2) *J. ADVERTISING RES.* 59-68 (1996).

117. *Id.*; Mike Allen & Kim Witte, *A Meta-analysis of Fear Appeals: Implications for Effective Public Health Campaigns*, 27 (5) *HEALTH EDUC. & BEHAV.* 591-615 (2000).

118. Annie Lang, Byungho Park, Ashley N. Sanders-Jackson, Brian D. Wilson, & Wang Zheng, *Cognition and Emotion in TV Message Processing: How Valence, Arousing Content, Structural Complexity, and Information Density Affect the Availability of Cognitive Resources*, 10 (3) *MEDIA PSYCHOL.* 317-38. (2007).

119. BOUSH ET AL., *supra* note 100, at 44.

assess the ways your assets might be at risk.”¹²⁰

- “Incorporat[ing] fake cues that misleadingly imply “authority” to consumers . . . creat[ing] the impression that this speaker is a true authority on the topic . . . [to] create a favorable state of mind.”¹²¹
- Framing effects—“focus[ing] on only one or a few aspects of a more complex decision problem” and “representing the losses and risks associated with a product in a biased and incomplete way[.]”¹²²
- Deceptive implied claims. Marketing research suggests that consumers “treat strongly implied (probabilistic) claims as equivalent to directly asserted (certain) claims, as they store the claims in memory.”¹²³

120. Eric Knowles & Jay Linn, *Alpha and Omega Strategies for Change*, in RESISTANCE AND PERSUASION 123 (2003).

121. BOUSH ET AL., *supra* note 100, at 50. The use of authority to persuade originates from Robert Cialdini’s book, *Influence* (1984). The FTC regulates some appeals to authority through what is known as the “substantiation doctrine,” where advertisers must have a factual basis for claims, where the amount of evidence required to support a claim depends on the type of claim made. SPANOGLA ET AL., *supra* note 63, at 67. In particular, when advertisers suggest their claims are backed by scientific evidence — through use of phrases such as “tests prove” or “studies show,” the FTC expects such claims to be backed up by “two well-controlled clinical studies, or ‘competent and reliable scientific evidence.’” *Sterling Drug Inc. v. F.T.C.*, 741 F.2d 1146 (9th Cir. 1984). For example, in an advertisement for aspirin, the FTC noted visual aspects of the advertisement that suggested scientific support for the advertisers claims that it was superior to competitor products. *Id.* The visuals suggested such support by including pictures of unspecified medical and scientific reports, and through the use of a “serious tone” or “scientific aura” and a background of shelves holding “ponderous books.” *Id.* Similarly, in a case against pomegranate juice maker POM Wonderful, the advertiser suggested that it is just “prevented or reduced the risk of heart disease, prostate cancer and erectile dysfunction.” *In re POM Wonderful, LLC*, F.T.C. Docket 9344, Final Decision & Order, January 10, 2013, www.ftc.gov/os/adjpro/d9344/index.shtm. This suggestion arose in part from “express language about study results” but also “medical imagery such as a blood pressure cuff, or the depiction of the caduceus, a well-recognized symbol of the medical profession.” In that case, the FTC applied the two-well controlled clinical studies standard.

122. BOUSH ET AL., *supra* note 100, at 62. *See also* DANIEL KAHNEMAN, PAUL SLOVIC & AMOS TVERSKY, *JUDGMENT UNDER UNCERTAINTY: HEURISTICS AND BIASES* (1982).

123. BOUSH ET AL., *supra* note 100, at 165. The Federal Trade Commission prosecutes deceptive implied claims. For example, it found foodmaker Kraft in violation of the FTC Act for the implied claim that its cheese slices “contained the same amount of calcium as five ounces of milk” and that they “contain more calcium than do most imitation cheese slices.” *Kraft Inc. v. F.T.C.*, 970 F.2d 311 (1992). Although they did not make either statement explicitly, Kraft implied as much through a visual image of milk pouring into a glass until it reached 5 ounces, which then turns into a package label for the cheese. *Id.* at 315. The advertising also stated that Kraft “has five ounces per slice” - which was an accurate depiction of product ingredients but failed to take into account the loss of calcium during processing. *Id.* The ads also included the statement that competitors had “hardly any” milk, alongside a nearly empty glass of milk. *Id.* at 316. That implication, the FTC claimed, was false because each individual slice only contained 70% as much calcium as 5 ounces of milk. *Id.* at 315. The implication that competitor slices contained substantially less milk was also inaccurate. *Id.* at 316. The FTC deemed the implied claims material, because they involved health claims, which are likely to be important to consumers. *Id.*

- “Deceptive disclosure tactics” which, “[a]ppea[r] to disclose something while really trying to conceal it.” This primarily consists of delaying disclosure as long as possible, delaying the consumer’s suspicion of deception as long as possible, or delaying the consumer’s discovery that “no meaningful disclosure” will be made.¹²⁴ The purpose of doing so is to forestall the disclosure until “earlier deception tactics ha[ve] created a solidified favorable inclination” toward the advertiser’s message.¹²⁵ This might involve “distract[ing] consumers away from the damaging disclosure” through size, vividness, noise, novelty, or stimuli “related to basic wants and needs, such as safety.”¹²⁶

B. Applying Marketing Insights to the Drug Injury Context

The PKM offers a number of insights that can be applied to drug injury advertising. First, the PKM suggests that consumers are not helpless when confronted with drug injury advertising. The folk knowledge and personal experience consumers have acquired enables them to evaluate medical information from an attorney advertisement differently from personal advice they receive from a doctor. While consumers infer a doctor’s advice is based on their medical expertise (and unlikely to be primarily motivated by profit), they might consider medical information from a lawyer with greater skepticism. The PKM also suggests that consumers are better equipped to evaluate drug injury advertising when they have a clear sense of the sponsor’s identity and the sponsor’s pecuniary motive. They may use knowledge about the sponsor and their persuasive intentions to discount or ignore certain information. Their knowledge about the sponsor may also lead them to be more vigilant regarding persuasion tactics, and more likely to experience a change of meaning in connection with the advertising.

However, consumers may be limited in their ability to cope with the message and apply their persuasion knowledge where the advertiser uses deceptive tactics, as previously summarized. Many drug injury advertisements appear to contain numerous deceptive tactics, sometimes in combination. They often include some element of fear appeals, through repetition of the medical adverse events associated with the drug in question. The adverse event often appears in large font on the screen, as well as in the narration. Advertisers also use visuals to represent these adverse events, such as a picture of a man clutching his chest overlaid with a picture of a heart monitor; a picture of a figure lying in a hospital bed with a concerned loved one sitting by their bedside; or an x-ray image of a skeleton. These advertisements also provide mental simulations of the adverse events, asking

124. BOUSH ET AL., *supra* note 100, at 42; Campbell, *supra* note 99, at 230.

125. *Id.*

126. *Id.*

viewers if they have taken the drug, and then referring to the medical events, and suggesting that one follows the other. The heavy focus on adverse events also represents a framing effect, where the focus is exclusively on the risks of the drug, sometimes without any reference to the condition it serves to treat, the benefits it might provide, or the risks associated with discontinuing the medication.

Drug injury advertising also commonly includes misleading appeals to authority, suggesting that the advertisement, or the information in the advertising originates from the government, or medical authorities. The spokesperson for the ad will sometimes appear in what appears to be a surgical suite or some form of hospital or treatment center. Other times, a spokesperson in a suit appears next to text on a screen, mimicking the format of a television newscast. Advertisements sometimes reference the “FDA” or use the term “medical alert.” They also sometimes include medical symbols and imagery, diagrams of the human body depicting internal organs or veins, or footage of a surgery. The extreme form of such appeals to authority represent a form of mimicry of non-advertising formats, or even an Omega strategy that masks the persuasive goal—suggesting the advertising has a public purpose rather than a pecuniary one.

Deceptive disclosure tactics are also common among drug injury advertisements, with disclaimers in small font such as “this is an advertisement.” As previously discussed, some ads that mimic public service announcements also delay disclosing their sponsor until the end. Although a later disclosure would theoretically trigger a “change of meaning” that could prompt consumers to reconsider the entire advertisement, the deceptive content may also inhibit consumers from experiencing a change of meaning at all. Overall, drug injury advertising tends to do a poor job of conveying the advertiser’s referral-based profit motive. At best, advertisements may include subtle references to referrals through disclaimers in small print at the end of the advertisement, or make reference to a “network of attorneys.” In the absence of transparent disclosures of the attorneys’ pecuniary motives, clearly identifying an ad as associated with a particular law firm, or making frequent reference to attorneys, a law firm, lawyers or lawsuits at least allows consumers the opportunity to identify a lawyer as the ad sponsor and consider their own skepticism towards lawyers generally. Consumers can then better cope with the advertisement and evaluate all of the ad’s content with enhanced scrutiny.

The PKM also explains some of the observed results in extant research on drug injury advertising. Consumers appear to respond differently to drug safety information depending on the content of the information they receive, the source from which it is received, and their reaction to the persuasive tactics used. Consistent with our *Urology* study, patients appear to have incorporated benefit-related information from conversations with their doctors, while incorporating risk-based information from the drug injury advertisements. Consumers also

appear to approach drug injury advertisements with some skepticism. The small absolute number of patients reported in the Janssen Pharmaceutical study who discontinued their medication and later suffered an adverse medical event could mean that many patients choose to ignore or discount the information in drug injury advertisements because they disbelieve the source of the medical information.

Lastly, the marketing literature provides some insight into the results from the Tippet and Chen study on Medicare drug prescription rates. Consumers appeared to respond differently to the same information when it originated from the FDA versus drug injury advertising. FDA action produced a negative trend in prescriptions, which was not observed for drug injury advertising. Consumers—and the doctors who prescribe their medication—perceive the FDA to be a more credible source of information than attorney advertisers. Consumers then act on FDA information, while taking a more measured or cautious approach when similar information is conveyed through drug injury advertising.

The current research serves to apply marketing theory to the drug injury advertising context more directly. First, extant research on drug injury advertising has treated drug injury advertising in a monolithic way.¹²⁷ However, some ads contain considerably more deceptive content than others. As previously discussed, some drug injury ads are very transparent from the outset that they originate from an attorney (“transparent ad”), while others seem to masquerade as public service announcements (“deceptive ad”). Marketing theory predicts that consumers will respond differently to the ads containing deceptive content because they will struggle to recognize the persuasive intent or tactics used by the advertiser. Ads employing more deceptive tactics will have a greater influence on consumer risk perceptions and attitudes because consumers will have more difficulty applying their persuasion knowledge and source knowledge in that context. Our first experiment thus compares how consumers respond to a transparent ad compared to a deceptive ad. We predict that consumers are more likely to be deceived by an ad using deceptive tactics than a more transparent ad. We test this hypothesis by asking viewers to identify the sponsor of the ad and then measuring the frequency with which they answer the question correctly.

We also assess whether educational efforts can mitigate or offset deceptive content. Marketing research suggests that deceptive content prevents consumers from experiencing a “change of meaning” regarding persuasion tactics used against consumers. Where consumers do not experience a change of meaning, they are much less likely to discount the medical information conveyed in the advertisement. Marketing theory would predict that an educational intervention—in our case, a set of written instructions prior to viewing the ad—would help inoculate viewers against persuasion tactics, essentially furnishing a “change of

127. Chen & Tippet, *supra* note 14; Koski, *supra* note 67; Tenggardjaja, *supra* note 70.

meaning” prior to viewing the ad. Consequently, marketing research would predict that participants who received the educational intervention would be less affected by the medical information in the drug injury advertisement.

In our second study, we attempt to measure whether drug injury advertising influences risk perceptions beyond a level that is warranted by medical evidence. Although prior research finds some evidence of increased risk perceptions from drug injury advertisements, it does not differentiate between warranted and unwarranted increases in risk. We disaggregate the two by measuring a so-called “spillover effect,” which refers to increased risk perceptions among patient populations unaffected by the particular risk.¹²⁸ Spillover effects are typically observed where a particular drug risk only affects a small subpopulation, but others outside that population behave as though the risk affects them. For example, following FDA warnings about a suicide risk for teenagers taking antidepressants, prescription rates dropped for the general population.¹²⁹ In our second study, we test for a spillover effect by presenting participants with a drug injury ad involving the antidepressant, Paxil, which is purported to present a risk to the fetus of pregnant women. To the extent that participants who are not female believe they have an increased risk after seeing the drug injury ad, it would suggest a spillover effect.

Lastly, in this second study we also investigate how consumers respond to different sources of drug safety information by comparing participant responses to drug injury advertisements to their responses to Direct-To-Consumer (DTC) pharmaceutical advertising, which contains some content similar to drug injury advertising, but ultimately delivers the opposite message—that the drug at issue is beneficial and safe. As the PKM suggests, consumers operate in complex media environments, obtain their information from many sources, and apply their persuasion knowledge to those sources. We expect that when shown alone, a DTC advertisement will lead consumers to perceive a medication as more favorable, offering more benefits and posing fewer risks.¹³⁰ We expect a drug injury advertisement to produce the opposite effects, reducing favorability and benefit evaluations while increasing perceived risk. The combination of conflicting information from viewing both the DTC and drug injury advertisements should

128. John Calfee, *Public policy issues in direct-to-consumer advertising of prescription drugs*, 21 J. PUB. POL'Y & MARKETING 174 (2002); E. Ray Dorsey et al. *Impact of FDA Black Box Advisory on Antipsychotic Medication Use*, 170 ARCH. INTERN. MED. 96 (2010); Staci Dusetzina, et al., *Impact of FDA Drug Risk Communications on Health Care Utilization and Health Behaviors: A Systematic Review*, 50 MED. CARE 466 (2012); Robert Valuck, et al., *Spillover effects on treatment of adult depression in primary care after FDA advisory on risk of pediatric suicidality with SSRIs*, 164 AM. J. PSYCHIATRY 1198 (2007).

129. Valuck et al., *supra* note 128.

130. Ali Alhakami, Melissa Finucane, Stephen Johnson & Paul Slovic, *The Affect Heuristic in Judgments of Risks and Benefits*, 13 (1) J. BEHAVIORAL DECISION MAKING 1-17 (2000).

become integrated, leading to risk judgments that are higher than the DTC advertisement alone would produce but lower than the drug injury advertisement alone would produce. Exposing consumers to one or both of the two types of ads in an experimental setting allows us to test the effect of each.

IV. METHODOLOGY

A. Study 1.

Our first study contrasts two real drug injury advertisements involving the drug Reglan (metoclopramide). Both ads were broadcast on television (see Appendix B for a transcript and images from each advertisement). Both of the advertisements are around 30 seconds long. Each ad warns viewers that Reglan is associated with tardive dyskinesia and that consumers injured by Reglan may have a claim for financial compensation. The transparent advertisement features the sponsoring attorney's name in a phone number appearing in large font on the bottom quarter of the screen (1-800-Call-Ken) and remains on the screen throughout the advertisement. The name of the sponsoring attorney's law firm appears in a small font above the phone number ("transparent Reglan advertisement"). The sponsoring attorney also appears during the advertisement and identifies himself as "attorney Ken Nugent."

By contrast, the deceptive advertisement does not reveal that it is sponsored by a law firm until the last two seconds of the advertisement and only does so in barely legible font on the bottom of the screen ("deceptive Reglan advertisement"). Although the deceptive advertisement prominently features a telephone number throughout the advertisement, the number does not reveal the sponsor of the advertisement (1-800-CAUTION). The deceptive advertisement begins with the words "CAUTION" appearing in bright red letters. The ad then asks if the viewer has taken Reglan, and describes the symptoms of tardive dyskinesia. One portion of the deceptive advertisement includes a picture of a man apparently doubled over in pain. We expect the cautionary language and imagery, combined with the delayed and inconspicuous disclosure of the advertisement's sponsor, to obscure the persuasive intent of the deceptive advertisement.

We predict that consumers may misidentify the purpose and sponsor of the deceptive ad relative to the transparent one. To the extent consumers misidentify the sponsor of the advertisement as an entity other than a lawyer, they may be more likely to avoid seeking treatment or discontinue otherwise beneficial treatment. In this study, we test if behavioral intentions towards using Reglan differ between the two advertising types.

We further predict that educational efforts to explain the purpose of the advertising may increase the likelihood that consumers correctly identify the

purpose of the advertisements. As such, Study 1 also considers different educational efforts. One educational effort focuses on the positive benefits of attorney advertising, in educating the public, providing redress for victims and in holding pharmaceutical companies accountable for undisclosed risks. The other focuses on the pecuniary motives of the ad's sponsor, describing how attorney advertisers profit through their referrals or by recovering a contingency fee when the case is settled or litigated. Also included is a control group that does not receive any educational information about the advertisements. We expect educational efforts will increase the rate at which consumers correctly identify a lawyer as the sponsor of a drug injury advertisement. We also expect that explaining the purpose of these types of advertisements will lead consumers to feel less susceptible to the side effects associated with the medications.

Participants. 381 native English speaking MTurk workers received \$0.50 (U.S.) each for their participation. Of these, 12 participants (3.15% of sample) were removed because they experienced problems with the task. Slightly more men (54.2%) participated and the mean age of participants was 35 (range: 18 to 79 years).

Procedure. The study featured a 3 (instructions: control vs. profit motive vs. pro-consumer motive) x 2 (advertisement type: transparent vs. deceptive) between participants design. All participants initially received instructions that they would be viewing a television advertisement.

Those assigned to either instruction condition (profit motive or pro-consumer motive) received instructions explaining that the advertisement was sponsored by a lawyer and that the purpose of the advertisement was to "recruit consumers for a lawsuit." In both conditions, participants were instructed that "consumers harmed by the medication may have a valid lawsuit against the drug manufacturer for failing to disclose the risk of the medical problem."

Those assigned to the profit motive condition were also informed that advertising lawyers usually refer the case to other attorneys and are compensated based on the volume of referrals their advertising generates. Those assigned to the pro-consumer motive condition were instructed that the advertisements are beneficial for consumers because they recover money for injured patients and inform the public about important drug safety information. Finally, those assigned to the control condition did not receive any information about the purpose of the advertisement and were instead told that they would watch an advertisement that had run during an episode of "Dancing with the Stars" and were provided a description of the television show (see full instructions of each condition in Appendix A).

After reading the instructions, participants were shown either the transparent

Reglan advertisement or the deceptive Reglan advertisement.

Measures. After viewing the advertisements, all participants were asked to evaluate the risks (not at all risky / very risky), benefits (not at all beneficial / very beneficial) and their overall attitudes (I like it / I dislike it; Favorable / Unfavorable; Good / Bad) towards Reglan on 7pt scales. In addition, participants were asked to “Consider if you, personally, took Reglan. What is the percentage chance that you would develop tardive dyskinesia?”

In order to evaluate if participants understood the source of the advertisement they watched, they were asked to identify the sponsor of the advertisement. Options included: “The Food and Drug Administration (FDA),” “the government,” “an attorney or law firm,” “a pharmaceutical company,” “I don’t know,” and an open response “other” option. All options except “an attorney or law firm” were coded as a misidentification.

Participants then answered a set of questions about how likely they were to perform a set of behaviors if they “personally needed and were prescribed Reglan” (7pt scale; Very unlikely/ Very likely). These items included two items related to using the medication (“Fill a new prescription for Reglan from your doctor” and “Refill a prescription for Reglan that you are already taking”) and three items relating to additional research on the medication: (“Research Reglan to learn more about the medication,” “Ask your doctor about the advertisement,” and “Call the number in the advertisement.”) Finally, all participants completed a measure of advertising skepticism.¹³¹

B. Study 2

In the second study we consider how drug injury advertisements and DTC pharmaceutical ads, in combination and individually, might affect evaluations of a medication. We also test for the previously discussed spillover effect by using ads involving the anti-depressant, Paxil.

Participants. 389 native English speaking MTurk workers received \$0.50 (U.S.) each for their participation. Of these, 5 participants (1.29% of sample) were removed because they experienced problems viewing the videos. Of the remaining 384 participants, slightly more were women (52.9%) and the mean age of participants was 35 (range 18 to 75 years). Three female participants indicated that they were currently pregnant.¹³²

131. Carl Obermiller & Eric R. Spangenberg, *Development of a Scale to Measure Consumer Skepticism Toward Advertising*, 7 (2) J. CONSUMER PSYCHOL. 159 (1998).

132. Note, these three pregnant women were included in the analyses reported in study 2. The analyses were also performed without including these women and the reported pattern of significant

Procedure. Participants were assigned to a 2 (DTC Advertisement: present vs. absent) x 2 (Drug Injury Advertising: present vs. absent) between subjects' design. All participants were informed that they would view two advertisements. First, participants either watched an existing DTC advertisement for the medication Paxil or an existing advertisement for a household surface cleaner (Clorox Clean-Up). Then, participants either viewed an existing drug injury advertisement or an existing advertisement for Dove soap. The drug injury advertisement focused on recruiting women who used Paxil while pregnant and subsequently delivered a child with birth defects. It was similar in format to the deceptive advertisement featured in study 1 by featuring a number of warning statements, focusing on the side effects of the medication and failing to disclose that the advertisement was sponsored by an attorney until the end (the sponsoring attorney was only disclosed in the onscreen text).

Measures. After viewing both advertisements, all participants were asked to evaluate the risks, benefits and their overall attitudes towards Paxil using the same scales from study 1. Items measuring behavioral intentions toward the same set of behaviors as those in study 1 (e.g., "fill a new prescription for Paxil from your doctor") were also included. In addition, participants were asked to estimate the odds that they would experience side effects if they personally took Paxil.

Participants were asked to classify each advertisement they watched as (a) a public service announcement, (b) a lawyer advertisement, (c) an advertisement from a pharmaceutical company, (d) an advertisement for a cleaning product or (e) an advertisement for soap. Finally, all participants completed the advertising skepticism scale¹³³ that was used in the first study.

V. RESULTS

A. Study 1 Results

Sponsor of Advertising. A hierarchical binomial logistic regression was conducted to assess whether the transparency of the advertisement, instructions provided to the participants and the interaction between these two variables, significantly predicted whether participants correctly classified the sponsor of the advertisements as a lawyer or misidentified the sponsor. Misidentifications were classified as either identifying the ad sponsor as someone other than a lawyer or indicating "I don't know" when asked to identify the sponsor of the ad. See the rates of correct and incorrect identification by condition in Table 2.

results do not change.

133. *Id.*

Table 2. Rates of Correct & Incorrect Identification by Condition

Instructions	Transparent		Deceptive		Total	
	Correct	Incorrect	Correct	Incorrect	Correct	Incorrect
Control	N 49	9	48	19	97	28
	% 84.48%	15.52%	71.64%	28.36%	77.60%	22.40%
Profit	N 56	1	56	12	112	13
Instructions	% 98.25%	1.75%	82.35%	17.65%	89.60%	10.40%
Pro-Consumer	N 58	7	47	7	105	14
Instructions	% 89.23%	10.77%	87.04%	12.96%	88.24%	11.76%
Total	N 163	17	151	38	314	55
	% 90.56%	9.44%	79.89%	20.11%	85.09%	14.91%

The main effects logistic regression model was found to be statistically significant, $X^2(3) = 16.36, p = .001$. The model explained 7.6% (*Nagelkerke R²*) of the variance in correctly classifying advertisements and correctly classified 85.1% of cases. Results indicated that the different instruction conditions influenced the likelihood of participants correctly identifying the advertisements; *Wald X²(2) = 7.88, p = .019*. Those assigned to the control condition misidentified the attorney ads at a higher rate than those assigned to either the pro-consumer or profit instruction conditions; $b = -.83, Wald X^2(1) = 7.65, p = .006$. There was no significant difference in the rate at which participants correctly identifying attorney advertisements between the pro-consumer and profit instruction conditions; $b = .22, Wald X^2(1) = .28, p = n.s.$ Those participants who received either the pro-consumer or profit oriented instructions were 1.24 times as likely to correctly classify the advertisement relative to those in the control instruction condition.

The transparency of the video also significantly influenced the likelihood of correctly classifying the advertisement; $b = .88, Wald X^2(1) = 7.75, p = .005$. Those encountering the transparent Reglan advertisement were 2.42 times more likely to correctly classify the advertisement as those who encountered the deceptive Reglan advertisement. The interaction between the transparency of the video and instruction condition was not significant ($p > .10$).

These results suggest that the instructional conditions improved the rate at which participants correctly identified the source of the advertisement. They also suggest that different educational messages may improve consumers' ability to correctly identify the sponsor of different forms of drug injury advertisements. Among deceptive advertisements that mimic public health warnings, educational efforts that explain the pro-consumer benefits may improve identification. Among transparent advertisements that are more clearly from a lawyer, educational efforts

that describe how lawyers profit from the advertisements may be more effective. Although not tested, it is possible that consumer education featuring both profit and pro-consumer descriptions may improve consumers' ability to correctly identify both types of drug injury advertisements.

Evaluations of Reglan. A series of 3 (instructions: control vs. profit motive vs. pro-consumer motive) x 2 (advertisement type: transparent vs. deceptive) analyses of covariance (ANCOVAs) with advertising skepticism, and gender as¹³⁴ covariates were conducted for the variables measuring evaluations of Reglan (i.e., overall evaluation, risk, benefit). Gender was significantly related to both overall attitudes and benefits, with women expressing more favorable attitudes towards Reglan than men. However, neither the type of advertisement, nor form of instruction was found to significantly affect any of the measures. These results suggest that participants' evaluations of Reglan were not affected by the advertising example (transparent vs. deceptive) they watched.

However, a main effect of instructional condition was observed on estimates of how likely participants believed they were to develop tardive dyskinesia from taking Reglan ($F(2, 354) = 3.65, p = .03$). Both those assigned to the profit motive instructions ($M = 20.77$) and those assigned to the pro-consumer instructions condition ($M = 21.93$) indicated that the likelihood of experiencing this side effect was less than those assigned to the control condition ($M = 28.17$). In other words, those who were not provided any instruction regarding the purpose of the advertisement estimated that they were more likely to experience this adverse side effect. No other significant effects were observed. This result suggests that consumers may discount the personal risks associated with the medication when they are made aware of the purpose underlying drug injury advertising.

Behavioral Intentions. Another set of ANCOVAs were conducted on the set of behavioral intentions. A significant main effect of advertising type was observed for both items related to using Reglan. Participants indicated that they were both less likely to fill a new prescription for Reglan ($F(1,358) = 9.26, p < .01$) and to refill an existing prescription ($F(1,358) = 7.09, p < .01$) for Reglan after watching the deceptive Reglan advertisement relative to the transparent Reglan advertisement. No other significant effects were observed. This result suggests that advertisements framed as warnings (e.g., similar to the deceptive drug injury advertisement used in this study) may encourage consumers to stop taking (or fail to start taking) medications.

Providing instructions to participants produced an observable effect for one of

134. Note, these analyses were also performed with gender as a fixed factor and gender was not found to significantly interact with any of the independent variables.

the three behavior items relating to information seeking: intention to “research Reglan to learn more about the medication”; $F(2,354) = 3.65$, $p = .027$. Those assigned to the control condition indicated that they were less likely to research the medication ($M = 5.82$) than those assigned to the profit motive instruction condition ($M = 6.24$). No significant differences were observed between the pro-social instruction condition ($M = 6.14$) or either of the other two conditions. This result suggests that educational efforts that focus on making consumers aware of how lawyers may profit from drug injury advertising may encourage consumers to learn more about the medications featured in those advertisements.

Overall, these results support our hypothesis that consumers may be confused by certain drug injury advertisements. While the two advertisements did not lead to different evaluations of the medication and its overall risks and benefits, those who watched the deceptive advertisement indicated that they were less likely to either fill a new prescription or refill an existing prescription for Reglan. This finding is concerning because it suggests that after viewing drug injury advertisements that appear to be public health warnings consumers may decide to avoid taking the featured medication. The two instructional conditions were found to improve the rate at which participants correctly identified the sponsor of the drug injury advertisements but did not affect evaluations or behavioral intentions towards the medication.

Providing information about the purpose of these advertisements was found to increase the likelihood that participants would seek additional information about the medication and to reduce the perceived likelihood of experiencing the primary side effect discussed in the advertisements. Both of these effects are encouraging as they suggest that educational efforts may lead consumers to discount apparent warnings in drug injury advertising and encourage them to seek additional information.

B. Study 2 Results

Sponsor of Advertising. Most participants (97.7% or 375 of 384) correctly classified the first advertisement (97.9% for the DTC advertisement, and 97.5% for the Clorox advertisement). In contrast, only 84% (323 of 384) of participants correctly identified the second advertisement (93.7% for the soap advertisement but only 75.1% for the drug injury advertisement). This finding supports those of study 1, participants appear to be confused about the sponsor of the deceptive drug injury advertisements.

Evaluations of Paxil. A series of 2 (DTC advertisement: present vs. absent) x 2 (Drug injury advertising: present vs. absent) analyses of covariance (ANCOVAs)

with advertising skepticism, and gender¹³⁵ as covariates were conducted for the variables measuring evaluations of Paxil (i.e., overall evaluation, risk, benefit). The presence of a DTC advertisement increased perceived benefits ($M = 4.57$, $SD = 1.51$) relative to when the DTC advertisement was not shown ($M = 3.80$, $SD = 1.36$); $F(1, 367) = 28.49$, $p < .01$. The presence of the drug injury advertisement produced the opposite effect. Participants perceived Paxil to be less beneficial when shown the drug injury advertisement ($M = 3.77$, $SD = 1.54$) than when the advertisement was not shown ($M = 4.56$, $SD = 1.31$); $F(1, 367) = 30.17$, $p < .01$. No DTC x Drug Injury Advertisement interaction was observed. No gender differences on perceived benefits were observed.

Main effects were observed for the drug injury advertisement but not a DTC advertisement on perceptions of risk. Those viewing the drug injury advertisement perceived Paxil to be riskier ($M = 5.32$, $SD = 1.40$) than those who did not ($M = 4.37$, $SD = 1.24$); $F(1,367) = 47.89$, $p < .01$). There was also a main effect for gender on risk perceptions. Women indicated that Paxil was riskier ($M = 5.04$, $SD = 1.38$) than men ($M = 4.63$, $SD = 1.41$); $F(1, 367) = 7.86$, $p = .01$. These main effects were qualified by a significant interaction between the DTC and Drug Injury Advertisement factors (see Figure 4); $F(1,367) = 4.66$, $p = .03$. When the drug injury advertisement was absent, the presence or absence of the DTC advertisement did not affect risk. However as expected, viewing the DTC significantly lowered risk perception among those also viewing the lawyer advertisement ($M = 5.07$, $SD = 1.39$) relative to those who did not view the DTC advertisement ($M = 5.56$, $SD = 1.37$). This finding suggests that the DTC advertisement established knowledge structures regarding risks associated with Paxil that were resistant to change from the drug injury advertisement.¹³⁶ However, it is important to note that those who viewed the drug injury advertisement (in any condition) indicated that Paxil was riskier than those who did not view the drug injury advertisement.

Table 3: Mean Risk Perceptions

Ad Condition	Mean Risk Perception
Drug injury ad only	5.56
Drug injury ad & pharmaceutical ad	5.07
No drug injury ad (with or without pharmaceutical ad)	4.37

135. Note, these analyses were also performed with gender as a fixed factor and gender was not found to significantly interact with any of the independent variables.

136. Curtis P. Haugtvedt & Duane T. Wegener, *Message Order Effects in Persuasion: An Attitude Strength Perspective*, 21 J. CONSUMER RES. 205-18 (1994).

Favorability measures closely matched benefit perceptions. Significant main effects for DTC ($F(1, 367) = 15.42, p < .01$) and Drug Injury Advertisements ($F(1,367) = 63.29, p < .01$) were observed on favorability evaluations. Those watching the DTC advertisement ($M = 3.88, SD = 1.62$) liked Paxil more than those who did not see the DTC advertisement ($M = 3.31, SD = 1.42$). Conversely, those who viewed the drug injury advertisement indicated that they held less favorable attitudes of Paxil ($M = 2.99, SD = 1.54$) relative to those who did not see the drug injury advertisement ($M = 4.16, SD = 1.31$). Again, no significant gender effects were observed on attitudes towards Paxil.

A main effect of gender was observed on estimates of how likely participants believed they were to develop experience side effects from taking Paxil ($F(1, 364) = 11.64, p < .01$). Female participants ($M = 33.87, SD = 26.66$) indicated that they were more likely to experience side effects from taking Paxil than men ($M = 24.59, SD = 25.36$). No other significant effects were observed.

Behavioral Intentions. Another set of ANCOVAs were conducted on the set of behavioral intentions. Significant main effects of the DTC Advertisement ($F_{\text{new prescription}}(1,367) = 7.69, p = .01$; $F_{\text{refill prescription}}(1,367) = 8.06, p < .01$) and the Drug Injury Advertisement ($F_{\text{new prescription}}(1,367) = 23.83, p < .01$; $F_{\text{refill prescription}}(1,367) = 14.99, p < .01$) were observed for both items related to using Paxil. In both cases, the DTC advertisement increased the likelihood that participants would fill, or refill, a Paxil prescription, whereas the presence of the drug injury advertisement decreased the likelihood that participations would fill, or refill, a Paxil prescription. These main effects were qualified by a significant DTC x Drug Injury Advertisement interaction for both items; $F_{\text{new prescription}}(1,367) = 9.62, p < .01$; $F_{\text{refill prescription}}(1,367) = 5.94, p = .02$. Intentions to use Paxil closely mirrored the effects observed among risk perceptions. In the absence of the drug injury advertisement, the DTC advertisement had little effect on likelihood to fill or refill a prescription. However, when the drug injury advertisement was shown, participants were less likely to fill a prescription if they had not seen the DTC advertisement relative to those who saw both the drug injury advertisement and the DTC advertisement. This finding again suggests that the drug injury advertisement more strongly increases perceived risk when not accompanied by a counterargument. Of the three behavioral items related to further investigating the medication, the only significant effect that was observed was that of the drug injury advertisement on the intention to “ask your doctor about an advertisement;” $F(1,367) = 16.52, p < .01$. Those who viewed the drug injury advertisement indicated that they were more likely to talk to their doctor than those who did not see the drug injury advertisement.

Findings from the second study reinforce those from the first by providing clear evidence that deceptive drug injury advertisements are likely to be

misidentified and serve to increase the perceived risks associated with the medications they feature. The drug injury advertisement caused Paxil to be perceived as riskier and participants indicated that they were less likely to start, or continue taking, Paxil after viewing a drug injury advertisement. Importantly, these effects were observed among consumers for which the risks featured in the drug injury advertisement did not apply. Although women indicated greater risks and likelihood of experiencing side effects if they took Paxil, the effect of the drug injury advertisement on evaluations or behavioral intentions towards Paxil did not depend upon gender. Thus, results suggest spillover effects from drug injury advertisements into populations that are not susceptible to the advertised side effects.

VI. DISCUSSION & REGULATORY IMPLICATIONS.

Results suggest that some consumers are in fact misled by drug injury advertising. Of the four types of advertisements included in these studies—a DTC pharmaceutical ad, a bleach advertisement, a soap advertisement and a drug injury advertisement—the drug injury ads produced the highest rates of misidentification. This was especially so for the deceptive ads. The deceptive Reglan ad in Study 1 produced misidentification rates of 28%, while the deceptive Paxil ad was misidentified by 25% of participants. This misidentification rate is especially striking given that the instrument did not ask participants to identify an individual sponsor (e.g. The Law Firm of Ken Nugent), but just the type of advertisement (e.g. “The first advertisement was a lawyer advertisement.”)

Educational interventions were somewhat effective at reducing rates of misidentification, both for the transparent advertisement and the deceptive advertisement. Educational instructions about the attorney’s profit motives for the transparent ad brought misidentification rates down to levels similar to that for DTC pharmaceutical advertising and for consumer products. However, for the deceptive ad, educational instructions were only able to bring misidentification levels down in the range of the transparent ad without disclosures.

When consumers are unable to recognize a drug injury ad as a form of attorney advertising, it has important implications for their ability to process the persuasive content. If they mistakenly believe, as some participants did, that the advertisement is a public service or government announcement, or originates from the manufacturer, they will process the medication information without the benefit of important knowledge about the advertiser. Consumers may also be less likely to apply their persuasion knowledge, on the assumption that the public entity has no pecuniary motive, or perhaps that the manufacturer has been forced by a government agency to issue corrective advertising. This too may limit their ability to “cope” with the medical information.

Table 4: Rates of Sponsor Misidentification in Studies 1 & 2

Type of Advertisement	Rates of Sponsor Misidentification
Transparent ad with education about attorney’s profit motive	1.8%
Direct to consumer pharmaceutical advertising	2.1%
Advertisement for bleach	2.5%
Advertisement for soap	6.4%
Transparent ad with education about attorney’s public service	10.8%
Deceptive ad with education about attorney’s public service	12.9%
Transparent ad (no education)	15.5%
Deceptive ad with education about attorney’s profit motive	17.6%
Deceptive ads (no education)	25% - 28%

These results also provide some support for the proposition that the deceptive advertisement (especially with no additional disclosures) had a greater influence on consumers than the transparent ad. Viewers of the transparent ad, or the deceptive advertisement with additional disclosures, appear to have discounted the risk-related information in the ad, evaluating the drug as less risky than those who viewed the deceptive ad in isolation. The deceptive ad also had a stronger influence on participants’ willingness to fill a Reglan prescription, which was unaffected by additional disclosures. However, one of the two disclosures did appear to increase motivation to conduct further research.

Results also suggest that drug injury ads may actually be somewhat more persuasive than DTC pharmaceutical ads, as an additional pharmaceutical ad did not produce an observable difference in risk perceptions and behavioral intentions compared to the control. By contrast, drug injury ads on their own had a strong influence on risk perceptions and behavioral intentions, which were only somewhat mitigated by pharmaceutical ads. How drug injury advertising is affected by counterarguments remains an important direction for future research. However, one explanation for the difference in the effects of drug injury advertising relative to DTC advertisements may be related to the higher rate of misidentification among the drug injury advertisements. As discussed above, if consumers are unable to understand the persuasive intent and tactics of such advertising, they are less able to effectively cope with those persuasive attempts.

Lastly, results suggest that deceptive ads may produce some spillover effects. Paxil posed no risk for men based on the adverse event described in the drug injury advertisement. Although men estimated they would be less likely to experience side effects than women, and viewed Paxil as less risky, the drug injury advertisement appears to have ultimately affected their behavioral intentions. Drug

injury ads led both men and women to reduce their reported likelihood of filling or refilling a prescription for the drug by statistically similar amounts. This suggests that drug injury ads in some cases may lead to unwarranted increases in risk perceptions and inappropriately influence the behavioral intentions of populations for whom the risks presented in the advertisements do not apply.

The results offer a number of implications for regulating drug injury advertisements. First, they offer some initial evidence in assessing the tradeoff between regulation focused on reducing deceptive content versus regulation that demands the inclusion of disclaimers. For example, the American Medical Association has recommended that all drug injury advertisements include a disclaimer that viewers should not discontinue medication without first consulting their doctor.¹³⁷ These types of disclaimers may help consumers trigger their source knowledge and persuasion knowledge and thereby consider the context in which medical information is presented. However, disclaimers are also somewhat limited in what they can achieve. The “disclaimers” used in Study 1 included a written instruction that participants were told to review before watching the ads. This likely represents a greater level of prominence and salience than the average disclaimer would produce; most disclaimers are less conspicuous. The disclaimer here was successful in helping participants identify the sponsor of the ad and also proved helpful for the transparent ad. Nevertheless, the disclaimer did not mitigate the influence of the deceptive ad on behavioral intentions towards filling a prescription.

The differences observed between the transparent ad and the deceptive ad in this case suggests that ad content can have a marked difference in how consumers process the persuasive content of messages and ultimately on their behavioral intentions. Regulators might usefully focus their efforts on reducing deceptive content in drug injury advertisements. State bars could do so in a manner consistent with the Association of Professional Ethics Lawyers’ recommendation that state bars simplify ethics rules by issuing a simple prohibition on false or misleading content.¹³⁸ As an alternative to adopting new rules, state bars could simply step up enforcement of rules prohibiting false or misleading advertising. Further, state bars could issue advisory opinions applying the false or misleading standard to drug injury ads. Finally, state bars could also selectively enforce the false or misleading prohibition for the worst content on the market.

Doing so would require state bars to take the initiative to identify the worst offenders and take action against them. This solution would require a change to their current approach to disciplinary matters, which relies on complaints by clients

137. Press Release, Am. Med. Ass’n., AMA Adopts New Policies on Final Day of Annual Meeting, (June 15, 2016), <https://www.ama-assn.org/ama-adopts-new-policies-final-day-annual-meeting>.

138. *2015 Report of the Regulation of Lawyer Advertising Committee*, *supra* note 9.

and competitors. As discussed in prior research, neither clients nor competitors have an incentive to complain about drug injury advertising.¹³⁹ Competitors of drug injury advertisers are unlikely to complain in order to avoid drawing attention to their own advertising practices. Consumers most likely to be harmed by the ads are not potential clients injured by the drug, but consumers influenced by the ads to reduce or discontinue a drug (or refuse a doctor's recommendation to begin treatment). As we have discussed herein, these consumers may not even realize that they have been influenced by the ads, or that the ads were in fact attorney advertising. Had they been aware of the source of the ads and the advertisers' pecuniary motives, they likely would have discounted the information and avoided influence. Moreover, these consumers are unlikely to know or recall the name of the advertiser's sponsor once they realize they have been influenced, and indeed, the influence may have resulted from cumulative exposure to the advertising. Even if they could identify a specific advertiser responsible for their decision, they would not know to complain to the state bar, nor be able to identify the state in which the firm is located.¹⁴⁰

However, states are somewhat limited in their ability to enforce prohibitions on false and misleading advertising against the deceptive advertising described here. First, the presence of corporate entities on the list of most prolific advertisers creates a regulatory challenge for ethics boards. Corporate entities have no bar license to threaten. Even referral networks present regulatory challenges. Although theoretically made up of individual lawyers, it is not at all clear which of the individual lawyers could or would be held responsible for the ads. Second, the large advertising market described herein is national in nature. Consumers in many states are affected by advertising originating from a firm in another state. Because the primary threat wielded by state bars is the ability to revoke or suspend an individual attorney's license, the non-licensing state is largely powerless to do anything about the advertising.

Consequently, meaningful change may require help from the FTC. The FTC can take action against the worst actors, whether they are law firms or corporate entities. The FTC is better positioned to act with respect to national advertising campaigns because its jurisdiction extends beyond individual states. The FTC also brings considerable expertise in deceptive advertising, drawing upon its decades of experience in that realm.

Lastly, further deregulation of attorney ethics rules around referral fees, when coupled with stringent rules regarding disclosure, may help consumers activate their persuasion knowledge in responding to drug injury ads. As previously described in Part I, only some drug injury advertisers litigate cases with any

139. Tippet, *supra* note 2, at 40-41.

140. *Id.* at 41.

frequency. Others would appear to generate revenue through complex referral arrangements with litigators, styled as “joint representation.” However, the nature of these referral arrangements is not at all apparent from the advertisements themselves. Although this non-disclosure may in part be a deceptive advertising tactic, it may also reflect advertiser concern about running afoul of ethical rules regarding referrals.

State rules regarding attorney referral fees vary somewhat, but have historically prohibited referral fees that exceed reimbursement for advertising costs.¹⁴¹ In 2012, the ABA modified commentary to its Model Rule of Professional Conduct 7.2, which allowed lawyers to purchase referrals through “lead generation services.”¹⁴² Even assuming that drug injury advertisers qualify as “lead generation services,” the 2012 exception includes a number of limitations. The lead generator cannot suggest that “it is recommending the lawyer” receiving the referral, nor that it has “analyzed a person’s legal problems when determining which lawyer should receive the referral.”¹⁴³ These limitations may be inconsistent with current referral practices among drug injury advertisers. In addition, not all states permit the use of “lead generation services,” and apply stringent restrictions on referral services.¹⁴⁴ In light of these restraints, drug injury advertisers may decide to continue their complex fee-sharing arrangements,¹⁴⁵ which are difficult to explain to consumers.

Complex fee sharing arrangements—particularly when they are not meaningfully disclosed in an advertisement—obscure advertisers’ persuasive intent. If consumers cannot glean the advertiser’s pecuniary motive, or even that they have a pecuniary motive, they will be less likely or able to bring their persuasion knowledge to bear. This may account for some of the increased influence of the deceptive ad compared to the transparent ad, and also why providing consumers with education around the purpose of the ad helped to mitigate the effect of the deceptive ad.

Overall, consumers would be best served if they clearly understood the business model of the advertiser. Consumers generally have good mental schema

141. MODEL RULES OF PROF’L CONDUCT r 7.2.

142. MODEL RULES OF PROF’L CONDUCT r 7.2[5] cmt. (AM. BAR ASS’N 2017). *See e.g.*, Wash. Rev. Code Ann. Rules of Prof’l Conduct 7.2 cmt. 5 (West 2017) (adopting ABA language); Ohio rev. Code Ann., Rules of Prof’l Conduct r 7.2 (West 2017).

143. *Id.*

144. *See, e.g.*, MD. CODE ANN., MD RULES ATTORNEYS, r 19-307.2 (West 2017); VA. CODE ANN. RULES OF PROF’L CONDUCT r 7.3 (Sest 2017); N.J. STAT. ANN. RPC 7.2 (West 2017); N.M. STAT. ANN. NMRA 16-701 (West 2017).

145. Fee sharing arrangements are also regulated by states, following ABA Model Rule of Professional Conduct 1.5. These rules require that “(1) the division is in proportion to the services performed by each lawyer or each lawyer assumes joint responsibility for the representation; (2) the client agrees to the arrangement, including the share each lawyer will receive, and the agreement is confirmed in writing; and (3) the total fee is reasonable.”

for understanding the motives of litigators. When they see a lawyer featured on a screen looking for clients, they can infer that the lawyer benefits financially from the additional business, whether it be from hourly fees or a contingency fee. This essentially reflects the content of the “transparent” ad featured in our first study. Ideally, a similar level of transparency could be applied for firms—and third party corporations—that base their business primarily on referrals. This approach would involve explaining to viewers that their business specializes in finding injured consumers, and receiving a fee to refer them to other lawyers. Finders’ fees and referral fees represent a common business model in other industries, for example, ‘headhunters’ in the human resources context. Consumers have a context for understanding these business arrangements, and can then place the medical information within a larger narrative of the advertisers’ business interests.

At least in the drug injury context, allowing such referral arrangements, provided they are prominently conveyed to viewers in their advertising, would help to mitigate some of the medical side effects of drug injury advertising.¹⁴⁶ In sum, increased enforcement of existing prohibitions on false and misleading advertising, when coupled with some deregulation of referral fee arrangements, would be beneficial to consumers without impairing the market for drug injury advertising.

CONCLUSION

This study draws from theory and research in the marketing field to shed light on how consumers respond to drug injury advertising. We find that deceptive drug injury advertising has a stronger influence on consumers than transparent advertising. Deceptive drug injury advertising may ultimately distort how consumers make decisions about whether to take the drug featured in the ad. Nevertheless, educational efforts, and counterarguments appear to mitigate some of this effect.

Marketing theory suggests that some of the effect of the deceptive ads can be explained by some consumers’ failure to identify the advertiser and their pecuniary motives. When consumers misunderstand the source of an advertisement, they may not be able to apply their knowledge and skepticism of that source, and identify the persuasive tactics used in the ad. Reducing the influence of drug injury advertising may therefore involve interventions designed to make the advertiser’s motives more transparent. Further research is warranted on the particular content within drug injury ads that is most harmful (or helpful) to consumers in processing and responding to the medical information contained therein.

146. While we do not explore the effect of such a rule on other aspects of the consumer transaction, such as the representation consumers receive following the referral, we urge state bars to explore the possibility.

APPENDIX A: STUDY 1 INSTRUCTION CONDITIONS

Profit Motive Instructions

In a moment, you will watch an advertisement that was paid for by a lawyer. The purpose of the advertisement is to recruit consumers for a lawsuit. In particular, the lawyer is looking for consumers that experienced a particular medical problem after taking a prescription drug. Consumers harmed by the medication may have a valid lawsuit against the drug manufacturer for failing to disclose the risk of the medical problem.

If the consumer has a valid lawsuit and contacts the lawyer in the advertisement, the lawyer's firm might then represent the viewer in a lawsuit. However, most advertising lawyers do not represent the consumers they recruit. Instead, advertising lawyers often sell their names to other law firms that will actually litigate the case.

The lawyers that run the advertisements are paid for their referrals. The more consumers they recruit, the more they are paid. Other law firms are willing to pay for referrals because they will eventually receive a portion of the money their clients recover from drug manufacturers.

Pro-consumer motive instructions

In a moment, you will watch an advertisement that was paid for by a lawyer. The purpose of the advertisement is to recruit consumers for a lawsuit. In particular, the lawyer is looking for consumers that experienced a particular medical problem after taking a prescription drug. Consumers harmed by the medication may have a valid lawsuit against the drug manufacturer for failing to disclose the risk of the medical problem.

These advertisements are beneficial for consumers for a number of reasons. First, lawyers representing injured consumers in lawsuits against drug manufacturers help consumers recover money for their injury and the pain and suffering they have experienced. These lawsuits help to hold drug manufacturers accountable for the harm they have caused. In addition, such lawsuits provide economic incentives for drug manufacturers to carefully disclose the risks of the medications they manufacture.

Second, these advertisements help inform the public about important drug safety information. Lawyers who purchase these advertisements typically base the content of their advertisements on announcements or warnings issued by the Food & Drug Administration (FDA) or based upon very large scientific studies. Therefore, these advertisements help patients by making them aware of the risks associated with certain medications.

Control condition instructions:

In a moment, you will watch an advertisement that was run during an episode of “Dancing with the Stars.” The show pairs a number of well known celebrities with professional ballroom dancers, who each week compete by performing one or more choreographed routines that follow the prearranged theme for that particular week.

The dancers are then scored by a panel of judges. Viewers are given a certain amount of time to place votes for their favorite dancers, either by telephone or (in some countries) online. The couple with the lowest combined score provided by the judges and viewers is eliminated. This process continues until there are only two or three couples left; when they have competed for the last time one couple is declared the champion.

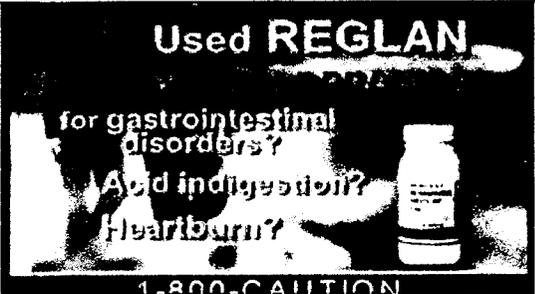
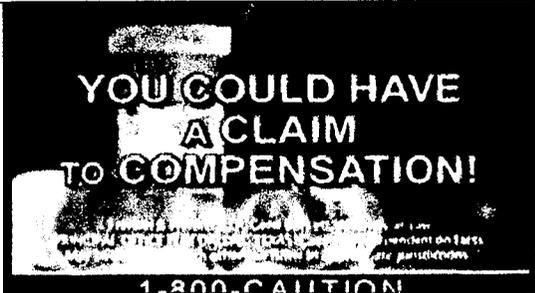
Versions have also been produced in dozens of countries across the world. As a result, the series became the world’s most popular television program among all genres in 2006 and 2007, according to the magazine *Television Business International*, reaching the Top 10 in 17 countries.

APPENDIX B: DRUG INJURY ADVERTISEMENTS

Transparent Advertisement

<p>Male Announcer</p>	<p>“If you have taken the drug Reglan this message is for you.”</p>	
<p>Female Announcer</p>	<p>“If you or a family member have taken the drug Reglan and have been diagnosed with Tardive Dyskinesia call attorney Ken Nugent right now.</p>	
<p>Ken Nugent</p>	<p>I’m attorney Ken Nugent if you or a loved one has taken this drug and were injured call us right now. You may be entitled to financial compensation.</p>	
<p>Female Announcer</p>	<p>“If you have taken the drug Reglan and have been diagnosed with tardive dyskinesia call attorney Ken Nugent right now. Call 1-800-CALL-KEN, that’s 1-800-CALL-KEN.”</p>	

Deceptive Advertisement

<p>Female Announcer</p>	<p>“Caution! Have you or a loved one taken the prescription drug Reglan to treat stomach problems, acid indigestion, or heartburn?”</p>	
	<p>”Caution! The use of Reglan may be linked to serious side effects - Tardive Dyskinesia, involuntary arm movements, facial grimacing or protrusion of the tongue.”</p>	
	<p>“If you took the prescription drug Reglan and suffered any of these symptoms you could have a claim to compensation.”</p>	
	<p>“Call today. Call 1-800-CAUTION, 1-800-CAUTION.”</p>	

Examining Pharmaceutical Exceptionalism: Intellectual Property, Practical Expediency, and Global Health

Govind Persad*

ABSTRACT

Advocates, activists, and academics have criticized pharmaceutical intellectual property (“pharma IP”) rights as obstacles to access to medicines for the global poor. These criticisms of pharma IP holders are frequently *exceptionalist*: they focus on pharma IP holders while ignoring whether others also bear obligations to assist patients in need. These others include holders of other lucrative IP rights, such as music copyrights or technology patents; firms, such as energy companies and banks, that do not rely on IP; and wealthy private individuals. Their resources could be used to aid patients by providing direct medical assistance, funding prizes or biomedical research, or purchasing pharmaceutical patents and granting rights to the disadvantaged.

After identifying this exceptionalism, this Article evaluates several arguments in its defense. These are that pharma IP holders are unique in (1) owning what poor patients need, (2) being in special proximity to these patients, (3) being able to assist at low cost to themselves, (4) having a professional duty to help these patients, or (5) being implicated by their past conduct in these patients’ plight. It concludes that none of these arguments are compelling: while IP holders have a duty to help, this duty is not fundamentally different from the duties others owe.

Even though this project criticizes exceptionalism, it does not absolve pharma IP holders of duties to help the sick. Rather, it argues that spreading the costs of aiding patients in need across a greater number of market actors, via publicly funded “pull” programs like prizes and patent buyouts or “push” programs like grants, would be preferable. So would allowing pharmaceutical firms to seek contribution from others who are able to help. However, if others cannot be held to account, imposing burdens on pharma IP holders can be justified in order to promote global health: treating wealthy firms arbitrarily is preferable to ignoring the urgent needs of the global poor.

* Assistant Professor, University of Denver Sturm College of Law. JD, PhD, Stanford University. An early draft of this article was selected for the 2018 American Society for Law, Medicine, and Ethics BioIP Scholars Workshop at Georgia State University; I am grateful to my workshop commentators Erin Fuse Brown, Cynthia Ho and Kevin Outtersen, as well as to Sam Halabi, Patti Zettler, Yaniv Heled, Deepa Varadarajan, Nicholson Price, Joe Miller, Sarah Conly, Scott Sehon, Matthew Stuart, Aaron Kesselheim, Ameet Sarpatwari, Leslie Wolf, Shubha Ghosh, Rebecca Wolitz, an audience at Bowdoin College, and the staff of the Yale Journal of Health Policy, Law, and Ethics for their suggestions and Kira Case for research assistance.

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INTRODUCTION

This Article examines and criticizes what it dubs *pharmaceutical exceptionalism* in debates over intellectual property (“IP”) and health. Pharmaceutical exceptionalists regard IP rights in medicines as a major impediment to global health, and therefore argue for eliminating IP protections or imposing greater obligations on IP holders. It agrees with exceptionalists that IP protections can impede global health goals. But it contends that exceptionalists err by focusing narrowly on IP holders and ignoring other actors whose resources could be harnessed to improve access to medicines and to improve global health more generally.

To see how a variety of actors might owe obligations to people in medical need, consider the following vignette.¹ Phumeza Tisile is a South African patient who contracted extensively drug-resistant tuberculosis (XDR-TB). Her diagnosis was delayed because the diagnostic device for XDR-TB was not available in South Africa. Linezolid, the recommended treatment for XDR-TB, cost US \$67 per pill in the South African private sector market. A patent was preventing market entry of a generic that would have cost under \$8 per pill. Because Phumeza could not afford linezolid, she took other medications that had serious side effects.²

Who should have helped Phumeza? The United Nations Secretary-General’s High-Level Panel on Access to Medicines focuses its analysis and criticism on holders of IP rights, such as the firm holding the patent rights to linezolid. But other firms and individuals could have helped as well. Some—like retailers selling linezolid and wholesalers generating the raw materials for it—could have helped by reducing their contribution to the final price. Other pharmaceutical companies could have helped by developing competing treatments that drive down the price of the patented intervention.³ Furthermore, Phumeza’s difficulty in affording linezolid reflects not merely its price but also her limited financial resources. Actors outside the medical sector, including individuals, corporations, civil society organizations, and national governments, could have helped her by lowering prices for other goods, increasing her wages, providing her with affordable insurance, or simply transferring money to her. Other actors could also have helped Phumeza by ameliorating the underlying social conditions that contributed to her contracting XDR-TB.

1. REPORT OF THE UNITED NATIONS HIGH LEVEL PANEL ON ACCESS TO MEDICINES (2016), <http://www.unsgaccessmeds.org/final-report/>, at 15 [hereinafter REPORT ON ACCESS].

2. *Id.*

3. See Jonathan J. Darrow & Aaron S. Kesselheim, *Promoting Competition to Address Pharmaceutical Prices*, Health Affairs Policy Options Paper, March 15, 2018, <https://www.healthaffairs.org/doi/10.1377/hpb20180116.967310/full/> (observing that competition among branded drugs can sometimes lower drug prices, using the case of Hepatitis C drugs as an example).

In Part I, this Article reviews a variety of exceptionalist assertions that IP holders are acting wrongly by failing to promote global health, as well as proposals to impose legal duties on IP holders or encourage private actors to hold them to account. In Part II, the Article evaluates five potential bases for the core exceptionalist claim that IP holders have a special duty to assist patients like Phumeza over and above the duties other firms or individuals might have. These are that pharma IP holders are unique in (1) owning what poor patients need, (2) being in special proximity to these patients, (3) being able to assist at low cost to themselves, (4) having a professional duty to help these patients, or (5) being implicated by their past conduct in these patients' plight. It concludes that none of these arguments are compelling: while IP holders have a duty to help, it is dubious that their duty is stronger than the duties owed by others.

In Parts III.A and III.B, the Article considers two strategies for moving beyond pharmaceutical exceptionalism. The first would promote access to medicines through public funding financed by broad-based taxes and giving. The second, modeled on the doctrine of contribution in tort law, would empower pharmaceutical IP holders to seek compensation from other actors who are also in a position to promote global health. In Part III.C, it argues that pharmaceutical exceptionalist laws can be a legitimate strategy for promoting global health even when they do not align with firms' moral obligations, but that pharmaceutical exceptionalism is a strategy rather than a goal in itself.

Because debates around pharmaceutical IP and global health have been so charged, situating this Article in the existing debate is crucial. This Article challenges the frequently advanced claim that holders of IP rights owe uniquely strong *moral* duties to patients like Phumeza in need of patented medicines.⁴ It argues that the lens of global health advocacy should be broadened beyond concerns about pharmaceutical IP. But—unlike scholarship that seeks to exempt pharmaceutical IP holders from global health responsibilities—the Article does not conclude that imposing uniquely strong *legal* duties on holders of IP rights would be wrong. Instead, it concludes that while the morally ideal solution would be a division of burdens among all who can help, it is acceptable to assign stricter legal duties to pharmaceutical IP holders than to others who have moral duties to assist. When others cannot be held to account, imposing burdens on pharmaceutical IP holders can be justified in order to promote global health: as Part III.C argues,

4. E.g. William W. Fisher & Talha Syed, *Global Justice in Healthcare: Developing Drugs for the Developing World*, 40 U.C. DAVIS L. REV. 581, 647 (2007) (discussing pharmaceutical patents through a lens of ethical obligation); Debora Halbert, *Moralized Discourses: South Africa's Intellectual Property Fight for Access to AIDS Drugs*, 1 SEATTLE J. SOC. JUST. 257, 282–83 (2002) (“Gradually, a viable international consensus on the importance of access to medication and affordable prices has developed and this access has been linked to health as a human right. Within this framework, actions taken by the pharmaceutical industry to protect their patents seem increasingly immoral.”).

underinclusiveness and arbitrariness are preferable to ignoring the urgent needs of the disadvantaged.

I. IP-FOCUSED SOLUTIONS TO GLOBAL HEALTH NEEDS

Commentators have criticized pharmaceutical IP holders for aggressive enforcement of intellectual property rights under current treaties; for seeking expanded intellectual property protections as part of new international trade agreements; and for resisting the use of procedures such as compulsory licensing. Some of the most broadly criticized IP rights are those found in the Agreement on Trade-Related Aspects of Intellectual Property Rights (generally referred to as the “TRIPS” agreement), which has been excoriated for undermining access to lifesaving medicines for patients in developing countries.⁵ More recent international agreements and proposed agreements, such as the Trans-Pacific Partnership, have been similarly criticized.⁶ So have bilateral treaties such as the recent Korea–United States free trade agreement.⁷ This Part reviews arguments that pharmaceutical IP holders are failing in their global health responsibilities, and also reviews proposals to impose greater responsibilities on pharmaceutical IP holders.

A. Criticisms of IP Holders

1. The United Nations: High Level Panel and Special Rapporteurs

The United Nations Secretary-General’s 2016 High Level Panel on Access to Medicines identified a variety of obstacles to access to medicines. Some were non-

5. See, e.g., Peter K. Yu, *Virotech Patents, Viropiracy, and Viral Sovereignty*, 45 ARIZ. ST. L.J. 1563, 1567 (2013) (“[S]ince the TRIPS Agreement entered into force in January 1995, it not only has taken away the wide policy space less developed countries once enjoyed at the international level, but it has also resulted in needless deaths and suffering to patients that have acquired either the human immunodeficiency virus (“HIV”) or the Acquired Immune Deficiency Syndrome (“AIDS”).”); see also Burcu Kilic, *Defending the Spirit of the Doha Declaration in Free Trade Agreements: Trans-Pacific Partnership and Access to Affordable Medicines*, 12 LOY. U. CHI. INT’L L. REV. 23, 30 (2014) (“To a great extent, the patent regime has been linked to rising healthcare costs and problems regarding access to medicine. Many developing countries, especially the least developed ones, were faced with public health crises. These countries have experienced the difficulties related to the increasing prices of medicines. It became evident that patents substantially delayed market entry of generic medicines, raising costs and reducing access. As a result, the Agreement has come under fierce criticism.”).

6. Alexander Stimac, *The Trans-Pacific Partnership: The Death-Knell of Generic Pharmaceuticals?*, 49 VAND. J. TRANSNAT’L L. 853, 874–75 (2016) (“Rohit Malpani, the director of policy and analysis at the MSF Access Campaign, has stated that “[t]he TPP is the most damaging trade agreement we have ever seen in terms of access to medicines for poor people.”).

7. Ruth Lopert & Deborah Gleeson, *The High Price of “Free” Trade: U.S. Trade Agreements and Access to Medicines*, 41 J.L. MED. & ETHICS 199, 210 (2013).

IP barriers to access, such as “[r]egulatory inefficiencies, poor health education, unavailability of health insurance and insufficient financial protection for those who have to pay for some or all of their treatment,” as well as “fees, profits, taxes and tariffs along the supply chain”; the Panel also observed that millions of patients remain unable to access essential off-patent medicine.⁸ However, it focused most of its analysis on pharmaceutical IP. This may reflect the nature of the Panel’s mandate: the Panel was tasked with addressing tension between the “justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies,”⁹ rather than “analyzing all the reasons why health technologies are not available [n]or affordable.”¹⁰

The Panel concluded that pharmaceutical IP rights can obstruct access to medicines. It began by observing that “the obligation to grant patents on medicines and other health technologies would affect the availability and affordability of health technologies,” and “had a clear potential to strain national budgets and to place health technologies out of the reach of those in need.”¹¹ This emphasis on the access-constricting effects of IP continues throughout the report. The Panel goes on to assert that there is a “misalignment between public health objectives and trade and intellectual property protection”¹² and that “the application of patent protections . . . can conflict with the right to health in rich and poor countries alike.”¹³ The report also explicitly endorses the primacy of health claims over property rights, stating that “[t]ensions between ministries responsible for the promotion of trade and the protection and enforcement of intellectual property on the one hand and those responsible for public health should not result in the prioritization of trade over health,” and that “[t]he very nature of fundamental human rights requires that they outweigh private interests under national law.”¹⁴ The Panel ultimately, however, elected to reaffirm the importance of the TRIPS Agreement and the flexibilities it includes, rather than rejecting pharmaceutical IP rights in medicines.

Some members of the Panel would have gone further and eliminated IP rights over a subset of essential medicines, and potentially over all health technologies. In a commentary annexed to the report, Jorge Bermudez, Winnie Byanyima and Shiba Phurailatpam, three members of the Panel, describe “the current R&D and access system – based on intellectual property (IP) protection as embodied in the WTO’s TRIPS Agreement and aggravated by free trade and investment

8. REPORT ON ACCESS, *supra* note 1, at 15-16.

9. *Id.* at 4.

10. *Id.*

11. *Id.* at 17.

12. *Id.* at 21.

13. *Id.*

14. *Id.* at 24.

agreements and treaties” as a “systemic failure.”¹⁵ In a separate commentary, Bermudez and Byanyima argue that, instead, “medicines on national lists or on the WHO Model List for Essential Medicines should be exempted from IP protection,”¹⁶ a proposal they assert was supported by two-thirds of the Panel but excluded from the final report. They likewise argue that the UN should examine how “IP constraints can be removed from all health technologies while protecting the justifiable rights of inventors.”¹⁷ Underscoring their belief that IP and pricing constitute the crucial barriers to access, they criticize the Panel’s claim that unavailability of health insurance constitutes a barrier to access, stating that “insurance does not protect people from the high cost of medicines nor does it guarantee access to the medicines they need even in high income countries.”¹⁸ In an individual commentary, Phurailatpam underscores his view that the pricing of patented medicines, rather than the resources available to patients to purchase medicines, should be the focus of critical attention.¹⁹

The two most recent former United Nations Special Rapporteurs on the Right to Health, Paul Hunt and Anand Grover, have similarly argued that uniquely strong duties apply to pharmaceutical IP holders.²⁰ In one article, Grover and his co-authors argue that “[t]ransnational pharmaceutical companies, along with states, play the largest role in determining whether medicines are equitably available and accessible,”²¹ and then go on to assert that

[M]any medicines currently available on the market are simply too expensive for millions around the world to afford. Many medicines available in the developing world are only available to a small percentage of the population due to economic inequities. The profit-seeking behavior of pharmaceutical companies exacerbates this problem. In most cases, the price reductions required to make drugs affordable to a broader class of people in

15. *Id.* at 53.

16. *Id.* at 61.

17. *Id.* at 61-62.

18. *Id.* at 55.

19. *Id.* at 63 (“Several people who put pressure on the work of the Panel accused it of ignoring the role of health systems in limiting access. In the case of patented medicines - it is my own personal experience and that of the multitude of patients in need of patented medicines - that the cascade of misery that we endure in being pushed from pillar to post, in navigating public and private healthcare systems and complicated health coverage and ultimately facing death or destitution, starts with or is certainly made far worse, by the pricing and restricted availability of those patented medicines.”).

20. Anand Grover et al., *Pharmaceutical Companies and Global Lack of Access to Medicines: Strengthening Accountability Under the Right to Health*, 40 J.L. MED. & ETHICS 234, 236 (2012); Joo-Young Lee & Paul Hunt, *Human Rights Responsibilities of Pharmaceutical Companies in Relation to Access to Medicines*, 40 J.L. MED. & ETHICS 220 (2012).

21. Grover et al., *supra* note 20, at 235.

the developing world are not offset by the resultant increase in sales volume. Simply stated, in most of the developing world, it is more profitable to sell drugs to the very wealthy at high prices than it is to sell cheaper drugs to a greater number of people. As a result, medicines remain unaffordable for the vast majority of people in many parts of the world. While this might be an acceptable outcome for certain commodities, such as luxury goods, it is completely unacceptable for life-saving medicines. Therefore, in order to effectively address the global lack of access to medicines, the role pharmaceutical companies play in the international intellectual property regime must be critically examined.²²

Grover et al. appear to place a special responsibility for providing access to medicines on pharmaceutical companies and focus in particular on pharmaceutical companies' conduct with respect to intellectual property rights. They also argue that IP holders who do not do what they need to do should be subject to external constraints.²³

Another former Special Rapporteur, Paul Hunt, took a similar position in a 2012 article. Hunt and Joo-Young Lee argue that:

[S]ociety has a legitimate expectation that the patent holder of a life-saving medicine will not only enjoy the privileges arising from the patent but also fulfill the corresponding responsibilities. The crucial right-to-health responsibility is to take all reasonable steps to make the medicine as accessible as possible, as soon as possible, to all those in need, within a viable business model. As soon as the new medicine is marketed at higher prices (usually in high-income countries), the patent holder has a right-to-health responsibility to put in place a range of mechanisms, such as differential pricing between and within countries, to enhance access for those who cannot afford those prices. Also, the patent holder has a right-to-health responsibility to develop formulations for children, the elderly, pregnant and lactating women, and extremes of climate. For the duration of the patent, only the patent holder is authorized (with limited exceptions) to take these steps. Thus, the agreement between society and patent holder includes a

22. *Id.*

23. *Id.* at 236 ("It is increasingly clear that the structure of the international intellectual property regime must be modified and that reasonable constraints be placed on the behavior of pharmaceutical companies in order to allow for adequate levels of industry competition.").

responsibility on the patent holder to take these steps, expeditiously and effectively, by way of deliberate, concrete, and targeted measures. If the patent is worked without these steps being taken (i.e., without a range of mechanisms being put in place to enhance access, and without steps being taken to develop formulations for children, etc.), then the patent holder is in breach of its right-to-health responsibilities. Of course, the success of the patent holder's actions will sometimes depend upon States, donors, and others in the pharmaceutical sector fulfilling their responsibilities. Nonetheless, the patent holder has a right-to-health responsibility to do what it reasonably can.²⁴

While Lee and Hunt note that other actors also have responsibilities, their focus is on the IP holder, who “has a right-to-health responsibility to do what it reasonably can.”²⁵

2. *Academics*

Many academic commentators have condemned pharmaceutical IP holders for depriving the global poor of essential medicines. A representative example is Chuan-Feng Wu, who asserts that

the cavalier conduct of [transnational pharmaceutical corporations] is . . . the primary cause of right-to-health violations, especially the right to access medicines. For example, because pharmaceutical leaders employ strategies, such as patent protection, to maximize profits and returns on investments to benefit the corporation and its shareholders, they are responsible for the high prices charged for life-saving drugs. Studies also show that the poor's healthcare needs are barely met in patent-based pharmaceutical markets because patent holders (i.e., pharmaceutical corporations), who are entitled to control the prices on all sales of their products, sometimes abuse their power of market dominance by charging excessive prices.²⁶

Other commentators similarly assert that intellectual property protections “have a particularly debilitating effect on how lower income countries provide

24. Lee & Hunt, *supra* note 20, at 228-29.

25. *Id.*

26. Chuan-Feng Wu, *Transnational Pharmaceutical Corporations' Legal and Moral Human Rights Responsibilities in Relation to Access to Medicines*, ASIAN J. WTO & INT'L HEALTH L. & POL'Y 77, 90 (2012).

their citizens access to life-saving medication”²⁷; that “[p]rohibitive drug prices are often the result of strong intellectual property protection”²⁸; and that “[i]n many parts of the world, overly restrictive intellectual property regimes place essential medicines beyond the reach of those who need them.”²⁹

Some commentators have not only criticized pharmaceutical IP holders but provided specific proposals that would impose burdens on them. Lisa Forman echoes the arguments made by Bermudez, Byanyima, and Phurailatpam, contending that because “existing policy initiatives have failed to adequately respond to the impact of trade-related intellectual property rights on access to medicines . . . bolder measures are required, including suspending the application of trade-related intellectual property rights to essential drugs for low- and middle-income countries.”³⁰ Talha Syed and Terry Fisher, meanwhile, argue that “international institutions, such as . . . the Agreement on Trade-Related Aspects of Intellectual Property Rights (‘TRIPS’) in particular . . . must be reformed so as to eliminate their complicity in unjustifiable harms to the residents of developing countries.”³¹

3. *Activists*

A poster tweeted by Melinda St. Louis, the Director of International Campaigns at Public Citizen’s Global Trade Watch, states a pharmaceutical exceptionalist view in particularly striking form: “Pfizer+Obama’s TPP=Death for People with AIDS.”³² This poster refers to the Trans-Pacific Partnership (TPP), a proposed international trade agreement, and alleges that the TPP would permit

27. Christina Bucci, *Responsible Patent Protections: Preserving Public Health Objectives in the Trans-Pacific Partnership Agreement*, 26 PAC. MCGEORGE GLOBAL BUS. & DEV. L.J. 213, 214 (2013).

28. Ellen ‘t Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 CHI. J. INT’L L. 27 (2002).

29. Tamar Ezer et al., *Promoting Public Health Through Clinical Legal Education: Initiatives in South Africa, Thailand, and Ukraine*, HUM. RTS. BRIEF, Winter 2010, at 27.

30. Lisa Forman, *The Inadequate Global Policy Response to Trade-Related Intellectual Property Rights: Impact on Access to Medicines in Low- and Middle-Income Countries*, 31 MD. J. INT’L L. 8, 9 (2016).

31. Fisher & Syed, *supra* note 4, at 662; see also Ruth Lopert & Deborah Gleeson, *The High Price of “Free” Trade: U.S. Trade Agreements and Access to Medicines*, 41 J.L. MED. & ETHICS 199, 199 (2013) (“[T]he proliferation of post-TRIPS bilateral and regional ‘free’ trade agreements (FTAs) has been characterized by a progressive ‘ratcheting up’ of IP protections for pharmaceuticals, with provisions intended to prolong monopolies, support high prices and frustrate market entry of generic medicines -- all of which undermine access to affordable medicines”).

32. Melinda St. Louis (@MelindaGTW), TWITTER (July 3, 2015, 3:00 AM), <https://twitter.com/MelindaGTW/status/616682828521025536>; see also Margaret Flowers, *Stopping The Trans-Pacific Partnership Essential To Universal Health Care*, POPULAR RESISTANCE (Sept. 4, 2013), <https://popularresistance.org/stopping-the-trans-pacific-partnership-essential-to-universal-health-care/> (using the same image).

pharmaceutical firms like Pfizer to worsen access to medicines for people living with AIDS. Medecins Sans Frontieres, meanwhile, referred to pharmaceutical companies' attempts to limit compulsory licensing (a patent law doctrine that permits governments to grant licenses without the patent-holder's consent) in South Africa as "one of the most stark acts of corporate inhumanity."³³

B. IP-Focused Law and Policy Proposals

The claims in Part I.A that pharmaceutical IP holders are wrongfully impeding global health has prompted proposals to either weaken IP holders' rights or to impose correlative responsibilities. This Subpart reviews these proposals.

1. Elimination of IP in some or all health technologies

A contribution to the High Level Panel's deliberations by the legal academic Brook Baker and several advocacy groups argues that intellectual property protections for health technologies should be completely eliminated. Baker and his co-submitters call for "eventually exempting all health technologies for all health conditions from IP protections in international, regional, bilateral, and national law,"³⁴ "an explicit exemption of medical technologies from patent, copyright, and data protections in the WTO TRIPS Agreement, in trade agreements, and in national legislation,"³⁵ and "unenforceability of investor rights concerning health technologies."³⁶ They also provide a detailed proposal that would revise the TRIPS agreement to eliminate IP rights. In support of this proposal, they claim that IP rights are inefficient at driving innovation and that "global, regional, bilateral, and national IP regimes adversely affect universal, equitable, and affordable access to health technologies, which should be treated as a global public good."³⁷ While they

33. David P. Fidler, "Geographical Morality" Revisited: *International Relations, International Law, and the Controversy over Placebo-Controlled HIV Clinical Trials in Developing Countries*, 42 HARV. INT'L L.J. 299, 302 n.16 (2001); see also Brook K. Baker, *International Collaboration on IP/Access to Medicines: Birth of South Africa's Fix the Patent Laws Campaign*, 60 N.Y.L. SCH. L. REV. 297, 329-30 (2016) (observing that activist groups such as the Treatment Action Campaign and Medecins Sans Frontieres "have chastened the multinational pharmaceutical industry for its continuing, pernicious, and backdoor efforts to prioritize monopoly profits over people's affordable access to essential public health goods"); Siddhartha Rao, *Closing the Global Drug Gap: A Pragmatic Approach to the Access to Medicines Problem*, 3 J. LEGAL TECH. RISK MGMT. 1, 13 (2008) (discussing "the success of activist groups in generating negative publicity towards pharmaceutical companies trying to enforce patents").

34. Brook Baker and Health GAP, Contribution to the United Nations Secretary-General's High-Level Panel on Access to Medicines, February 26, 2016, <http://www.unsgaccessmeds.org/inbox/2016/2/26/z73kpodxk4jw96mhqe2tivq0sd1g3v>

35. *Id.*

36. *Id.*

37. *Id.*

acknowledge that their proposal may be difficult to implement politically, they argue that it is preferable to incremental reforms. Their proposal is also endorsed by other contributors to the Panel's deliberation.³⁸

Other contributors offer the more limited suggestion that IP rights in essential medicines should be eliminated or severely restricted. As previously mentioned, Bermudez, Byanyima, and Phurailatpam propose the complete elimination of IP rights in relation to essential medicines. Less drastically, Chandni Raina, from the Center for WTO Studies at the Indian Institute of Foreign Trade, argues that patents in medicines that are essential for treating a disease should be subject to mandatory licensing, which would allow any pharmaceutical company to produce such medicines after paying a reasonable royalty.³⁹

2. *IP-focused taxes and regulatory mandates*

Rather than weakening property rights in IP, some contributors to the High Level Panel, as well as some of the members themselves, argue for imposing correlative responsibilities on holders of IP. One such proposal, offered by the Treatment Action Campaign (TAC) and endorsed by other organizations, would require "compliance with a research mandate as a condition for maintaining intellectual property rights on medical products."⁴⁰ Their mandate would have the following structure:

- For a company in possession of any pharmaceutical patents to maintain the rights to those patents it must, on an annual basis, file information confirming the following:

38. Saoirse Fitzpatrick and STOPAIDS, Contribution to the United Nations Secretary-General's High-Level Panel on Access to Medicines, February 26, 2016, <http://www.unsgaccessmeds.org/inbox/2016/2/26/saoirse-fitzpatrick> (endorsing Baker proposal on behalf of "STOPAIDS, Health Action International, Health Gap (Global Access Project), Wemos, UAEM Europe, Youth Stop AIDS, ACTSA, Health Poverty Action, Commons Network, Grupo de Ativistas em Tratamentos, Coalition Plus, Restless Development, T1International, Aids Orphan, Declaration de Berne, Medicines in Europe Forum, European Public Health Alliance, PRAKSIS, EKPIZO, Verein Demokratischer Pharmazeutinnen und Pharmazeuten, European AIDS Treatment Group, Global Youth AIDS Coalition, Health Projects for Latvia, Salud Por Derecho, Global Health Advocates").

39. Chandni Raina, Contribution to the United Nations Secretary-General's High-Level Panel on Access to Medicines, February 22, 2016, <http://www.unsgaccessmeds.org/inbox/2016/2/22/contributionchandni-rainaon-behalf-of-the-centre-for-wto-studies>.

40. Marcus Low on behalf of the Treatment Action Campaign, Contribution to the United Nations Secretary-General's High-Level Panel on Access to Medicines, February 22, 2016, <http://www.unsgaccessmeds.org/inbox/2016/2/27/marcus-low>. The contribution was also endorsed by SECTION27 and Knowledge Ecology International. *Id.*

- That over the last 12 months the company spent a minimum of 30% of revenue on R&D and
- Spending on R&D over the last 12 months was at least double the combined spending on marketing and advertising over the same period and
- Spending on R&D over the last 12 months was at least double the company's profits.
- For the purpose of this mechanism investment on R&D must include direct contributions made to approved medical R&D grant-making institutions at the national level or as part of a UN agency or a partnership with a UN agency . . . A minimum of 20% of the patent holder's R&D investment must be contributed to such institutions. Such institutions should be obliged to invest these funds in R&D relating to areas of greatest medical need.
- In cases where fewer than four companies hold a license or licenses to market a specific patented medical product, these provisions will apply to all license holders in exactly the same way as it applies to the original patent holder.⁴¹

In its contribution, TAC also reviewed a variety of other proposed R&D mandates on pharmaceutical IP holders. These include a proposed Brazilian “tax on pharmaceutical profits that would go toward an R&D fund . . . used only for R&D on medicines and vaccines that address public health needs of developing countries”⁴² and a 1996 proposal by then-Rep. Bernie Sanders that would impose “minimum R&D requirements on companies that sell drugs in the United States,”⁴³ with the requirements depending on “patent protection, orphan drug status, and the magnitude of sales.”⁴⁴ They also discussed mandates that fund pharmaceutical R&D by taxing antibiotic use or mineral resource exploitation.⁴⁵

Fisher and Syed, whose work is discussed in Part I, submitted a contribution advocating a regulatory approach similar to TAC's, but which focuses on outcomes achieved as a result of the firm's products rather than on R&D spending. They advocate requiring all pharmaceutical firms to “demonstrate compliance, annually, with a ‘social-responsibility index,’ which index would consist of the

41. *Id.*

42. *Id.*

43. *Id.*

44. *Id.*

45. *Id.*

ratio between (1) the total number of Disability Adjusted Life Years (DALYs) saved as a result of the consumption of the firm's products during the year and (2) the firm's global gross revenues during the year."⁴⁶ They would allow a "cap-and-trade" system for DALYs, where a firm whose products saved insufficient DALYs could buy them from another firm.⁴⁷

Finally, Grover et al. proposed a UN framework convention on global health that would incorporate a tax on pharmaceutical companies. Grover et al.'s proposed convention would establish a "judicial committee with the authority to issue binding judicial decisions enforceable under international law"⁴⁸; the committee would have the authority to hear complaints that pharmaceutical companies have violated the right to health, and provide remedies including "compensation for victims, guarantees of non-repetition, commitments to research and development priorities for neglected diseases, and the granting of compulsory licenses."⁴⁹ These remedies would be financed by "taxes levied on pharmaceutical companies by the state in which they are domiciled,"⁵⁰ and "based upon the companies' compliance with the obligations in the framework convention; companies with poor records would be required to pay more taxes than those who fare better under review by the convention body."⁵¹

3. *IP-focused social responsibility and ethical consumerism initiatives*

Several organizations have proposed campaigns that leverage market mechanisms and consumer power to pressure pharmaceutical IP right-holders to promote global health. One such campaign is the Global Health Impact scorecard, proposed by Nicole Hassoun, which would label products made by firms that hold IP rights according to those firms' contribution to global health.⁵² Hassoun submitted a contribution to the High Level Panel arguing that this approach should

46. William Fisher and Talha Syed, Contribution to the United Nations Secretary-General's High-Level Panel on Access to Medicines, February 28, 2016, <http://www.unsgaccessmeds.org/inbox/2016/2/28/jaime-espino>.

47. *Id.*

48. Grover et al., *supra* note 20, at 246.

49. *Id.*

50. *Id.*

51. *Id.*

52. Nicole Hassoun, *Individual Responsibility for Promoting Global Health: The Case for A New Kind of Socially Conscious Consumption*, 44 J.L. MED. & ETHICS 319, 323 (2016) (proposing the use of "the Global Health Impact rating system for pharmaceutical companies' key impacts on global health to incentivize positive change" via "a Global Health Impact certification and labeling campaign" within which "the best companies, in a given year, will be given a license to use a Global Health Impact label on all of their products - everything from lip balm to food supplements").

be part of the Panel's efforts.⁵³ A similar proposal has been advanced by Nir Eyal.⁵⁴

Another campaign, focused on universities rather than pharmaceutical manufacturers, is the Universities Allied for Essential Medicine (UAEM) scorecard, which evaluates universities by how well their IP licensing proposals promote access to medicines.⁵⁵ UAEM has also developed what it calls an Equitable Access License, which requires IP licensees to grant their exclusive rights in the drugs they produce using that IP back to the university.⁵⁶ A number of universities, as well as the American Association of Medical Colleges, the National Institute of Health, and the Centers for Disease Control, have endorsed a commitment to promoting access to university-held IP in developing countries.⁵⁷

II. EVALUATING THE JUSTIFICATIONS FOR IP-FOCUSED PROPOSALS

An implicit premise of the IP-focused proposals above is that pharmaceutical IP holders have a greater responsibility to promote global health than other firms or individuals do. This premise requires defense, as we can see by examining Fisher and Syed's proposal discussed in Part I.B. If Fisher and Syed's proposal applied to all firms, Coca-Cola (as an example) would have a *negative* social responsibility index, since consuming its products does not avert DALYs and arguably causes them.⁵⁸ Many other firms, like Gucci, would at best have a zero social responsibility index. Yet Fisher and Syed's proposal would impose

53. Nicole Hassoun, Contribution to the United Nations Secretary-General's High-Level Panel on Access to Medicines, February 16, 2016, <http://www.unsgaccessmeds.org/inbox/2016/2/16/contributionn-hassoun>.

54. Nir Eyal, *Global-Health Impact Labels*, in GLOBAL JUSTICE IN BIOETHICS 241-78 (Ezekiel J. Emanuel & Joseph Millum eds. 2012).

55. See Ian Ayres & Lisa Larrimore Ouellette, *A Market Test for Bayh-Dole Patents*, 102 CORNELL L. REV. 271, 318 (2017) (discussing the "establishment of the activist group Universities Allied for Essential Medicines (UAEM), which has pushed universities to consider how their patent policies affect global health, and which helped craft--and convince universities to sign--two licensing policy statements related to the dissemination of medical technologies," and observing that "UAEM now issues an annual report card that grades universities on their global health impact in an effort to increase transparency about university policies").

56. Beirne Roose-Snyder & Megan K. Doyle, *The Global Health Licensing Program: A New Model for Humanitarian Licensing at the University Level*, 35 AM. J.L. & MED. 281, 296-98 (2009) (describing and evaluating the Equitable Access License).

57. Lisa Larrimore Ouellette, *How Many Patents Does It Take to Make A Drug? Follow-on Pharmaceutical Patents and University Licensing*, 17 MICH. TELECOMM. & TECH. L. REV. 299, 310 (2010) (describing commitment signed by AAMC that "[u]niversities have a social compact with society' that gives them 'a responsibility . . . to share the fruits' of their inventions with 'the world's poor,' and also describing endorsement by the CDC and NIH of the 2009 Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies, which contains similar language).

58. See Gitanjali M. Singh et al., *Estimated Global, Regional, and National Disease Burdens Related to Sugar-Sweetened Beverage Consumption in 2010*, 132 CIRCULATION 639, 639 (2015).

obligations on pharmaceutical firms but not on Coca-Cola or Gucci. This is so even though Coca-Cola and Gucci could both improve global health for patients like Phumeza by, for instance, donating profits to enable the global poor to purchase medicines or to obtain needed surgeries. An identical critique applies to taxes and regulatory mandates, like Grover's proposal, that fall exclusively on pharmaceutical firms. And a similar critique applies to the proposals for eliminating IP — Coca-Cola and Gucci could improve the financial circumstances of the global poor tremendously if they granted the poor access to the lucrative IP they control.

UAEM's "University Report Card," which assigns failing global health grades to the University of Cincinnati and Wake Forest University,⁵⁹ but assigns no grade at all to universities without global health programs, faces a similar criticism. Wake Forest spends money promoting global health goals, even though it may spend less than the top-scoring universities,⁶⁰ whereas these other universities do not spend on global health at all. Castigating Wake Forest as a failure for doing too little while ignoring universities that do nothing at all requires defense.

This Part will examine five potential justifications for focusing on holders of pharmaceutical IP rather than on other firms or wealthy individuals. These justifications are that pharmaceutical IP holders, unlike other firms or individuals:

- a) own what patients need;
- b) interact with patients;
- c) can help without incurring significant costs;
- d) have a professional responsibility to help; and/or
- e) have caused patients' plight by creating barriers to access.

I argue that none of these justifications succeed in differentiating IP holders from others who can help.

A. Ownership of what patients need

Grover et al. claim that "unlike in many other forms of intellectual property . . . the chemical compounds that constitute drugs are necessary to protect the health and the human rights of millions of people."⁶¹ They use this claim as a justification for IP-focused policies.

59. See Ayres & Ouellette, *supra* note 55.

60. See Wake Forest School of Medicine, Global Health Funding, <https://school.wakehealth.edu/About-the-School/Global-Health/Funding>.

61. Grover et al., *supra* note 20, at 236.

This argument cannot justify the broad elimination of all IP rights in health technologies that Baker and others defend, because many health technologies are not necessary to protect health or human rights. Some are “me too” drugs that provide only marginal benefits.⁶² Others are drugs for conditions like baldness, treatments which are not essential to human rights.⁶³

Even when deployed in defense of proposals to remove IP rights over medicines that do protect health and human rights, this argument faces three additional problems. First, many pharmaceuticals represent an additional treatment option without being necessary for improving health. As an example, both older and newer medications can treat HIV, although older medications are often less effective or more toxic.⁶⁴ Similarly, older, off-patent antipsychotic drugs can be as effective as patented treatments.⁶⁵

Second, property other than pharmaceutical IP can also be harnessed to protect health and human rights. Within the pharmaceutical supply chain, retailers could sell pharmaceuticals more cheaply and raw material producers could lower their prices.⁶⁶ Outside the pharmaceutical supply chain, wealthy firms and individuals could transfer their property rights in non-pharmaceutical IP, money, or real property to the global poor to enable them to purchase patented drugs or improve their health in other ways.

Third, there can be compelling reasons to recognize property rights in essential goods—not only essential medicines, but also food, water, housing, and non-pharmaceutical health care. Where individuals lack the ability to pay, recognizing and enforcing a collective responsibility to assist is typically preferable to abrogating property rights for specific essential goods. Abrogating property rights in essential goods would create perverse incentives. For instance, if food could not be owned but inessential goods like Gucci handbags could, there would be an incentive to produce handbags instead of food. It would also produce dubious distributive outcomes, as wealthier consumers in developed countries would receive essential goods at low or no cost. This parallels the problem with using price caps, rather than financial assistance, to ensure that poorer consumers

62. Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 183 (2016) (“In a recent five-year period, 67% of the ‘new’ drugs approved by the FDA were ‘me-too’ drugs — drugs that are slight chemical variants of their predecessor and that produce essentially the same medical results in patients”).

63. Cynthia M. Ho, *Unveiling Competing Patent Perspectives*, 46 HOUS. L. REV. 1047, 1063 (2009) (discussing the exemption of “‘lifestyle’ drugs, such as those to treat baldness, acne, or erectile dysfunction” from some access to medicines proposals).

64. See Govind Persad, *The Medical Cost Pandemic: Why Limiting Access to Cost-Effective Treatments Hurts the Global Poor*, 15 CHI. J. INT’L L. 559, 563-65 (2015).

65. Francis Collins, *Opportunities for Research and NIH*, 327 SCIENCE 36 (2010).

66. This does not imply anything about retailers’ or producers’ *relative* contribution to prices.

can access essential goods like food, water, or electricity.⁶⁷ Last, abrogating property rights in essential goods would lead to a misalignment between aid and needs: if a firm has IP rights in essential medicines, but poor patients need off-patent drugs, it would be preferable to have the firm transfer cash to the poor rather than transferring or not enforcing its IP rights.

B. Interaction with patients

The suggestion that interacting with poor patients can generate duties to assist is familiar from other contexts, such as clinical research conducted by pharmaceutical firms abroad,⁶⁸ and is therefore worth examining as a basis for the claim that pharmaceutical IP holders owe special duties to the poor. In the law, friendly interaction with others, or participation in a common undertaking, can sometimes generate obligations to assist.⁶⁹ However, there is no obvious tie of friendship between pharmaceutical IP holders and poor patients, nor are the two involved in a common venture. The law of unjust enrichment also indicates that reciprocity can be a basis for duties to assist;⁷⁰ but pharmaceutical IP holders are not attempting to profit substantially from the global poor.

The most plausible basis for the idea that pharmaceutical IP holders have a special relationship with the global poor involves their intervention in countries where the global poor live in order to assert their IP rights. When an IP holder goes into court in South Africa or India to assert its rights, its interaction with that nation might appear to be a basis for assigning it a special obligation. In contrast, a wealthy private individual or a firm that makes its money purely or primarily via domestic commerce (think of Shake Shack or a local taxi company) would not have similar special obligations.

Appeals to mere interaction, however, faces two of the problems discussed in the prior Subpart. First, others—such as pharmaceutical retailers and non-pharmaceutical firms that do business in developing countries—interact more with patients than pharmaceutical IP holders do, and would be subject to equally strong duties to assist. More importantly, allowing interaction to generate a special responsibility will produce a perverse incentive to avoid interaction. To see how

67. JOSEPH HEATH, *ECONOMICS WITHOUT ILLUSIONS*, ch. 7 (2010) (“[F]iddling with the price of electricity is a terrible way of addressing the underlying problem of distributive justice, simply because the benefits of low prices are available to everyone, not just those who are in need.”).

68. See ALAN WERTHEIMER, *RETHINKING THE ETHICS OF CLINICAL RESEARCH: WIDENING THE LENS* 255 (2010) (discussing the “interaction principle”); James V. Lavery, *Putting International Research Ethics Guidelines to Work for the Benefit of Developing Countries*, 4 *YALE J. HEALTH POL’Y, L. & ETHICS* 319, 321 (2004).

69. Michael Moore, *For What Must We Pay? Causation and Counterfactual Baselines*, 40 *SAN DIEGO L. REV.* 1181, 1186 (2003); cf. *Farwell v. Keaton*, 240 N.W.2d 217 (Mich. 1976) (holding that there is a duty to assist companions in a common undertaking).

70. *Id.* at 1187.

making responsibility contingent on interaction can provide perverse incentives, consider the following example discussed by Alan Wertheimer and Thomas Pogge:

A filmmaker wishes to produce a documentary about behavior of fishermen whose boats are in distress. He believes that the film will help others avoid counterproductive panic-induced behavior. A successful film requires that the fishermen not be rescued until it is too late. The film crew flies to a location off the coast of a poor country and waits for a radio signal of a ship in distress. When it receives a distress signal, the film maker radios back with the following proposal. If the fishermen agree, the filmmaker will flip a coin. If it comes up heads, the filmmaker's crew will fly by helicopter and save them. If it comes up tails, it will fly by helicopter and film them and make no effort to save them, but will remain in the area until another ship is in distress and it will then save those fishermen. Because the fishermen have no better option, they readily agree.⁷¹

Unlike pharmaceutical IP holders, the filmmaker in this case is not only interacting with the fishermen, but potentially benefiting substantially from his interaction with them. Nonetheless, examining this case is useful because if the filmmaker lacks an obligation to aid even though he potentially benefits from the interaction, pharmaceutical IP holders—who merely interact without substantially benefiting—will also lack a special obligation to aid.

Wertheimer and Pogge evaluate the above example in opposing ways. Pogge recognizes that imposing a duty to assist on the filmmaker once he interacts with the fishermen (regardless of how the coin lands) would produce a strong incentive to avoid interacting, but elects to bite the bullet, stating that duties sometimes produce perverse incentives and that “morality cannot plausibly be purged of such counterproductivity entirely.”⁷² In contrast, Wertheimer argues that “this is not the sort of counterproductivity that we have come to expect of a sensible morality.”⁷³ He goes on to assert that

In the case at hand, the moral requirement to save the fishermen does not serve to protect the fishermen from being sacrificed for the benefit of others; it leads to the preventable deaths of the

71. WERTHEIMER, *supra* note 68, at 245–46 (paraphrasing Thomas Pogge, *Testing Our Drugs on the Poor Abroad*, in *EXPLOITATION AND DEVELOPING COUNTRIES* 116 (Jennifer Hawkins & Ezekiel J. Emanuel eds. 2008)).

72. Pogge, *supra* note 71, at 122.

73. WERTHEIMER, *supra* note 68, at 247.

fishermen themselves. If it is hard to have confidence in a morality that allows that allows filmmakers to deliberately refrain from rescuing fishermen in distress, it is also hard to have confidence in a morality that renders it certain that the fishermen will not be rescued.⁷⁴

If we find Wertheimer's reasoning plausible in the fisherman example, the case for rejecting interaction-based duties is even stronger in the case of IP holders who—unlike the fisherman—do not derive a benefit from their interactions with the global poor. We can see the counterproductive results Wertheimer identified in the context of Fisher and Syed's suggestion, where a pharmaceutical company that is judged to under-contribute to global health would receive a lower "social responsibility rating" than a firm like Coca-Cola that does not contribute to global health at all. On this approach, a firm producing multiple products would have an incentive to divest its pharmaceutical division, or stop producing pharmaceuticals: such activities expose the firm to a "moral rescue burden" it would not otherwise have faced.⁷⁵

C. Ability to assist at lower burden to oneself

The capacity to forestall a harm at low cost to oneself is a recognized basis for moral and legal obligations.⁷⁶ One way that pharmaceutical IP holders could be able to forestall harm at a lower cost than other property holders involves the non-rival nature of IP: allowing patients to access a patented drug does not prevent the patent-holder from selling or manufacturing medicines, whereas allowing poor patients to access money or real property does prevent others from using that money or property.⁷⁷

This argument faces two problems. First, it does not explain why pharmaceutical IP holders have a greater responsibility to assist than holders of non-pharmaceutical IP, which is equally non-rival. Allowing patients to access other forms of IP could free patients to purchase medicines or health care that they need. The pharmaceutical exceptionalist needs to explain why requiring

74. *Id.*

75. *Cf.* Pogge, *supra* note 71, at 122 (acknowledging that "[t]he filmmaker has no earthly reason to be near the ocean with his radio equipment and helicopter if this can win him no exciting filming opportunity, but can only slap him with a moral rescue burden.").

76. See Rebecca E. Wolitz, *A Corporate Duty to Rescue: Biopharmaceutical Companies and Access to Medications*, 94 IND. L.J. 1163 (2019); *Wilder Corp. of Delaware v. Thompson Drainage & Levee Dist.*, 658 F.3d 802, 806 (7th Cir. 2011) ("[L]iability for inflicting a harm should come to rest on the party that could, at the lowest cost, have prevented the harm in the first place").

77. Kevin Outterson has developed this non-rivalry argument in *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL'Y, L. & ETHICS 193, 199 (2005).

pharmaceutical companies to share their IP rights with the global poor is more justified than requiring firms like Coca-Cola to share their lucrative IP.

The nonrivalry argument might also fail to differentiate pharmaceutical IP from some forms of real property, because the technically rivalrous use of some real property imposes little cost on the better-off. Historically, the poor were permitted to enter land they did not own, glean crops that would otherwise go unused,⁷⁸ and doctrines like adverse possession are often understood as resting on the benefits of allowing access to unused property.⁷⁹ In the health context, an example of non-rivalrous use might be the use of medical equipment or expired but still usable pharmaceuticals that are currently thrown out rather than being made available for reuse.⁸⁰

Second, it does not acknowledge that even though IP is non-rival, allowing patients to bypass IP rights could create a disincentive to innovate. Robert Merges argues that the view that “there is no need for property where goods are non-rivalrous” ignores the role of IP in stimulating new contributions.⁸¹ While completely eliminating IP rights in medicines would not prevent researchers and corporations from manufacturing and selling the medicines they discover, it could reduce the incentive to engage in discovery.

Another argument would appeal to the great wealth of some pharmaceutical firms.⁸² While this argument does make some pharmaceutical IP holders more appropriate targets for responsibility than many other actors, such as the governments of less developed countries, it also fails to establish that pharmaceutical IP rightsholders should be the unique object of duties. Firms like Coca-Cola and Gucci also are very wealthy—wealthier than many holders of pharmaceutical IP, such as startup firms and university researchers.

D. Professional obligations

Another potential basis for special obligations involves the fact that some individuals who work for pharmaceutical companies are members of professions who owe special obligations to meet the health needs of the global poor. For

78. Randall Bezanson & Andrew Finkelman, *Trespassory Art*, 43 U. MICH. J.L. REFORM 245, 284 (2010) (“The common law also deprived a landowner of a remedy for a trespass when use of private resources benefited the public without harm to the landowner. Blackstone, for example, wrote that the “common law and custom of England” held that it was no trespass for the poor to enter another’s land after harvest to glean another’s grounds.”).

79. See Oskar Liivak & Eduardo M. Peñalver, *The Right Not to Use in Property and Patent Law*, 98 CORNELL L. REV. 1437, 1462 (2013).

80. See Persad, *supra* note 64, at 571-76.

81. ROBERT MERGES, JUSTIFYING INTELLECTUAL PROPERTY 37 (2011).

82. See, e.g., Timothy S. Jost, *The Globalization of Health Law: The Case of Permissibility of Placebo-Based Research*, 26 AM. J.L. & MED. 175, 185 (2000) (noting the “justice issues raised by the pricing policies of wealthy pharmaceutical companies for sale of drugs in the developing world”).

instance, if pharmaceutical companies employ physicians and nurses to carry out clinical trials, these physicians and nurses may owe a professional ethical duty to poor patients, a duty whose fulfillment requires the provision of professional services rather than through the provision of other goods.⁸³ This could be a basis for imposing greater obligations on pharmaceutical IP holders than on Coca-Cola or Gucci. Even if pharmaceutical firms' employees are not directly interacting with the global poor, they are departing from their duty to focus on healing the sick when they work as pharmaceutical employees. In contrast, it might be argued, designers at Gucci do not have role-based professional duties to the global poor, and so Gucci does not have obligations to serve the needs of the global poor.

This argument faces several problems. First, it is contentious whether the duties of professionals should take the specific form of providing professional services. It is plausible that professionals instead have duties to serve the public good, but that these professional duties can be fulfilled in other ways.⁸⁴ Second, many—probably most—employees of pharmaceutical firms are not physicians or nurses, and so do not have the specific role-based obligations to the global poor that physicians do. Last, even physicians and nurses at pharmaceutical firms do not have a permission to set back the firm's economic position in order to fulfill their professional duties to promote global health, just as they do not have a permission to set back the corporation's economic position in order to fulfill other special responsibilities they might have. (Analogously, in-house lawyers are limited in their ability to provide *pro bono* services on company time, and such services must typically be authorized.⁸⁵)

E. Past conduct

Another way to support the claim that pharmaceutical IP holders owe a distinctive obligation to patients like Phumeza is to look to their past conduct. If pharmaceutical IP holders' conduct has brought about the bad health outcomes that

83. See, e.g., AM. MED. ASS'N, COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, Opinion 9.065-Caring for the Poor (2011), <https://journalofethics.ama-assn.org/article/ama-code-medical-ethics-opinion-physicians-duty-poor/2011-08> ("Each physician has an obligation to share in providing care to the indigent."). Some scholars also suggest that these duties apply to physicians conducting clinical research on pharmaceuticals. See, e.g., Paul B. Miller & Charles Weijer, *Fiduciary Obligation in Clinical Research*, 34 J. L. MED. & ETHICS 424, 425 (2006).

84. See WILLIAM MACASKILL, *DOING GOOD BETTER* 77 (2015) (arguing that physicians can often save more lives by "earning to give" — i.e. donating a portion of their salaries to effective charities — than by providing *pro bono* services).

85. See Ronald T. Y. Moon, *Access to Civil Justice: Is There A Solution?*, 88 JUDICATURE 155, 157 (2005) ("Survey results of corporate legal departments indicated 40 percent in-house *pro bono* participation with another 40 percent indicating plans to start in-house *pro bono* programs. Of those reporting active in-house *pro bono* participation, 83 percent permit counsel to perform *pro bono* legal services on company time.").

produce the need for health care, this could support the imposition of obligations.

The legal academic Kevin Outterson and the medical sociologist Donald Light argue that pharmaceutical IP constitutes an affirmative barrier placed in the way of access to health care.⁸⁶

[T]he patent-based drug companies are not strangers to the global access to medicines problem; nor are they innocent bystanders who happen upon a tragedy by chance. They cannot rely on libertarian arguments to absolve themselves of responsibility. They helped create the global system of intellectual property law that stands as a barrier to generic production for the poor . . . The patent-based drug companies are among the chief architects and beneficiaries of this global system, and thus bear enhanced responsibility for its effects on the poor, even in the absence of fault or negligence. They are active participants in the creation of the problem rather than innocent bystanders. The patent-based drug companies actively work to prevent rescue by others. Generic production and distribution of patented drugs for low- and medium-income country populations is possible, as demonstrated by the actions of generic drug companies such as Cipla Ltd of India and charities such as Médecins Sans Frontières. But the drug companies can use patent law to block generic production of the best available medicines and to drive “unreasonable bargains” on pricing . . . Patent law gives companies the right to block generic production for poor countries during the patent period, but exercising it transforms the companies from innocent bystanders into entities claiming the legal right to prevent rescue.⁸⁷

I agree with Outterson and Light that pharmaceutical IP holders who assert their rights are placing a barrier in the way of access to medicines. But so are holders of rights to real property or to money. When a pharmaceutical retailer—as opposed to an IP holder—refuses to let an impoverished parent bring home a prescription for her child without paying, the retailer is also asserting the “legal right to prevent rescue.” The same is true when the bank next door locks its vaults, or wealthy customers in the store close their wallets and refuse to pay for needy patients’ medicines. While Outterson and Light assert that “[t]he drug company’s status is . . . unique because of the patent law’s ability to block the activities of

86. Kevin Outterson & Donald W. Light, *Global Pharmaceutical Markets*, in *A COMPANION TO BIOETHICS* 417 (Helga Kuhse & Peter Singer eds., 2009).

87. *Id.* at 418.

others,”⁸⁸ this assertion of uniqueness does not survive scrutiny. Property and contract law prevent rescue just as surely as patent law does.⁸⁹ As such, Outterson and Light’s attempt to distance themselves from ethicists who would more generally “find positive duties on the rich to care for the needy” is unavailing.⁹⁰

Thomas Pogge has also argued that pharmaceutical firms are affirmatively harming the global poor. As Glenn Cohen summarizes,

Pogge begins with the idea that all people have rights to a “minimally worthwhile life” and therefore require a share of minimum levels of basic goods, including health care, that are essential to a decent life — he terms such goods “human rights.” According to Pogge’s theory, citizens of one state have an obligation to avoid “harming” citizens of another state by imposing “deficits” on their access to these human rights; that is, he argues that “[w]e are harming the global poor if and insofar as we collaborate in imposing” a “global institutional order . . . [that] foreseeably perpetuates large-scale human rights deficits that would be reasonably avoided through foreseeable institutional modifications.”⁹¹

While Pogge’s claim that everyone has a right to a minimally decent life is plausible and is consistent with human rights documents,⁹² his claim that the global international order is affirmatively harming the poor, rather than failing to provide them with fair benefits, has been vigorously and persuasively challenged by Norman Daniels and others who point out that describing the international order

88. *Id.* at 419.

89. See Ronald H. Coase, *The Federal Communications Commission*, 2 J.L. & ECON. 1, 27 (1959) (“All property rights interfere with the ability of people to use resources. What has to be insured is that the gain from interference more than offsets the harm it produces.”); James Sterba, *From Liberty to Welfare*, 105 ETHICS 65, 70 (1994) (observing that property rights interfere with “the liberty of the poor not to be interfered with in taking from the surplus possessions of the rich what is necessary to satisfy their basic needs”).

90. Outterson & Light, *supra* note 86, at 420.

91. I. Glenn Cohen, *Medical Tourism, Access to Health Care, and Global Justice*, 52 VA. J. INT’L L. 1, 43 (2011) (quoting THOMAS W. POGGE, *WORLD POVERTY AND HUMAN RIGHTS* (2002)). While this Article cites Pogge’s work because of its influence on the debate, it also acknowledges the numerous charges of sexual misconduct against Pogge. See Colleen Flaherty, *Separating the Philosophy from the Philosopher*, INSIDE HIGHER ED., Aug. 3, 2016, <https://www.insidehighered.com/news/2016/08/03/philosophers-move-limit-alleged-harassers-influence-within-discipline> (reporting numerous allegations that Pogge has harassed women students, and discussing efforts to respond, including syllabus and citation boycotts).

92. See Persad, *supra* note 64, at 603-06 (discussing conceptions of the right to health as a right to a decent minimum)

as inflicting harm requires adopting a tendentious definition of harm.⁹³ More importantly, even if we grant its correctness for the sake of argument, Pogge's view — like Outterson and Light's — is unable to support pharmaceutical exceptionalism. Firms like Coca-Cola and Gucci also rely on and lobby for international trade rules, and are embedded in networks of global commerce.

Activists' more provocative suggestion that pharmaceutical IP holders who enforce their rights actively kill patients in need faces the same problem.⁹⁴ Even if the IP holder could be described as killing the poor by depriving them of medicines, the same is true of the retailer and the fellow customer. It is more plausible to say that all three fail to aid the poor than to say that some kill the poor while others merely fail to help.

Some have instead argued that pharmaceutical IP holders owe special obligations to the global poor because they benefit from publicly funded research investments by universities and governments.⁹⁵ The case for such duties appears normatively compelling, particularly where universities and governments provide the fruits of their research below cost or for free, and would differentiate at least some pharmaceutical IP from many types of non-pharmaceutical IP.⁹⁶ However, this argument does not support the IP-focused policies discussed in Part I.B. Only pharmaceutical IP holders who benefited from such investments would owe duties. More importantly, these duties would be owed to universities and developed world governments, not directly to the global poor: the extent to which these universities and governments should direct pharmaceutical IP holders to assist the global poor,

93. See Cohen, *supra* note 91, at 44 (citing NORMAN DANIELS, *JUST HEALTH* 337-40 (2008)); see also Mathias Risse, *Do We Owe the Global Poor Assistance or Rectification?* 19 *ETHICS & INT'L AFF.* 9, 9 (2005) (arguing that the "global order does not harm the poor according to the benchmarks of comparison used by Pogge"); Debra Satz, *What Do We Owe the Global Poor?*, 19 *ETHICS & INT'L AFF.* 47, 53-54 (2005) (agreeing that the global status quo is unjust, but rejecting Pogge's "specific argument that the advantaged citizens of the affluent countries *actively cause* most of the severe poverty in the world" and suggesting that this argument relies on an "understanding of causation" that "erodes the distinction between harming and failing to remedy").

94. See, e.g., Andrew Beckerman-Rodau, *The Problem with Intellectual Property Rights: Subject Matter Expansion*, 13 *YALE J. L. & TECH.* 36, 89 (2011) (reporting Swedish Pirate Party's assertion that "Pharmaceutical patents kill people in third world countries every day"); Lisa C. Pavento et al., *International Patent Protection for HIV-Related Therapies: Patent Attorneys' Perspective*, 17 *EMORY INT'L L. REV.* 919, 920 (2003) (describing editorial alleging that "the U.S. pharmaceutical companies were, in essence, killing millions of people" through patent enforcement).

95. I am grateful to Ameet Sarpatwari for suggesting that I examine this argument. See Lisset Ferreira, *Access to Affordable HIV/AIDS Drugs: The Human Rights Obligations of Multinational Pharmaceutical Corporations*, 71 *FORDHAM L. REV.* 1133, 1142 (2002) ("[D]evelopment of new drugs frequently is subsidized heavily by the taxpayer's money and performed in publicly-funded laboratories. Thus, critics . . . argue that it is unfair for drug companies to reap huge profits from the inflated prices they charge for products developed using taxpayer money."); see also Outterson & Light, *supra* note 86, at 423.

96. This argument could be understood as appealing to ideas of unjust enrichment; see Moore, *supra* note 69, at 1187.

rather than to assist the domestic poor or to invest in scientific research, is a complex question.

A final argument would point to egregious misconduct by pharmaceutical IP holders, such as false advertising, anticompetitive conduct, and the funding of misleading clinical trials. Scholars have identified compelling evidence of such misconduct.⁹⁷ But this misconduct likewise does not support the proposals in Part I.B. Rather, it supports efforts to enforce greater clinical trial transparency, to regulate advertising, and to ensure competition. A focus on corporate misconduct would also sweep more broadly than pharmaceutical firms, given the many non-pharmaceutical firms and wealthy private individuals who hamper global health aims through egregious misconduct like pollution, tax evasion, and the sale of harmful products.

III. CAN WE MEET GLOBAL HEALTH NEEDS WITHOUT EXCEPTIONALISM?

Part II's conclusion is that assigning *special* responsibility to pharmaceutical IP holders is difficult to defend. However, pharmaceutical IP holders retain the same responsibilities to assist patients in need, like Phumeza, that others who are equally well-off and equally well placed to aid do. This Part will consider two strategies for assisting patients like Phumeza that do not focus narrowly on the elimination or weakening of IP rights. It will then argue that while non-exceptionalist strategies for helping poor patients are the best option, it is acceptable to employ pharmaceutical exceptionalist policies when doing so is the most attainable way of achieving important global health goals.

A. Funding Access to Medicines

Access to medicines can be achieved via routes other than IP, such as “pull” programs that reward the development of medicines and “push” programs that encourage research.⁹⁸ A prominent example of a pull program is a prize system, which would offer a prize to firms or other actors who develop drugs that have certain desirable outcomes.⁹⁹ These desirable outcomes can be overall

97. See, e.g., BEN GOLDACRE, *BAD PHARMA: HOW DRUG COMPANIES MISLEAD DOCTORS AND HARM PATIENTS* (2013); PETER GÖTZCHE, *DEADLY MEDICINES AND ORGANIZED CRIME: HOW BIG PHARMA HAS CORRUPTED HEALTHCARE* (2013); MARCIA ANGELL, *THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT* (2004).

98. See Evan Wisser, Note, *Simulating Pharmaceutical Markets in the Developing World: The Problems with “Pull” Funding Mechanisms*, 30 B.U. INT'L L.J. 261, 272–73 (2012).

99. See Amy Kapczynski, *The Cost of Price: Why and How to Get Beyond Intellectual Property Internalism*, 59 UCLA L. REV. 970, 973 (2012); Daniel J. Hemel & Lisa Larrimore Ouellette, *Beyond the Patents-Prizes Debate*, 92 TEX. L. REV. 303, 317 (2013).

improvements in health or can be more specific subcategories of improvements such as new antibiotics. These prizes would incentivize research in these areas, just as the monopoly granted to patent recipients is supposed to incentivize research. However, unlike with IP, the prizewinning intervention would then enter the public domain and be producible by generic manufacturers, enabling its provision at a lower cost.¹⁰⁰ In fact, as Amy Kapczynski notes, patients like Phumeza may benefit more from pull programs than from limitations on IP rights.¹⁰¹ Another type of pull program is a patent buy-out, in which the patent rights to drugs that poor patients need would be bought out to enable generic production.¹⁰² “Push” programs, meanwhile, include grants that fund research.¹⁰³

Unlike IP systems, which incentivize innovation by granting monopolies, grants, prizes and patent buy-outs all need to be paid for in advance.¹⁰⁴ This makes them more politically challenging, but also more able to surmount pharmaceutical exceptionalism because paying for them requires identifying revenue sources. Push or pull programs could be funded by a variety of actors, including governments, international organizations, and NGOs. These actors could exhort wealthy firms like Gucci and Coca-Cola, as well as wealthy private individuals, to donate. Or, if politically feasible, governments or international organizations could impose taxes or fees that reach a variety of actors who have the ability to pay. Two such proposals are a financial transactions tax and a global wealth tax. Thomas Piketty has recently proposed a global wealth tax as a way of rectifying economic inequality.¹⁰⁵ However, such a tax could also be used to promote access to global health for the global poor. Unlike pharmaceutical-exceptionalist policies, a global wealth tax would treat pharmaceutical IP identically to other forms of property. It would align the burdens of the duty to assist with individuals’ capacity to assist. Another possibility would be a financial transactions tax, which imposes a small

100. Kapczynski, *supra* note 99, at 973 (“[A] government offers a financial reward to anyone who creates a desired invention—say, a vaccine. The inventor enjoys the benefit of the reward, and the government puts the information it has purchased in the public domain.”).

101. *Id.* at 998-99 (“It is no accident that the global access to medicines campaign and its focus on addressing patent barriers to medicines arose out of the HIV/AIDS movement. A large enough community of people living with HIV in wealthy countries existed to attract investment into new medicines to treat HIV. No similar interest exists in developing treatments for conditions such as extensively drug-resistant tuberculosis (TB)—the largest impact of which is felt in South Africa. No patent exception can give patients with this form of TB better access to simple and fast-acting medicines, because such medicines do not exist.”).

102. Kevin Outterson, *Patent Buy-Outs for Global Disease Innovations for Low- and Middle-Income Countries*, 32 AM. J.L. & MED. 159, 160–61 (2006).

103. W. Nicholson Price, *Grants*, 34 BERKELEY TECH. L.J. 1 (2019).

104. Wisser, *supra* note 98, at 273.

105. Saul Levmore, *Inequality in the Twenty-First Century*, 113 MICH. L. REV. 833, 850 (2015) (discussing THOMAS PIKETTY, CAPITAL 529 (2014)).

fee on stock trades and other transactions involving financial instruments.¹⁰⁶ Such a tax would not track ability to assist perfectly, as it would impose greater burdens on financial transactors than on wealthy individuals or firms who simply sit on their assets. However, it would be more equitable than pharmaceutical-exceptionalist approaches.

B. Contribution

A more modest way of moving away from pharmaceutical exceptionalism would be to continue imposing duties to aid on pharmaceutical IP holders, while creating a mechanism for them to seek contributions from those who hold other forms of property. This approach would resemble the right of contribution in the common law of torts, which permits a tortfeasor who is jointly liable for a harm to seek contribution from other tortfeasors. As a recent article explains,

Contribution arose as an equitable rule to ameliorate the perceived unfairness of holding one joint tortfeasor jointly and severally liable for all of an indivisible harm caused by multiple parties. The common law of contribution provides such a joint tortfeasor with a cause of action “to collect from others responsible for the same tort after the tortfeasor has paid more than his or her proportionate share.” A common law contribution plaintiff can recover if she proves a common liability with defendants and a payment to resolve that liability in excess of her equitable share.¹⁰⁷

While early common law did not provide for a right to contribution, most jurisdictions now do.¹⁰⁸ One prominent justification for permitting contribution is fairness — that it is inequitable to impose the full cost of a harm on only one among many parties who are jointly responsible for causing it.¹⁰⁹ The Supreme Court has recognized this fairness principle when discussing contribution.¹¹⁰ The imposition of responsibilities on pharmaceutical IP holders is arguably a case of liability for

106. Lawrence O. Gostin & Eric A. Friedman, *Towards A Framework Convention on Global Health: A Transformative Agenda for Global Health Justice*, 13 YALE J. HEALTH POL’Y, L. & ETHICS 1, 60–61 (2013) (suggesting financial transaction tax for funding global health); Kevin A. Klock, Note, *The Soft Law Alternative to the WHO’s Treaty Powers*, 44 GEO. J. INT’L L. 821, 846 (2013) (discussing a “financial transaction tax . . . meant to generate funds to support ‘health and health R&D relevant to developing countries’”); David Gartner, *Innovative Financing and Sustainable Development: Lessons from Global Health*, 24 WASH. INT’L L.J. 495, 508 (2015).

107. Justin R. Pidot & Dale Ratliff, *The Common Law of Liable Party CERCLA Claims*, 70 STAN. L. REV. 191, 239–40 (2018).

108. John H. Langmore & Robert H. Prentice, *Contribution Under Section 12 of the Securities Act of 1933: The Existence and Merits of Such A Right*, 40 EMORY L.J. 1015, 1020–21 (1991).

109. *Id.* at 1059–63.

110. *Cooper Stevedoring Co. v. Fritz Kopke, Inc.*, 417 U.S. 106, 111 (1974).

nonfeasance, rather than liability for misfeasance. Dividing liability for nonfeasance among multiple nonfeasant parties, however, is a recognized challenge.¹¹¹ Essentially, if holders of IP are responsible for the health deficits the global poor face, as the authors discussed in Part I argue, they should be permitted to seek contribution from others who are also failing to contribute to the realization of the right to health.¹¹²

The contribution-based approach could be implemented by allowing pharmaceutical IP holders to obtain contributions from others who share joint responsibility for global health deficits. This contribution could take the form of monetary transfers and could be obtained via traditional legal channels. Another way of implementing this contribution-based approach would be to permit pharmaceutical IP holders whose rights are abrogated to in turn abrogate the IP of other similarly situated actors. So, for instance, if both Gucci and a pharmaceutical IP holder have a duty to alleviate the problems of the global poor, but only the latter is facing the imposition of legal duties to aid, the pharmaceutical IP holder would in turn have a (potentially transferable) right to use Gucci's IP. Even if this sort of IP cascade is inefficient, it could serve as a penalty default that motivates a move toward a prize system or some other way of improving health care access for the global poor that distributes the burden of doing so more equitably.¹¹³

I use Gucci, of course, only as an example, and not to suggest that Gucci is uniquely deficient in its contribution to global health. A detailed analysis of how responsibility for global health deficits should be apportioned is beyond this Article's scope. However, the two most relevant factors in assigning responsibility to help are an actor's (a) affirmative contribution to deficits, and (b) its capacity to remedy deficits. Actors who affirmatively contribute to global health deficits might include, for instance, polluting industries and marketers of unhealthy foods or tobacco. Actors with the capacity to remedy deficits, meanwhile, will be those with substantial resources--whether fungible, like money, or non-fungible, like food or medicines. Gucci's substantial capacity to remedy deficits can justify imposing more substantial duties on it than on, for instance, a local fast food restaurant or trucking business, even if the latter two businesses make more obvious contributions to health deficits.

111. Harold F. McNiece & John V. Thornton, *Affirmative Duties in Tort*, 58 YALE L.J. 1272, 1288 (1949) ("Suppose A is in danger and fifty men are at hand to rescue him. Must all attempt the rescue under pain of liability?").

112. Cf. Liam Murphy, *Beneficence, Law, and Liberty: The Case of Required Rescue*, 89 GEO. L.J. 605, 623 (2001) ("If all fifty fail to rescue the one, then . . . they are all liable (though in this case we would add that the plaintiff can recover only once and that the enforced-against tortfeasor may seek contribution from the others).").

113. Cf. Ian Ayres & Robert Gertner, *Filling Gaps in Incomplete Contracts: An Economic Theory of Default Rules*, 99 YALE L.J. 87, 91-93 (1989).

C. An Expediency-Based Case for Pharmaceutical Exceptionalism

If neither broad-based funding for push and pull programs nor contribution prove politically feasible, we face the question of whether pharmaceutical exceptionalism is an acceptable, even if nonideal, policy approach. This Subpart will argue that pharmaceutical exceptionalist policies can be acceptable, but should be recognized as creatures of practical expediency rather than as fundamentally required by justice.

Why might pharmaceutical exceptionalism be more politically attractive than broad-based funding for access to medicines? One reason is that the legal incidence of exceptionalist policies falls on a small and unpopular set of actors (pharmaceutical IP holders), rather than middle-class taxpayers.¹¹⁴ Another is that pharmaceutical exceptionalist policies provide in-kind benefits to poor patients that can neither be misspent nor redirected to other social priorities.¹¹⁵ These factors make pharmaceutical exceptionalism analogous to other policy choices, such as the preference for regulatory mandates rather than taxes, that are criticized as inefficient by scholars and “policy wonks” but frequently implemented in practice.¹¹⁶ One analogue for pharmaceutical exceptionalism is the effort to improve housing affordability via inclusionary zoning requirements imposed on developers, rather than via taxpayer-subsidized housing vouchers. Commentators have criticized inclusionary zoning for treating developers unfairly and for creating perverse incentives:

If people knew that landowners had to bear the cost of providing affordable housing, the policy might be considered unfair or even a taking because landowners have no more responsibility to pay the full cost of social policies than anyone else. If people knew that market-rate home buyers had to bear the cost of providing affordable housing, the policy also might be considered counterproductive because rather than creating more affordable

114. Cf. Edward J. McCaffery & Jonathan Baron, *The Political Psychology of Redistribution*, 52 UCLA L. REV. 1745, 1761, 1782 (2005) (hypothesizing and confirming that people prefer “hidden” taxes that initially fall on a third party (e.g. corporate taxes) to taxes that initially fall on individuals).

115. Cf. Johanna Brenner, *Towards A Feminist Perspective on Welfare Reform*, 2 YALE J.L. & FEMINISM 99, 105 (1989) (“While popular attitudes toward welfare are generally negative, voters tend to prefer in-kind benefits to cash handouts.”).

116. Cf. Thomas Merrill & David M. Schizer, *Energy Policy for an Economic Downturn: A Proposed Petroleum Fuel Price Stabilization Plan*, 27 YALE J. ON REG. 1, 27 (2010) (“Given . . . infrastructural and political realities, there is no mystery why command and control strategies succeed politically while Pigouvian taxes fail. The costs of regulations are not explicitly tied to the regulatory mandate, but instead are quietly passed on by manufacturers in the form of higher prices or lower wages and investment returns[.]”).

housing, the policy would be making the majority of homes more expensive.¹¹⁷

Despite these criticisms, inclusionary zoning is popular and widely used.¹¹⁸ Its popularity likely reflects the fact that it can be implemented without imposing visible burdens on taxpayers.¹¹⁹

Assuming that pharmaceutical exceptionalism is politically tenable, three concepts are useful in assessing its desirability: vertical equity, horizontal equity, and efficiency. Vertical equity is achieved by appropriately responding to different actors' economic circumstances, and is often associated with policies that impose lesser burdens on the disadvantaged.¹²⁰ Horizontal equity is achieved by treating like actors alike.¹²¹ Efficiency is achieved by enlarging the total sum of societal resources.¹²² While these concepts are most familiar in tax policy, they have also been used to analyze, *inter alia*, real estate regulation and health policy.¹²³

Pharmaceutical exceptionalist policies typically advance vertical equity, because they transfer entitlements from wealthier pharmaceutical firms to the global poor. However, as Part II argued, they violate horizontal equity, because

117. Benjamin Powell & Edward Stringham, "The Economics of Inclusionary Zoning Reclaimed": How Effective Are Price Controls?, 33 FLA. ST. U. L. REV. 471, 483 (2005); see also Jai Keep-Barnes, *Inclusionary Zoning as a Taking: A Critical Look at Its Ability to Provide Affordable Housing*, 49 URB. LAW. 67, 100 (2017) (similar); Robert C. Ellickson, *The Irony of "Inclusionary" Zoning*, 54 S. CAL. L. REV. 1167, 1184-85 (1981).

118. Keaton Norquist, *Local Preferences in Affordable Housing: Special Treatment for Those Who Live or Work in A Municipality?*, 36 B.C. ENVTL. AFF. L. REV. 207, 208 (2009) (stating that "[o]ne of the most popular and effective solutions" to lack of affordable housing "has been the enactment of inclusionary zoning ordinances requiring residential developers to set aside a specified percentage of new units — often ten to fifteen percent — which must be sold or rented at prices deemed affordable to low- and moderate-income households"); Cecily T. Talbert et. al., *Recent Developments in Inclusionary Zoning*, 38 URB. LAW. 701, 706 (2006) (similar).

119. See Paul Boudreaux, *Infill: New Housing for Twenty-First-Century America*, 45 FORDHAM URB. L.J. 595, 632 (2018) (observing that inclusionary zoning is "perhaps the most popular mechanism to ensure the creation of permanent new low-cost housing," and that its popularity may reflect its implementability without "financial expenditures by the government, in contrast to techniques such as subsidies, tax breaks, and duties to provide fair shares" because "[t]he expenses of providing low-cost housing are borne by housing developers.").

120. Nancy C. Staudt, *The Hidden Costs of the Progressivity Debate*, 50 VAND. L. REV. 919, 933 (1997) ("[V]ertical equity entails appropriately differentiating among individuals in dissimilar economic circumstances."); Vernellia R. Randall, *Racist Health Care: Reforming an Unjust Health Care System to Meet the Needs of African-Americans*, 3 HEALTH MATRIX 127, 165 (1993) ("Vertical equity suggests that a good policy proposal is one that favors the have-nots over the haves in the distribution of benefits.").

121. Robert C. Ellickson, *Suburban Growth Controls: An Economic and Legal Analysis*, 86 YALE L.J. 385, 415 (1977) ("Horizontal equity requires government to treat like persons alike.").

122. Randall, *supra* note 120, at 165.

123. See Ellickson, *supra* note 121; Randall, *supra* note 120.

there is no compelling basis for treating pharmaceutical IP holders as more responsible for the plight of poor patients than other firms or wealthy individuals are. Pharmaceutical exceptionalism's effects on efficiency, meanwhile, are unclear: although exceptionalist policies create perverse incentives to avoid investment in pharmaceutical research, current intellectual property law contains its own suboptimal incentives.¹²⁴

When vertical and horizontal equity conflict, it can be acceptable to violate horizontal equity in order to achieve vertical equity.¹²⁵ To the extent that it can genuinely improve vertical equity, pharmaceutical exceptionalism represents this sort of allowable violation. In taking this position, this Article parts company with recent commentators who worry about unfairness to pharmaceutical firms. For example, Rebecca Wolitz has worried that

Without additional argument, it seems unfair to single out biopharmaceutical companies to sacrifice their profits or products to rescue others. Why not say that other groups . . . have an obligation of rescue to pitch in and pony up? Why effectively impose a moral tax on a particular industry merely qua that industry being that industry?¹²⁶

Other commentators assert that society should not require pharmaceutical companies to help the poor unless everyone with comparable ability to pay is also required to do so.¹²⁷ These objections go wrong by allowing the perfect to be the

124. See Rachel Sachs, *The Uneasy Case for Patent Law*, 117 MICH. L. REV. 499, 544-45 (2018) (observing that innovation in microbiome technology has proceeded without the need for patent protection); Hannah Brennan et. al., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J. L. & TECH. 275, 295 (2016) (contending that the patent system's conferral of monopoly power on patent-holders produces avoidable "deadweight loss"); Peter K. Yu, *The International Enclosure Movement*, 82 IND. L.J. 827, 898 (2007) (arguing that "there is insufficient empirical evidence to warrant the recent expansion of intellectual property rights").

125. Cf. LIAM MURPHY & THOMAS NAGEL, *THE MYTH OF OWNERSHIP: TAXES AND JUSTICE* 170-72 (2002); Zachary Liscow, *Reducing Inequality on the Cheap: When Legal Rule Design Should Incorporate Equity As Well As Efficiency*, 123 YALE L.J. 2478, 2501 (2014) ("Arguing for the unimportance of horizontal equity is the idea that the government should take the opportunity to distribute an entitlement to the poor at a low efficiency cost because the poor need the money . . . [C]riticizing aiding some of the poor but not others amounts to holding the desperately needed aid for the poor hostage to the desire to help all of the poor.").

126. Wolitz, *supra* note 76, at 1204.

127. Anita Ho, *Global Health Disparity and Pharmaceutical Companies' Obligation to Assist*, in PHILOSOPHICAL ISSUES IN PHARMACEUTICS 29, 36 (Dien Ho ed., 2017) (suggesting that "holding only pharmaceutical companies responsible without calling upon other industries to assist under the duty of rescue is going too far and unfair to drug companies"); Pepe Lee Chang, *Who's in the Business of Saving Lives?*, 31 J. MED. & PHIL. 465, 476 (2006) ("If we do not require other types of corporations to save lives then we should not require drug companies to do so.").

enemy of the good. Just as “[t]here would be nothing unfair . . . in a tax on chocolate ice cream but not on vanilla, though it would be arbitrary,”¹²⁸ there similarly is nothing fundamentally unfair about taxing pharmaceutical IP holders while not taxing others who have equal ability to pay. (Although — as Part II argues — there is also nothing fundamentally just about taxing pharmaceutical IP holders either.) Courts are rightly reluctant to find that violations of horizontal equity constitute violations of the right to equal protection.¹²⁹ Instead, courts typically find that governments are permitted to tax and regulate in overinclusive or underinclusive ways, so long as there is a rational relationship between the objective and the means selected to achieve that objective.¹³⁰ Even though pharmaceutical exceptionalism is often suboptimal from both fairness and efficiency perspectives, it can be justified where fairer or more efficient policy options are politically or practically impossible.

CONCLUSION

I have reviewed the arguments for and against pharmaceutical exceptionalism and found much to doubt in both. Ultimately, this Article disagrees with pharmaceutical exceptionalism’s most vehement advocates, but also with its most vehement critics. Pharmaceutical IP holders — like developers subjected to inclusionary zoning requirements — have no special moral obligation to assist the disadvantaged: their duties are the same as those of anyone else who can help, including firms like Gucci and Coca-Cola. But — as with developers — even though pharmaceutical IP holders have no special *moral* obligation to help, it can be acceptable to task them with a special *legal* obligation to do so. The imposition of such a legal obligation is analogous to the creation of other civil obligations that track no antecedent moral rule.¹³¹

Whether it is wise to require pharmaceutical IP holders to assist poor patients depends on what the available alternatives are, and what the consequences of

128. MURPHY & NAGEL, *supra* note 125, at 170.

129. Stephen W. Mazza & Tracy A. Kaye, *Restricting the Legislative Power to Tax in the United States*, 54 AM. J. COMP. L. 641, 656 (2006) (“The Court’s reluctance to second guess a legislature’s decision has led it to establish a high threshold in order to find a tax provision unconstitutional on equal protection grounds.”); John A. Swain, *The Taxation of Private Interests in Public Property: Toward a Unified Theory of Property Taxation*, 2000 UTAH L. REV. 421, 436 (2000) (“[T]ax laws can be highly discriminatory (horizontally inequitable) and still pass Equal Protection muster.”).

130. *Williamson v. Lee Optical, Inc.*, 348 U.S. 483, 489 (1955) (“[R]eform may take one step at a time, addressing itself to the phase of the problem which seems most acute to the legislative mind . . . The legislature may select one phase of one field and apply a remedy there, neglecting the others.” (citing *Semler v. Oregon State Board of Dental Examiners*, 294 U.S. 608 (1935) and *Am. Fed’n of Labor v. Am. Sash & Door Co.*, 335 U.S. 538 (1949))).

131. *See, e.g., H.L.A. HART, THE CONCEPT OF LAW* 68 (2d ed. 1994) (“There can be legal rights and duties which have no moral justification or force whatever.”).

imposing such an obligation would be. While the arbitrary treatment of pharmaceutical IP holders is not a sufficient reason to reject pharmaceutical exceptionalism, decreases in long-term innovation and ensuing losses for future patients would be. The risk of such an outcome can only be determined by empirical analysis.

This Article's conclusion, then, is that pharmaceutical exceptionalism should neither be reviled nor exalted, but instead should be recognized as resting on pragmatic and contingent, rather than principled, foundations. It is, fundamentally, a kludge.¹³² As with any other kludge, we should recognize and examine the short-term risks of eliminating it, but also investigate whether some more elegant alternative will serve us better in the long run.

132. See D. Casey Flaherty, *Copy, Paste, Repeat . . . No More*, ACC ASS'N OF CORP. COUNS. DOCKET, Sept. 2014, at 128, 128 ("A kludge is a crude workaround, an assortment of poorly matching parts that form a sub-optimal but serviceable whole. A kludge is often the outcome of jury-rigging -- in the nautical, rather than the courtroom, sense -- a semi-functional contrivance made from materials that happen to be on hand."); Mark A.R. Kleiman, *Is "Medical Marijuana" an Idea Whose Time has Come - and Gone?*, 13 CONN. PUB. INT. L.J. 173, 175 (2014) ("Allowing for medical use of an otherwise-banned drug that has not passed through the usual drug-approval process is no doubt a regulatory kludge, but it is arguably the "least-bad" of the politically and operationally available options.").

More Prices, More Problems: Challenging Indication-Specific Pricing as a Solution to Prescription Drug Spending in the United States

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ABSTRACT

In the United States, high prices of prescription drugs and rapidly increasing prescription drug spending have caused public outrage and calls for action. There is bipartisan acknowledgement of the problem by lawmakers, but no agreement on how to fix it. Value-based pricing models have gained increasing support and have been suggested as one possible solution to controlling prescription drug spending. One proposed value-based pricing model is indication-specific pricing: linking the price of a multi-indication prescription drug with the indication for which it is prescribed to a patient. Indication-specific pricing is intended to incentivize using higher-value treatments and allocating prescription drugs to patients who will receive the greatest benefit. However, there are many barriers to implementing indication-specific pricing in federal health insurance programs in the United States. Further, as a policy matter, indication-specific pricing would likely not decrease overall prescription drug spending and could worsen the accessibility and affordability of prescription drugs. This Note argues that lawmakers should not pursue an indication-specific pricing regime as a means to decrease prescription drug spending. Instead, lawmakers seeking prescription drug reform should consider methods that will more likely decrease prescription drug prices and spending while also ensuring patients' access to medicines.

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INTRODUCTION

The high cost of prescription drugs is a matter of serious concern in the United States. Several drug pricing scandals have elicited public outrage.¹ Gilead Sciences priced a twelve-week course of treatment for its first two hepatitis C treatments, Sovaldi and Harvoni, at \$84,000 and \$94,500 respectively.² Turing Pharmaceuticals raised the price of Daraprim, a treatment for toxoplasmosis, by 5,000 percent, from \$13.50 to \$750 per pill, immediately after acquiring rights to the drug.³ Many new cancer drugs have been released and priced at hundreds of thousands of dollars per year.⁴ Amgen's cancer drug Blincyto was approved in 2014 at a price of \$178,000⁵ and Novartis' cancer treatment Kymriah was approved in 2017 at a price of \$475,000.⁶ The average cancer drug now costs four times the average household income.⁷ Unaffordable prescription drugs can lead to patient non-adherence, worsening health outcomes and increasing use and cost of

1. See, e.g., Peter J. Neumann & Joshua T. Cohen, *Measuring the Value of Prescription Drugs*, 373 NEW ENG. J. MED. 2595, 2595 (2015) (“Escalating drug prices have alarmed physicians and the American public and led to calls for government price controls.”); Charles Ornstein & Katie Thomas, *Prescription Drugs May Cost More With Insurance Than Without It*, N.Y. TIMES (Dec. 9, 2017), <https://www.nytimes.com/2017/12/09/health/drug-prices-generics-insurance.html> (describing the current time period as “an era when drug prices have ignited public outrage and insurers are requiring consumers to shoulder more of the costs”); Andrew Pollack, *High Cost of Sovaldi Hepatitis C Drug Prompts a Call to Void Its Patents*, N.Y. TIMES (May 19, 2015), <https://www.nytimes.com/2015/05/20/business/high-cost-of-hepatitis-c-drug-prompts-a-call-to-void-its-patents.html> (on Sovaldi scandal) [hereinafter Pollack, *High Cost*]; Andrew Pollack, *Drug Goes From \$13.50 a Tablet to \$750, Overnight*, N.Y. TIMES (Sept. 20, 2015), <https://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html> (on Daraprim scandal) [hereinafter Pollack, *\$750 Overnight*].

2. See; Carolyn Y. Johnson & Brady Dennis, *How an \$84,000 drug got its price: 'Let's hold our position ... whatever the headlines'*, WASH. POST (Dec. 1, 2015), https://www.washingtonpost.com/news/wonk/wp/2015/12/01/how-an-84000-drug-got-its-price-lets-hold-our-position-whatever-the-headlines/?utm_term=.68eea7c17de8.

3. See Pollack, *\$750 Overnight*, *supra* note 1.

4. See SUSAN DENTZER & TOM HUBBARD, VALUE-BASED CONTRACTING FOR ONCOLOGY DRUGS: A NEHI WHITE PAPER 10, 11 (2017) (discussing Keytruda, a \$150,000 per year treatment for metastatic melanoma, and Kymriah, a \$475,000 personalized treatment for pediatric and adult patients with a type of acute lymphoblastic leukemia); Emily K. White, *Killing U.S. Slowly: Curing the Epidemic Rise of Cancer Drug Prices*, 72 FOOD AND DRUG L. J. 189, 191 (2017) (“Over the past fifteen years, the average price of a cancer drug has increased ten to fifteen times, costing patients over \$100,000 a year in 2012.”).

5. See White, *supra* note 4, at 191.

6. See Denise Grady, *F.D.A. Approves First Gene-Altering Leukemia Treatment, Costing \$475,000*, N.Y. TIMES (Aug. 30, 2017), <https://www.nytimes.com/2017/08/30/health/gene-therapy-cancer.html>.

7. Julia Belluz, *The Nobel Prize is a reminder of the outrageous cost of curing cancer*, VOX (Oct. 2, 2018), <https://www.vox.com/science-and-health/2018/10/1/17923720/immunotherapy-cancer-cost>.

other health services.⁸

The problem of high prescription drug prices goes far beyond these few surprising examples. On average the United States spends twice as much as other countries on prescription drugs.⁹ Prescription drug spending accounted for approximately 17 percent of all healthcare spending in 2015 and is the fastest growing portion of the healthcare budget.¹⁰ Total prescription drug spending in the United States rose 12 percent in 2015 and another 6 percent in 2016, reaching \$450 billion.¹¹ These high and increasing prices are a result of several factors, including the higher prices paid for prescription drugs under patent compared to generics, weaker negotiating power of federal government payers, and rapid adoption of newly released prescription drugs in the United States.¹²

When polled in 2015, the public expressed that its top health policy priority

8. See White, *supra* note 4, at 190 (explaining the strategic choices of the pharmaceutical industry “have also left many Americans unable to afford their medications; particularly patients who are elderly, socioeconomically disadvantaged, or suffer from chronic diseases.”); Steven G. Morgan & Augustine Lee, *Cost-related non-adherence to prescribed medicines among older adults: a cross-sectional analysis of a survey in 11 developed countries*, *BMJ OPEN* 1, 1 (2017); Peter B. Bach & Steven D. Pearson, *Payer and Policy Maker Steps to Support Value-Based Pricing for Drugs*, 314 *J. AM. MED. ASS’N* 2503, 2503 (2015); Aurel O. Iuga & Maura J. McGuire, *Adherence and health care costs*, 7 *RISK MGMT. AND HEALTHCARE POL’Y* 35, 37 (2014) (“Between \$100 and \$300 billion of avoidable health care costs have been attributed to nonadherence in the US annually, representing 3% to 10% of total US health care costs.”).

9. See Margot Sanger-Katz, *Prescription Drug Costs Are Rising as a Campaign Issue*, *THE UPSHOT* (Sept. 21, 2015), <https://www.nytimes.com/2015/09/22/upshot/prescription-drug-costs-are-rising-as-a-campaign-issue.html>. See also DAVID O. SARNAK ET AL., *PAYING FOR PRESCRIPTION DRUGS AROUND THE WORLD: WHY IS THE U.S. AN OUTLIER?* 2 (2017). Interestingly, this is not the case for generic drugs, which are cheaper in the United States. See Tal Gross & Miriam J. Laugesen, *The Price of Health Care: Is the United States an Outlier?*, 42 *J. HEALTH POLITICS, POL’Y & L.* 771, 774 (2018). Humira, which costs on average \$2,669 for a 28-day supply in the United States, costs just \$1,362 in the United Kingdom and \$822 in Switzerland. THE PEW CHARITABLE TRUSTS, *PAYMENT POLICIES TO MANAGE PHARMACEUTICAL COSTS: INSIGHTS FROM OTHER COUNTRIES* 9 (Mar. 2017). Similarly, Harvoni, which costs on average \$32,114 for a 28-day supply, costs \$22,554 in the United Kingdom and \$16,861 in Switzerland. *Id.*

10. AARON BERMAN ET AL., *CURBING UNFAIR DRUG PRICES: A PRIMER FOR STATES* 4 (Aug. 2017). In 2014, after a period of relatively stable drug spending, prescription drug spending in the United States increased by 12 percent when adjusted for inflation. See Sanger-Katz, *supra* note 10.

11. Aaron S. Kesselheim, *Health Law Year in P/Review: Prescription Drug Prices* (Dec. 12, 2017), <https://vimeo.com/247814795#t=27m14s>.

12. THE PEW CHARITABLE TRUSTS, *supra* note 9, at 9-10; Aaron S. Kesselheim et al., *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 *J. AM. MED. ASS’N* 858, 860 (2016) (“Drug prices are higher in the United States than in the rest of the industrialized world because, unlike that in nearly every other advanced nation, the US health care system allows manufacturers to set their own price for a given product.”). New prescription drugs often enter the market at extremely high prices: the average price of a new drug or biologic in 2016 was over \$17,000 per month. See EXPRESS SCRIPTS, *PRESCRIPTION DRUG PRICING: A PUBLIC POLICY ANALYSIS* 5 (Feb. 2017).

was making prescription drugs more affordable.¹³ Since then, politicians from both sides of the aisle have called for prescription drug pricing reform.¹⁴ President Trump has asserted that he and Secretary of Health and Human Services Azar will decrease the price of prescription drugs.¹⁵ Since then, the Trump Administration has made various proposals to combat high prescription drug prices. In his first proposal, President Trump focused on the high list prices, the lack of negotiating tools, high out-of-pocket costs, and the lower prices for drugs in other countries.¹⁶ Another proposal suggested decreasing prescription drug prices and spending under Medicare Part B by changing the way physicians pay for and are reimbursed for drugs.¹⁷

The federal government has shown interest in exploring value-based payment

13. Erin Trish et al., *Medicare Beneficiaries Face Growing Out-Of-Pocket Burden For Specialty Drugs While In Catastrophic Coverage Phase*, 35 HEALTH AFF. 1564, 1564 (2016) (“the public’s top health policy priority for the president and Congress is ‘making sure that high-cost drugs are affordable to those who need them.’” (quoting *Kaiser Health Tracking Poll: October 2015*, KAISER FAM. FOUND. (Oct. 28, 2015), <https://www.kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-october-2015/>). See also Karen Van Nuys et al., *Reining in pharmaceutical costs*, BROOKINGS (Aug. 3, 2017), <https://www.brookings.edu/blog/up-front/2017/08/03/reining-in-pharmaceutical-costs/> (“Most Americans believe that President Trump and the Congress should make lowering the cost of prescription drugs a priority.”); THE COUNCIL OF ECONOMIC ADVISERS, *REFORMING BIOPHARMACEUTICAL PRICING AT HOME AND ABROAD I* (Feb. 2018).

14. See, e.g., Katie Thomas, *The Fight Trump Faces Over Drug Prices*, N.Y. TIMES (Jan. 23, 2017), <https://www.nytimes.com/2017/01/23/health/the-fight-trump-faces-over-drug-prices.html> (“During the campaign, Mr. Trump joined his Democratic opponents, Mr. Sanders and Hillary Clinton, in calling for the federal government to be allowed to negotiate the price of drugs.”); Rachel Sachs et al., *Innovative Contracting for Pharmaceuticals and Medicaid’s Best-Price Rule*, 42 J. HEALTH POLITICS, POL’Y & L. 5, 5 (2017) (“Even in today’s polarized political landscape, a consensus has emerged: Americans deserve better value for their health care dollars. The focus on value sits well with liberals and conservatives, health insurers and pharmaceutical manufacturers, and a host of disparate stakeholder groups.”).

15. Ike Swelitz, *Trump says new health secretary will ‘get those prescription prices way down,’* STAT (Jan. 29, 2018), <https://www.statnews.com/2018/01/29/trump-azar-drug-prices/>; Katie Thomas & Reed Abelson, *Lower Drug Prices: New Proposals Carry Lots of Promises*, N.Y. TIMES (Feb. 9, 2018), <https://www.nytimes.com/2018/02/09/health/trump-drug-prices-medicare.html>. Former Food and Drug Administration Commissioner Scott Gottlieb has also expressed concern over high prescription drug prices and has been clearer with proposed policy solutions, including faster regulatory approvals and promoting increased generic drug market entry. See Sarah Jane Tribble & Liz Szabo, *FDA vows to combat high drug prices and companies ‘gaming the system,’* CNN MONEY (Feb. 16, 2018), <http://money.cnn.com/2018/02/16/news/economy/fda-drug-prices/index.html>; Nathaniel Weixel, *FDA chief becomes point man on drug prices*, THE HILL (Mar. 14, 2018), <http://thehill.com/business-a-lobbying/business-a-lobbying/378254-fda-chief-becomes-point-man-on-drug-prices>.

16. See generally U.S. DEP’T HEALTH & HUMAN SERVS., *AMERICAN PATIENTS FIRST: THE TRUMP ADMINISTRATION BLUEPRINT TO LOWER DRUG PRICES AND REDUCE OUT-OF-POCKET COSTS* (2018) (hereinafter *AMERICAN PATIENTS FIRST*) (outlining President Trump’s drug pricing priorities).

17. See Rachel Sachs, *Administration Outlines Plan To Lower Pharmaceutical Prices In Medicare Part B*, HEALTH AFF. BLOG (Oct. 26, 2018), <https://www.healthaffairs.org/doi/10.1377/hblog20181026.360332/full/>.

models to reform prescription drug pricing. The Department of Health and Human Services suggested value-based pricing, including indication-specific pricing, as possible opportunities to decrease high prescription drug prices. With a growing number of prescription drugs indicated for the treatment of several different conditions, especially in oncology,¹⁸ indication-specific pricing, one type of value-based pricing model, has received increased attention as a potential solution to high prescription drug prices.¹⁹

Indication-specific pricing, sometimes called indication-based pricing, is a value-based payment scheme where a prescription drug used to treat multiple conditions is priced based on the condition for which it is prescribed.²⁰ Indication-specific pricing sets higher prices for higher-value indications, and lower prices for lower-value indications.²¹ This scheme intends for prescription drug prices to better reflect value received by an individual patient.²² Despite its intent, an indication-specific pricing model may not actually accomplish the overarching policy goal of decreasing prescription drug spending and prices.²³ Further, there are several significant legal, regulatory, and policy barriers to implementing indication-specific pricing in the United States healthcare system.²⁴ This Note, therefore, will argue that lawmakers should not pursue an indication-specific pricing regime and should instead consider other methods to control prescription

18. See Peter B. Bach, *Indication-Specific Pricing for Cancer Drugs*, 312 J. AM. MED. ASS'N 1629, 1629 (2014). See generally STEPHEN D. PEARSON ET AL., INDICATION-SPECIFIC PRICING OF PHARMACEUTICALS IN THE UNITED STATES HEALTH CARE SYSTEM: A REPORT FROM THE 2015 ICER MEMBERSHIP POLICY SUMMIT (Mar. 2016) (analyzing the potential for implementing an indication-specific pricing regime in the United States).

19. See also Tara O'Neill Hayes, *Current Impediments to Value-Based Pricing for Prescription Drugs*, AM. ACTION F. (June 12, 2017), <https://www.americanactionforum.org/research/current-impediments-value-based-pricing-prescription-drugs/> (“With the unprecedented number of specialty medicines and oncology treatments expected over the next few years, the cost of prescription drugs will continue to be a concern for all stakeholders. QuintilesIMS Institute finds that 28 percent of new drugs currently being developed are oncology medicines, and nearly half of all drug spending in the U.S. will be for specialty medicines by 2021.”).

20. See PEARSON ET AL., *supra* note 18, at 2 (defining indication-specific pricing as “setting different prices for different indications or for distinct patient subpopulations eligible for treatment with a medication.”).

21. See Amitabh Chandra & Craig Garthwaite, *The Economics of Indication-Based Drug Pricing*, 377 NEW ENG. J. MED. 103, 103-04 (2017).

22. See *id.*

23. See *id.* (“relative to uniform pricing, indication-[specific] pricing results in higher prices for patients who benefit the most, higher utilization by patients who benefit least, higher overall spending, and higher manufacturer profits”). See also Part III, *infra*.

24. See generally PEARSON ET AL., *supra* note 18 (analyzing the potential for implementing an indication-specific pricing regime in the United States and discussing the legal, regulatory, and policy barriers to implementation).

drug prices and spending.²⁵

Part I provides background on value-based pricing models and defines indication-specific pricing of prescription drugs. Part II identifies and describes the legal and regulatory barriers to indication-specific pricing under Medicare, Medicaid, the 340B Drug Discount Program, and the Veterans Health Administration program. Part III presents the policy incentives raised by indication-specific pricing of prescription drugs in federal health insurance programs and discusses how it would impact the FDA regulatory system, off-label prescribing and promotion, and prescription drug prices. Ultimately, Part III argues that lawmakers should explore other methods, instead of indication-specific pricing, to decrease prescription drug prices and spending. Part IV suggests alternatives to indication-specific pricing that could be considered, introduces some initiatives that have already been raised, and recommends next steps for lawmakers.

I. VALUE-BASED PRICING MODELS AND INDICATION-SPECIFIC PRICING

A. *Value-Based Pricing of Prescription Drugs*

Currently in the United States, prescription drugs are generally reimbursed in a fee-for-service model.²⁶ Insurance companies reimburse per unit of the prescription drug without regard to outcome, indication, value to the patient, or any other factors. Critics of this payment model stress that not all patients receive the same benefit or value from a prescription drug even though they pay the same amount as patients who do benefit.²⁷ To avoid paying for ineffective treatments and to lower prescription drug prices, some advocates propose value-based pricing models.

Value-based pricing models link the price paid for a prescription drug with the expected or actual benefit to the patient.²⁸ There are several different types of

25. As the majority of prescription drugs for which indication-specific pricing is being proposed are high-priced brand name drugs with no generic alternative, typically for cancer treatment or other rare diseases, *see generally* Bach, *supra* note 18 (discussing indication-specific pricing for cancer drugs), this Note will focus only on the issues presented by indication-specific pricing of brand-name prescription drugs.

26. *See* Gregory Daniel et al., *Advancing Gene Therapies and Curative Health Care Through Value-Based Payment Reform*, HEALTH AFF. BLOG (Oct. 30, 2017), <https://www.healthaffairs.org/doi/10.1377/hblog20171027.83602/full/>. This is sometimes referred to as a “price-per-dose basis.” *See* Sachs et al., *supra* note 14, at 5.

27. *See* Sachs et al., *supra* note 14, at 6 (“[M]any patients receive little or no benefit from their prescription drugs—yet they pay precisely the same amount as those who do benefit.”).

28. *See* Daniel et al., *supra* note 26 (“[Value-based payment models] are designed to link payment more explicitly to a treatment’s value, expected or realized.”). *See generally* Sachs et al., *supra* note 14, at 7-14 (discussing how different value-based payment models work for prescription drugs).

value-based pricing models, differentiated based on the types of value measured (considering various contexts, benchmarks, or outcomes) in the model.²⁹ Value-based pricing models apply the determination of value to ultimately calculate the value-based price. The overall goal of value-based pricing is to incentivize providers to choose higher value, more effective prescription drugs, resulting in better outcomes for patients and lower overall healthcare spending.³⁰ Value-based pricing models therefore also encourage manufacturers to develop more effective and more profitable prescription drugs.

While the general concept of value-based pricing is simple, determining the value-based price of a prescription drug is exceedingly challenging. Most difficult is deciding what constitutes value and what factors represent this definition of value.³¹ Value is typically considered to be “the benefit of a treatment with respect to its cost,”³² but various factors must be taken into account in calculating the magnitude of this benefit with respect to cost. The determination of value can be made with respect to an individual patient (did this specific patient receive the intended benefit from this prescription drug?), to a sub-population (did the sub-population with a specific characteristic receive the intended benefit?),³³ or to a population as a whole (did this prescription drug lower the overall mortality or improve a health outcome to a predetermined benchmark related to clinical trial demonstrations?).³⁴ The value could be based on clinical measures, for example, a final treatment outcome, achieving a benchmark outcome in the course of treatment, or the disease requiring treatment.³⁵ This value could also be more subjective and include patient-centered benchmarks, such as patient satisfaction, increased quality of life, or decreased pain.

29. This Note focuses on indication-specific pricing, discussed in detail in Part I.B, *infra*. Other types of value-based payment models include outcome-based payment, drug licenses, and drug mortgages. For a detailed description of these value-based payment models, see Sachs et al., *supra* note 14, at 10-14.

30. See Daniel et al., *supra* note 26.

31. See *id.* at 2595-97 (“Value is an elusive target, and there’s no consensus about what dimensions should be taken into account.”). Several organizations have developed their own methodologies of evaluating prescription drugs and calculating their value to patients. See *id.* For example, Memorial Sloan Kettering Cancer Center’s framework focuses on the cancer drug’s mode of action, efficacy, and toxicity. *Id.* By contrast, the Institute for Clinical and Economic Review’s framework primarily looks at a prescription drug’s cost effectiveness in terms of cost per quality-adjusted life year and overall budget impact, but also looks at clinical effectiveness and other benefits in context. *Id.*

32. Bach, *supra* note 18, at 1629.

33. See *id.* (“What is the right price for any particular level of benefit? How should benefit be determined? What if the condition is rare? What if the average benefit is small but a subgroup of patients derives a large benefit?”).

34. See Hayes, *supra* note 19 (describing value-based payment agreements where the benchmarks were based on the results observed in clinical trials).

35. See Sachs et al., *supra* note 14, at 10-14 (discussing types of value-based pricing models).

B. Indication-Specific Pricing of Prescription Drugs

Prescription drugs are often used to treat more than one disease state or indication.³⁶ For example, Keytruda treats two different types of cancers and Avastin treats both cancer and macular degeneration.³⁷ However, despite the varied effectiveness of individual prescription drugs for different indications, prescription drug companies must charge the same price for the prescription drug regardless of the indication for which it is prescribed to a patient.

Indication-specific pricing would change this scheme by linking the price of the prescription drug to the condition for which it was prescribed.³⁸ In indication-specific pricing models, prescription drug manufacturers are paid more when their prescription drug is used to treat an indication for which the product is more effective or has a higher value (high-value indications) than when it is used to treat an indication for which the product is less effective or has a lesser value for the patient (low-value indications).³⁹ For example, in an indication-specific pricing regime, Keytruda would cost a different price when it is prescribed for the treatment of advanced non-small cell lung cancer than it is for advanced melanoma, based on its effectiveness in treating the condition.⁴⁰ The determinations of value or effectiveness are typically based on the data collected during clinical trials.⁴¹ Depending on an individual's prescription drug coverage, these higher prices for high-value indications are likely less affordable and less accessible as a result.⁴² Conversely, indication-specific pricing sets lower prices for lower-value indications, resulting in them being more affordable, more accessible, and used more by patient populations who receive a comparatively lesser benefit from them.⁴³ Indication-specific pricing models can be a pure indication-specific pricing regime, meaning that each different indication has a different price, or a partially indication-specific pricing regime, generally meaning

36. See PEARSON ET AL., *supra* note 18, at 6 (“A multi-indication medication is a drug that is approved or prescribed for more than one condition or for a single condition with multiple identifiable patient sub-groups that have important differences in baseline risk and/or treatment outcomes.”); Chandra & Garthwaite, *supra* note 21, at 103 (“in oncology, for instance, response to a treatment varies with the type of tumor and stage of disease.”).

37. See Sachs et al., *supra* note 14, at 7-8.

38. See Sachs et al., *supra* note 14, at 7-8; Chandra & Garthwaite, *supra* note 21, at 103; PEARSON ET AL., *supra* note 18, at 2 (defining indication-specific pricing as “setting different prices for different indications or for distinct patient subpopulations eligible for treatment with a medication.”).

39. See Chandra & Garthwaite, *supra* note 21, at 103.

40. See Sachs et al., *supra* note 14, at 7-8; KEYTRUDA © (pembrolizumab), KEYTRUDA.COM (Nov. 2017), <https://www.keytruda.com> (listing the FDA-approved indications of Keytruda)

41. Hayes, *supra* note 19.

42. See Chandra & Garthwaite, *supra* note 21, at 103-04.

43. See *id.*

that indication-specific prices are combined into a weighted-average price.⁴⁴

Some countries have implemented indication-specific pricing regimes for prescription drugs, either in part or in a pure form.⁴⁵ Italy has adopted a pure indication-specific pricing regime for some prescription drugs, including some cancer drugs and an anti-inflammatory prescription drug, through the use of managed entry agreements.⁴⁶ Managed entry agreements are contracts between payers and a pharmaceutical company that allows a prescription drug to be covered subject to certain conditions.⁴⁷ Italy permits three types of managed entry agreements, each involving some sort of refund to the payer for insufficient outcomes.⁴⁸ Some of these managed entry agreements consider different outcomes (and thus different refunds) for different indications, resulting in a *de facto* indication-specific price.⁴⁹ Even with some indication-specific pricing and outcomes-based pricing arrangements, Italy has not seen any resulting decrease in the cost of prescription drugs.⁵⁰ Other countries have incorporated the value of each indication of a drug into their prescription drug prices, resulting in a partially indication-specific pricing regime. Australia has used weighted-average prices for prescription drugs with multiple indications, combining the different value-based prices for each indication into a single weighted average price.⁵¹ The United Kingdom allows prescription drugs to increase their reimbursement price once if a prescription drug manufacturer identifies a new high-value indication.⁵²

In theory, indication-specific pricing may help better allocate prescription drugs, incentivizing prescribing high-value indications instead of less effective treatments and incentivizing prescription drug manufacturers to develop more effective treatments and support their products with demonstrations of effectiveness.⁵³ However, indication-specific pricing would face several legal barriers to implementation in federal health insurance programs in the United

44. See PEARSON ET AL., *supra* note 18, at 11-12 (describing different variations of indication-specific pricing models).

45. See *id.* at 12.

46. See *id.* at 13; Mathias Flume, et al., *Feasibility and Attractiveness of Indication Value-based Pricing in Key EU Countries*, 4 J. MARKET ACCESS & HEALTH POL'Y (2016).

47. Jacoline C. Bouvy et al., *Managed Entry Agreements for Pharmaceuticals in the Context of Adaptive Pathways in Europe*, 9 FRONTIERS IN PHARMACOLOGY 280, 280 (2018).

48. See Flume, et al., *supra* note 46.

49. See *id.*

50. See Noemie Bisserbe, *For New Trump Drug Plan, a Cautionary Tale in Italy*, WALL ST. J. (Apr. 17, 2018), <https://www.wsj.com/articles/italy-serves-cautionary-lesson-for-new-trump-drug-plan-1523959644> (discussing the results of outcomes-based contracts).

51. See PEARSON ET AL., *supra* note 18, at 13 (describing different variations of indication-specific pricing models).

52. See *id.*

53. See generally Susan Abedi, *Indication-Based Pricing- The Good, The Bad, and the Ugly*, IMS CONSULTING GROUP (June 2016), http://www.ehcca.com/presentations/PharmaMM/abedi_c.pdf.

States.⁵⁴ Additionally, the policy effects of indication-specific pricing are debated.⁵⁵ There are several reasons advocates support indication-specific pricing, including having prescription drug prices better reflect their value to patients and incentivizing manufacturers to develop high-value treatments. Supporters of indication-specific pricing assert that this regime would decrease spending for high-cost prescription drugs, while critics claim it will increase spending.⁵⁶

The remainder of this Note will detail the legal, regulatory, and policy barriers to implementing an indication-specific pricing regime in the United States, particularly in federal health insurance programs.⁵⁷ Further, this Note will demonstrate that although these barriers may not be insurmountable, indication-specific pricing is not the appropriate solution to high prescription drug spending and prices in the United States.

II. INDICATION-SPECIFIC PRICING IN FEDERAL HEALTH INSURANCE PROGRAMS

Implementing an indication-specific pricing regime would require rethinking the prescription drug pricing and reimbursement models of federal government health insurance programs. The federal government pays for healthcare, including prescription drugs, through several independent health insurance programs. Each program has, among other things, different eligibility requirements, different benefits packages, and different means of determining the price, provision, and reimbursement of prescription drugs. These systems pose different barriers to indication-specific pricing. This Part introduces four of the major federal health insurance programs purchasing prescription drugs (Medicare, Medicaid, the 340B Drug Discount Program, and the Veterans Health Administration); describes how each program structures pricing, reimbursement, and payment for prescription drugs; and discusses the barriers to implement an indication-specific pricing

54. See Part II, *infra*. See also Bach, *supra* note 18, at 1630.

55. Compare Bach, *supra* note 18, with Chandra & Garthwaite, *supra* note 21.

56. See Part III, *infra*. See also Chandra & Garthwaite, *supra* note 21, at 103 (“Supporters hope that such a system will re-duce prices for low-value indications but that prices for high-value indications will not increase.” (citing Bach, *supra* note 18, at 1629-30)); Chandra & Garthwaite, *supra* note 21, at 103-04 (arguing that indication-specific pricing would increase overall drug spending); PEARSON ET AL., *supra* note 18, at 8-10 (listing the risks and benefits of indication-specific pricing of prescription drugs to payers and prescription drug manufacturers).

57. In considering indication-specific pricing as a solution to high prescription drug prices and spending, this Note assumes that if an indication-specific pricing model were allowed or adopted, all prescription drugs purchased in the United States by federal health insurance programs would now be subject to an indication-specific price. Further, this indication-specific price would reflect the value of the treatment to a patient population relative to other treatments. While this is ideally the case, adopting this policy does not guarantee that the negotiated price would in fact accurately reflect the actual value of a treatment received by a patient. This may affect the degree of the impact and incentive effects of indication-specific pricing. Regardless, the legal and regulatory barriers to indication-specific pricing and the policy incentives identified remain significant.

regime for prescription drugs in each program.

A. Medicare

Medicare provides health insurance coverage for people age sixty-five and over, some younger people with disabilities, and people with end-stage renal disease.⁵⁸ Medicare currently provides health insurance for approximately fifty-five million people in the United States,⁵⁹ covering \$672.1 billion in healthcare services in 2016.⁶⁰ Medicare alone comprises approximately 40 percent of the pharmaceutical market in the United States.⁶¹

The Medicare program covers different healthcare services under different parts of the program.⁶² Medicare Part A, sometimes referred to as Hospital Insurance, covers healthcare during certain inpatient stays.⁶³ Prescription drugs used during a hospital stay are included in the broader reimbursement for the inpatient stay.⁶⁴ Medicare Part B primarily covers services provided in a doctor's office.⁶⁵ Prescription drugs administered during a physician office visit or in a hospital outpatient clinic are included under Medicare Part B.⁶⁶ Medicare Part C, also called Medicare Advantage Plans, provides coverage for Medicare Part A and Medicare Part B benefits, and often prescription drug coverage, through a private company contracting with Medicare.⁶⁷ Medicare Part D provides prescription drug

58. See *What's Medicare*, MEDICARE.GOV: THE OFFICIAL U.S. GOVERNMENT SITE FOR MEDICARE, <https://www.medicare.gov/sign-up-change-plans/decide-how-to-get-medicare/whats-medicare/what-is-medicare.html>; *Health Policy Brief: Medicare Part D*, HEALTH AFF. (Aug. 10, 2017), https://www.healthaffairs.org/doi/10.1377/hpb20171008.000172/full/healthpolicybrief_172.pdf [hereinafter *Medicare Part D Brief*].

59. See *Health Policy Brief: Implementing MACRA*, HEALTH AFF. (Mar. 27, 2017), <https://www.healthaffairs.org/doi/10.1377/hpb20170327.272560/full/> (55 million people on Medicare) [hereinafter *MACRA Brief*]. See also *The Medicare Part D Prescription Drug Benefit*, KAISER FAM. FOUND. (Oct. 2, 2017), <https://www.kff.org/medicare/fact-sheet/the-medicare-prescription-drug-benefit-fact-sheet/> (59 million people on Medicare).

60. *NHE Fact Sheet*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Dec. 6, 2017), <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html>.

61. See Greg D'Angelo, *The VA Drug Pricing Model: What Senators Should Know*, HERITAGE FOUND.: WEBMEMO (Apr. 11, 2007).

62. See *What's Medicare*, *supra* note 58.

63. See *id.* (explaining Medicare Part A “covers inpatient hospital stays, care in a skilled nursing facility, hospice care, and some home health care.”).

64. See *Health Policy Brief: Medicare Part B*, HEALTH AFF. (Aug. 10, 2017), https://www.healthaffairs.org/doi/10.1377/hpb20171008.000171/full/healthpolicybrief_171.pdf [hereinafter *Medicare Part B Brief*].

65. See *What's Medicare*, *supra* note 58 (explaining Medicare Part B covers “certain doctors’ services, outpatient care, medical supplies, and preventive services.”).

66. See *Medicare Part B Brief*, *supra* note 64; *Medicare Part D Brief*, *supra* note 58.

67. See *What's Medicare*, *supra* note 58.

coverage through contracts with private companies and Medicare Advantage Plans.⁶⁸ Each part of Medicare calculates prescription drug prices and reimbursement rates differently, posing various challenges to indication-specific pricing. As the majority of prescription drug spending through Medicare occurs under Parts B and D,⁶⁹ the following sections further detail their prescription drug pricing schemes.

1. Medicare Part B

Medicare Part B covers prescription drugs prescribed and administered in outpatient clinics and physician's offices.⁷⁰ These include prescription drugs administered by injection or intravenously in a physician's office or hospital outpatient setting and some oral cancer drugs that also have intravenous forms.⁷¹ Medicare Part B must cover all prescription drugs that are "reasonable and necessary for the diagnosis or treatment of illness or injury;" price cannot be taken into account while deciding reimbursement coverage.⁷² Medicare Part B spending on prescription drugs totaled approximately \$25 billion in 2015, at least half of which was spent on cancer drugs.⁷³

Prescription drug manufacturers participating in Medicare Part B are required to report prescription drug prices to the federal government on a per-unit basis without a reported indication.⁷⁴ Prescription drugs provided under Medicare Part B are reimbursed at the average sales price to a non-federal government payer plus 6 percent paid as a handling fee to doctors.⁷⁵ Patients are personally responsible for paying a 20 percent co-insurance for all prescription drugs under Medicare Part

68. *See id.*

69. *See* Rachel E. Sachs, *Delinking Reimbursement*, 102 MINN. L. REV. 2307, 2314 (2018).

70. *See Medicare Part B Brief, supra* note 64; *Medicare Part D Brief, supra* note 58.

71. White, *supra* note 4, at 194-95.

72. *See* Sachs, *supra* note 17 (quoting 42 U.S.C. § 1395y(a)(1)(A)).

73. Sachs, *supra* note 69, at 2314.

74. *See* Daniel et al., *supra* note 26. Manufacturers must report the average sales price and average wholesale price of their products quarterly by the National Drug Code (NDC), and physicians report the NDC and/or the Healthcare Common Procedure Coding System (HCPCS) code for the product administered, but the indication for which the prescription drug was eventually prescribed by physicians is not reported. *See* DEP'T OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GENERAL, AVERAGE SALES PRICES: MANUFACTURER REPORTING AND CMS OVERSIGHT 3-4 (Feb. 2010); Report to the Congress: Medicare and the Health Care Delivery System (June 2016). *See also* CTRS. FOR MEDICARE & MEDICAID SERVS., HEALTHCARE COMMON PROCEDURE CODING SYSTEM (HCPCS) LEVEL II CODE MODIFICATION REQUEST PROCESS 2019 UPDATE (APR. 2017), <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/HCPCS-Application.pdf> (briefly advising on HCPCS coding through Medicare for prescription drugs).

75. *See* 42 U.S.C. § 1395w-3a (dictating average sales price methodology); 42 C.F.R. § 414.804 (providing further regulations on average sales price methodology); *Medicare Part B Brief, supra* note 64.

B with no upper limit on out-of-pocket spending.⁷⁶

Medicare Part B poses a few significant challenges to adopting an indication-specific pricing model. First, the price reporting requirements for prescription drug manufacturers could cause a compliance issue; as indication-specific pricing by definition is not a price-per-unit model, this regulation would have to be modified in order for an indication-specific pricing model to be possible.⁷⁷ The regulation could be changed to require a price-per-unit-per-indication model, or otherwise repealed or modified to allow indication-specific pricing. Further, because prices are reported by product, not indications for the product,⁷⁸ the current reporting regime would need to be amended in order to include the indication for the reported code. Second, there is no requirement for physicians to report the indication for which they prescribe a prescription drug. In order for an indication-specific pricing regime to be implemented, a law or regulation mandating physicians to report the indication associated with each prescription would be necessary. Third, Medicare Part B reimburses based on the average sales price not differentiated by indication.⁷⁹ Average sales price would have to be redefined as average sales price per indication, or the formula would have to be otherwise modified for an indication-specific pricing regime to be implemented.

An indication-specific pricing scheme also would not address the questionable policy incentives for physicians under Medicare Part B. The 6 percent handling fee for physicians incentivizes physicians to prescribe prescription drugs with higher costs.⁸⁰ The prescription drug with the higher price would theoretically be the most effective treatment for the specific indication. This could effectively ensure that physicians make rational choices and maximize the value of their prescribing. However, with further incentives for doctors to prescribe the higher-priced prescription drug, prescription drug spending may not decrease under an indication-specific pricing model. In order to lessen the incentive for physicians, the Centers for Medicare and Medicaid Services (CMS) proposed a demonstration

76. See *id.*; Bach & Pearson, *supra* note 8, at 2503 (“the current policy of flat 20% co-insurance without an upper limit has put some highly effective but expensive drugs out of reach for the roughly 6 million Medicare beneficiaries who have no supplemental insurance.”).

77. See Daniel et al., *supra* note 26 (“Value-based payment arrangements by definition depart from a per-unit price, but current statutory and regulatory provisions are not designed to capture such arrangements. Manufacturers could be exposed to compliance risk when they seek to reflect a value-based arrangement in their price reporting, and reflecting a value-based arrangement in a per-unit metric could result in unintended reimbursement and payment consequences.”).

78. See *National Drug Code Directory*, FOOD AND DRUG ADMIN. (Nov. 2017), <https://www.fda.gov/drugs/informationondrugs/ucm142438.htm>. See also MEDICARE PAYMENT ADVISORY COMM’N, REPORT TO THE CONGRESS: MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM 131 (June 2016) (listing multiple indications in relation to one HCPCS code).

79. See 42 U.S.C. § 1395w-3a (dictating average sales price methodology not taking into account indication); *Medicare Part B Brief*, *supra* note 64.

80. See *Medicare Part B Brief*, *supra* note 64.

project in 2016 (which was never implemented) that would have changed physician reimbursement for prescription drugs under Medicare Part B to a flat handling fee of \$16.80 plus 2.5 percent of the average sales price.⁸¹ This proposal was intended to maintain the same aggregate prescription drug spending under Medicare Part B while increasing the handling fee for lower priced prescription drugs.⁸² President Trump has also proposed a similar reform.⁸³ While changing this formula would address physician incentives to some extent, it would do little to help beneficiaries afford prescription drugs. Reforms to prescription drug pricing under Medicare Part B must consider this formula and the existing reimbursement model so as not to exacerbate the existing incentives for physicians to prescribe high priced prescription drugs and increase drug spending.

2. Medicare Part D

Medicare Part D is the largest federal program paying for prescription drugs.⁸⁴ Medicare Part D covers exclusively prescription drugs purchased at pharmacies by consumers.⁸⁵ Medicare Part D plans are run by private companies contracting with the federal government.⁸⁶ Medicare pays private companies running the Medicare Part D plans a fixed grant to help pay for all prescription drugs used by covered beneficiaries instead of paying for specific prescription drugs.⁸⁷ Everyone on Medicare has access to Medicare Part D and in 2017 over forty million people enrolled in Medicare Part D plans.⁸⁸ The largest Medicare Part D plans represent approximately 21 percent of Medicare Part D recipients.⁸⁹ Consumers eligible for both Medicare and Medicaid receive their prescription drug coverage under Medicare Part D.⁹⁰ Total drug spending under Medicare Part D in 2015 was

81. See *id.* See also Deborah Schrag, *Reimbursing Wisely? CMS's Trial of Medicare Part B Payment Reform*, 374 NEW ENG. J. MED. 2101, 2101 (2016).

82. See *Medicare Part B Brief*, *supra* note 64.

83. See Sachs, *supra* note 17.

84. See *Medicare Part D Brief*, *supra* note 67.

85. See *id.*

86. Michael Adelberg & Marissa Schlaifer, *The Other Side of Managed Competition: The Tension Between Protection And Innovation In Medicare Advantage And Part D Benefits*, HEALTH AFF. BLOG (Dec. 8, 2017), <https://www.healthaffairs.org/doi/10.1377/hblog20171205.156064/full/> (“Medicare Advantage and Medicare Part D are prime examples of managed competition markets, where the government provides services by contracting with private entities to serve program beneficiaries in a regulated market.”).

87. See *Medicare Part B Brief*, *supra* note 64.

88. See *The Medicare Part D Prescription Drug Benefit*, *supra* note 59 (42 million people enrolled on Medicare Part D plans).

89. See *Medicare Part D Brief*, *supra* note 67.

90. See *The Medicare Part D Prescription Drug Benefit*, *supra* note 59. This allocation of Medicaid-eligible individuals to Medicare Part D prescription drug coverage raises its own prescription drug spending problems, as on average “Medicare Part D pays . . . 73% more than

approximately \$135 billion.⁹¹

CMS requires all Medicare Part D plans to cover at least two prescription drugs in each therapeutic class and all drugs in six classes, called protected classes, which include antidepressants, antiretrovirals, antipsychotics, anticonvulsants, immunosuppressants (to prevent organ transplant rejection), and antineoplastics (a type of cancer treatment).⁹² There is still substantial variation between Medicare Part D plans with regard to drugs included on the formularies and copayments (or cost-sharing amounts for which patients are responsible at the point of service).⁹³ The formularies of Medicare Part D plans generally tier drugs, differentiating preferred prescription drugs (which are associated with lower copayments) from more expensive non-preferred prescription drugs.⁹⁴ Beneficiaries cover 25 percent of prescription drug costs until the catastrophic cap of \$4,950 in beneficiary spending.⁹⁵ After reaching the catastrophic cap, under a provision of the Affordable Care Act to be implemented by 2020, beneficiaries are responsible for 5 percent of prescription drug costs, with the Medicare Part D plan covering 15 percent and a federal government reinsurance subsidy covering the remaining 80 percent.⁹⁶

Medicare is prohibited by law from negotiating or setting prices for Medicare Part D.⁹⁷ However, individual Medicare Part D plans can and do negotiate prices

Medicaid and 80% more than [the Veterans Health Administration] . . . for the same brand-name drugs.” Micah Vitale, Note, *The Rise in Prescription Drug Prices: The Conspiracy Against The Cure*, 20 QUINNIAC HEALTH L. J. 75, 92 (2017) (quoting MARC-ANDRÉ GAGNON & SIDNEY WOLFE, MIRROR, MIRROR ON THE WALL: MEDICARE PART D PAYS NEEDLESSLY HIGH BRAND-NAME DRUG PRICES COMPARED WITH OTHER OECD COUNTRIES AND WITH U.S. GOVERNMENT PROGRAMS 12 (2015), <http://carleton.ca/sppa/wp-content/uploads/Mirror-Mirror-Medicare-Part-D-Released.pdf>.) (alteration in original). Because Medicare Part D pays more for drugs than Medicaid, the system has essentially chosen to spend more for prescription drugs than is necessary. Some scholars have proposed that consumers eligible for both Medicare and Medicaid, sometimes called “dual-eligibles,” should be moved back to Medicaid for their prescription drug coverage, arguing that it would lead to lower prescription drug spending and better access to prescription drugs for patients. See Kevin Outterson & Aaron S. Kesselheim, *How Medicare Could Get Better Prices on Prescription Drugs*, HEALTH AFF. W832, w834-35 (2009).

91. See Sachs, *supra* note 69, at 2314.

92. *Medicare Part D Brief*, *supra* note 67; CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE PRESCRIPTION DRUG BENEFIT MANUAL 28 (2016), available at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>.

93. Adelberg & Schlaifer, *supra* note 86.

94. See *Medicare Part D Brief*, *supra* note 67.

95. See *id.*

96. See *id.*

97. 42 U.S.C. § 1395w-111(i) (2012). See also *Medicare Part D Brief*, *supra* note 67; Sachs, *supra* note 69, at 2325-26 (“Often referred to as the noninterference clause, the statute provides that the Secretary of Health and Human Services (HHS) “may not interfere with the negotiations between drug manufacturers and pharmacies and [Prescription Drug Plan] sponsors and “may not require a

with prescription drug manufacturers.⁹⁸ The cost-sharing model and the competition between Medicare Part D plans, both in attracting consumers and in bidding for federal government contracts, incentivize them to negotiate prescription drug prices as low as possible.⁹⁹ Prescription drug spending, including for high-cost brand name prescription drugs, is a concern under Medicare Part D. In 2013, while the top ten drugs paid for by Medicare Part D plans were all generics (306.6 million claims totaling \$4.14 billion), the top ten most expensive were all brand name prescription drugs (54.63 million claims totaling \$19.78 billion).¹⁰⁰

The barriers to implementing indication-specific pricing in Medicare Part D are perhaps more formidable than those present in Medicare Part B. The laws forbidding Medicare from negotiation with prescription drug manufacturers would pose a challenge to implementing an effective indication-specific pricing scheme in Medicare Part D. Because Medicare cannot negotiate as a whole, even though individual Medicare Part D plans can negotiate with prescription drug manufacturers, Medicare Part D plans cannot leverage the buying power of the whole Medicare population.¹⁰¹ This negotiation model weakens the bargaining power of Medicare Part D to lower prescription drug prices, likely making prices higher than they would be if Medicare negotiated as a whole. However, this limitation alone is not the most substantial barrier to lowering prescription drug prices and spending.

The requirement that Medicare Part D plans cover all prescription drugs in six protected classes, which includes cancer drugs, further challenges the ability for indication-specific pricing to lower prescription drug spending.¹⁰² This regulation significantly weakens Medicare Part D plans' negotiating power, leaving the prescription drug manufacturers with all the bargaining power and forcing manufacturers to accept high prices for these drugs.¹⁰³ Even if the indication-

particular formulary or institute a price structure for the reimbursement of covered part D drugs.”).

98. See *Medicare Part D Brief*, *supra* note 67.

99. See Theodore T. Lee et al., *The Politics of Medicare and Drug Price Negotiation (Updated)*, HEALTH AFF. BLOG (Sept. 19, 2016), <https://www.healthaffairs.org/doi/10.1377/hblog20160919.056632/full/>.

100. See Nicole M. Gastala et al., *Medicare Part D: Patients Bear The Cost Of 'Me Too' Brand Name Drugs*, 35 HEALTH AFF. 1237, 1238 (2016) (citing *Press release, CMS releases prescriber-level Medicare data for first time*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Apr. 30, 2015), <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-04-30.html>)).

101. See *Medicare Part D Brief*, *supra* note 67.

102. See *id.*

103. See Thomas, *supra* note 14 (“‘You get your largest negotiating power from your ability to walk away,’ said Dr. Aaron S. Kesselheim, an associate professor at Harvard Medical School who has written frequently on drug prices.”). See also Sachs, *supra* note 69, at 2326 (“Medicare might be able to achieve some savings where there is already market competition and where Medicare is permitted to cover two drugs in that class, although it is difficult to see why private plans have not negotiated such deals already. But for the six protected classes in which Medicare must cover all

specific price somewhat lowered the prices, the lack of negotiation power undermines the ability of Medicare Part D plans to negotiate a price truly reflecting the value. With this mandate still in place, not only would insurers be unable to demand an indication-specific price for a high-cost cancer drug based on its value to a patient population, but they would still be forced to accept inflated prices for prescription drugs in these protected classes.

While the negative physician incentives present in Medicare Part B are not present in Medicare Part D, the negative incentives for patients are significant. Instead of the 20 percent co-insurance under Medicare Part B, beneficiaries under Medicare Part D are responsible for a 25 percent co-insurance up to the catastrophic cap of \$4,950 and then 5 percent co-insurance after reaching the catastrophic cap.¹⁰⁴ As many prescription drugs cost more than the catastrophic cap,¹⁰⁵ many consumers face a significant and possibly prohibitive out-of-pocket spending requirement. An indication-specific pricing regime would do nothing to address the cost to patients unless the indication was less effective. If the relevant indication of the prescription drug was a relatively less effective than other treatments, it would cost relatively less and be more affordable to the patient at the point of service. However, high-cost, high-value indications of prescription drugs would remain expensive to both consumers and to the system, and an indication-specific pricing model would give manufacturers and patients no incentives to lower prices or seek better care options.

In addition to not addressing the affordability of drugs for patients, an indication-specific pricing regime would do nothing to decrease the government's overall prescription drug spending. Under Medicare Part D, a federal government subsidy pays for 80 percent of prescription drug costs after the catastrophic cap is reached; the reinsurance, or subsidy, portion of Medicare Part D is the fastest growing Medicare Part D cost as so many prescription drugs now cost thousands of dollars annually.¹⁰⁶ An indication-specific pricing regime would do nothing to decrease or slow the reinsurance costs. Reforms to Medicare Part D should both slow spending and improve patient access, and an indication-specific pricing regime would accomplish neither.

B. Medicaid

Medicaid is the federal government health insurance program that provides health insurance coverage for low-income people in the United States,¹⁰⁷ covering

products, or for expensive new drugs with few, if any, substitutes, Medicare cannot walk away from the table if it does not like the deal companies are offering.”).

104. See *Medicare Part D Brief*, *supra* note 67.

105. See *id.*

106. *Id.*

107. See *About Us*, MEDICAID.GOV, <https://www.medicaid.gov/about-us/index.html>.

approximately seventy million Americans.¹⁰⁸ It is one of the largest payers for healthcare in the United States.¹⁰⁹ Medicaid is administrated by the states and jointly funded by the states and the federal government.¹¹⁰

Medicaid comprises approximately 20 percent of the prescription drug market.¹¹¹ Prescription drugs are a small but growing portion of Medicaid spending (6 percent to 9 percent from 2010 to 2015).¹¹² The growth rate of Medicaid prescription drug spending in 2014 outpaced that of overall prescription drug spending in the United States.¹¹³ While prescription drug coverage is an optional benefit under Medicaid, all states currently cover prescription drug costs for Medicaid beneficiaries.¹¹⁴ Most states charge copayments for prescription drugs purchased under Medicaid, but these copayments are very low, capped at a few dollars per prescription and less than \$30 per month.¹¹⁵

The price Medicaid pays for prescription drugs is regulated by the Medicaid Drug Rebate Program and the Medicaid Best Price Rule.¹¹⁶ Under the Medicaid Drug Rebate Program, prescription drug manufacturers receive Medicaid coverage for essentially all of their prescription drug products in exchange for agreeing with the Department of Health and Human Services to provide rebates to Medicaid, the 340B Drug Discount Program, and the Department of Veterans Affairs.¹¹⁷ As long as the prescription drug manufacturer participates in the Medicaid Drug Rebate

108. See *Medicaid*, MEDICAID.GOV, <https://www.medicaid.gov/medicaid/index.html> (68 million covered as of the October 2017 open enrollment period); *Medicaid State Fact Sheets*, KAISER FAM. FOUND. (June 16, 2017), <https://www.kff.org/interactive/medicaid-state-fact-sheets/> (“Medicaid and the Children’s Health Insurance Program (CHIP) provide health and long-term care coverage to more than 70 million low-income children, pregnant women, adults, seniors, and people with disabilities in the United States.”).

109. See *About Us*, MEDICAID.GOV, *supra* note 107.

110. See *Medicaid*, *supra* note 108.

111. See *Health Policy Brief: Veterans Health Administration*, HEALTH AFF. (Aug. 10, 2017), https://www.healthaffairs.org/doi/10.1377/hpb20171008.000174/full/healthpolicybrief_174.pdf [hereinafter *Veterans Health Administration Brief*].

112. See David Dranove et al., *A Dose of Managed Care: Controlling Drug Spending in Medicaid* 9 (National Bureau of Economic Research Working Paper 23956, Oct. 2017), <http://www.nber.org/papers/w23956>.

113. See Hefei Wen et al., *Number Of Medicaid Prescriptions Grew, Drug Spending Was Steady In Medicaid Expansion States*, 35 HEALTH AFF. 1604, 1604 (2016) (citing Anne B. Martin et al., *National Health Spending in 2014: Faster Growth driven By Coverage Expansion and Prescription Drug Spending*, 35 HEALTH AFF. 150 (2016)).

114. See *Prescription Drugs*, MEDICAID.GOV, <https://www.medicaid.gov/medicaid/prescription-drugs/> (accessed Dec. 31, 2017).

115. See *id.* (presenting the prescription drug payments and copayments under Medicaid in each state).

116. See *Health Policy Brief: Medicaid Best Price*, HEALTH AFF. (Aug. 10, 2017), <https://www.healthaffairs.org/doi/10.1377/hpb20171008.000173/full/> [hereinafter *Medicaid Best Price Brief*].

117. See *id.*

Program, states must cover all of the manufacturer's prescription drugs approved by the Food and Drug Administration (FDA).¹¹⁸ Because prescription drug manufacturers who do not participate in the Medicaid Drug Rebate Program are excluded from participating in all federal government health insurance programs (a massive share of the prescription drug market), prescription drug manufacturers are basically required to participate.¹¹⁹

The value of the rebates is set by statute.¹²⁰ Rebates are collected directly by Medicaid.¹²¹ State Medicaid programs are allowed to negotiate further discounts in addition to these rebates.¹²² For the majority of new, high-cost prescription drugs (innovator drugs), Medicaid is entitled to a minimum of a 23.1 percent rebate off the average manufacturer price.¹²³ The rebate is also subject to the Medicaid Best Price Rule: if the lowest price offered by the prescription drug manufacturer is lower than the price Medicaid would pay for the drug after the guaranteed rebate, then Medicaid is entitled to pay for the lower price – the “best price.”¹²⁴ Certain programs are excluded from the Medicaid Best Price Rule, including Medicare Part D,¹²⁵ Medicare Advantage plans,¹²⁶ the 340B Drug Discount Program,¹²⁷ and the Veterans Health Administration.¹²⁸ This means that these programs can receive lower prices than those paid by Medicaid without triggering the Medicaid Best Price Rule.

Medicaid raises significant legal and regulatory challenges to implementing

118. 42 U.S.C. 1396r–8. See Manatt Phelps & Phillips LLP, *Efforts to Cut Drug Prices in Medicaid*, LEXOLOGY (Feb. 27, 2018), <https://www.lexology.com/library/detail.aspx?g=9f8fef25-d178-40f6-9c0b-9ee511c018e9>.

119. See *Medicaid Best Price Brief*, *supra* note 116.

120. See *Drug Rebate Program*, MEDICAID.GOV, <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html>.

121. See *Medicaid Best Price Brief*, *supra* note 116.

122. See David Blumenthal & David Squires, *Drug Price Control: How Some Government Programs Do It*, COMMONWEALTH FUND (May 10, 2016), <http://www.commonwealthfund.org/publications/blog/2016/may/drug-price-control-how-some-government-programs-do-it>.

123. See *Medicaid Best Price Brief*, *supra* note 116; Sachs et al., *supra* note 14, at 7. Some other products are subject to different minimum rebates: blood clotting factors and drugs approved by the FDA for exclusively pediatric indications are subject to a minimum rebate of 17.1 percent off the average manufacturer price, non-innovator drugs are subject to a minimum rebate of 13 percent of the average manufacturer price per unit. See *Drug Rebate Program*, *supra* note 120.

124. See Sachs et al., *supra* note 14, at 7; *Medicaid Best Price Brief*, *supra* note 116. See also 42 U.S.C. § 1396r-8 (Medicaid Drug Rebate Program and Best Price Rule statute).

125. See Sachs et al., *supra* note 14, at 7.

126. See *id.*

127. See *Health Policy Brief: The 340B Drug Discount Program*, HEALTH AFF., (Sept. 14, 2017), https://www.healthaffairs.org/doi/10.1377/hpb20171409.000175/listitem/healthpolicybrief_175.pdf [hereinafter *340B Brief*].

128. See *Veterans Health Administration Brief*, *supra* note 111.

an indication-specific pricing model.¹²⁹ First, the Medicaid Best Price Rule applies to the lowest price of each prescription drug, not each indication for a prescription drug.¹³⁰ Implementing an indication-specific pricing regime without any modification or guidance with respect to the Medicaid Best Price Rule would require prescription drug manufacturers to accept the lowest price for any indication of a product, thereby providing the prescription drug for high-value indications at the cost for its lowest-value indications.¹³¹ With a threat of the price assigned to a lower value indication applying across the board to all indications of the product, prescription drug manufacturers may be less likely, even disincentivized, to research or seek approval for these lower value indications.

Additionally, as these Medicaid rebates are calculated based on the average manufacturer price of a prescription drug, not the average manufacturer price of a specific indication of a prescription drug,¹³² modifications to how Medicaid calculates prescription drug prices would be necessary if implementing a pure indication-specific pricing regime. Several potential solutions to this problem have been recommended, including adopting a partial indication-specific pricing regime (an average weighted price incorporating indication-specific prices), product differentiation (seeking FDA approval for each indication as a different drug product), and CMS redefining a drug as “a chemical compound approved for a particular indication.”¹³³

Despite the guaranteed rebates and the Medicaid Best Price Rule limiting prescription drug prices, Medicaid spending on prescription drugs would likely increase under an indication-specific pricing regime. As Medicaid prices are based on the average sales price to other insurers, who would also have indication-specific prices and likely pay high prices for high-value indications, even the lower price paid by Medicaid would likely increase. This is further aggravated by the law under the Medicaid Drug Rebate Program requiring Medicaid and other federal health insurance programs to cover all FDA-approved drugs by participating prescription drug manufacturers. Even though state Medicaid programs can negotiate additional discounts beyond the mandated Medicaid price, because Medicaid programs cannot decline to cover most prescription drugs, their bargaining power is significantly weakened. This lack of leverage and inability to walk away, like the situation seen with Medicare Part D plans, prevents Medicaid from negotiating true value-based, indication-specific prices. Medicaid reforms to

129. For an in-depth analysis of the Medicaid Best Price Rule as a barrier to implementing value-based payment models, including indication-specific pricing, *see generally* Sachs et al., *supra* note 14.

130. *See* Sachs et al., *supra* note 14, at 8.

131. *See id.*

132. *See Medicaid Best Price Brief*, *supra* note 116; Sachs et al., *supra* note 14, at 8.

133. *See* Sachs et al., *supra* note 14, at 8-9.

prescription drug pricing would need to consider the strengths and weaknesses of the Medicaid Drug Rebate Program and the Medicaid Best Price Rule, and indication-specific pricing would worsen the problems of the current Medicaid prescription drug pricing model.

C. 340B Drug Discount Program

The 340B Drug Discount Program mandates the sale of outpatient prescription drugs to covered entities at reduced prices.¹³⁴ Covered entities include federally qualified health centers, certain disease specific programs, and publicly owned hospitals with a disproportionate share hospital percentage¹³⁵ of at least 11.75 percent.¹³⁶ There were approximately 35,000 individual covered entity sites registered by the Health Resources and Services Administration in 2016,¹³⁷ encompassing approximately 45 percent of hospitals.¹³⁸ Covered entities are able to purchase outpatient prescription drugs at significant discounts, approximately 20 to 50 percent off of the average manufacturer price.¹³⁹ This price can be no higher than the net price paid by Medicaid after rebates.¹⁴⁰ Prescription drug manufacturers are allowed to sell outpatient prescription drugs to 340B-eligible purchasers without triggering the Medicaid Best Price Rule, allowing and even incentivizing further reductions.¹⁴¹ Purchases by covered entities totaled approximately \$12 billion in 2015, with savings estimated at \$6 billion.¹⁴²

134. See *340B Brief*, *supra* note 127; MARK RILEY, WHITE PAPER: MAKING SENSE OF THE 340B DRUG PROGRAM 1 (July 2012).

135. Disproportionate share hospitals are hospitals which serve a disproportionately large number of low income and uninsured patients and are thus entitled to additional payments from the Centers for Medicare and Medicaid Services. See *Disproportionate Share Hospitals*, HEALTH RES. & SERVS. ADMIN. (May 2018), <https://www.hrsa.gov/opa/eligibility-and-registration/hospitals/disproportionate-share-hospitals/index.html>. The disproportionate share percentage is calculated by statute and described by the Centers for Medicare and Medicaid Services here: *Disproportionate Share Hospital*, CTRS. MEDICARE & MEDICAID SERVS. (last modified Oct. 4, 2018), <https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps/dsh.html>. The requirements for a disproportionate share hospital qualifying for the 340B program are codified in 42 U.S.C. § 256b(a)(4)(L).

136. See *340B Brief*, *supra* note 127.

137. See *id.*

138. See Blumenthal & Squires, *supra* note 122. A separate study reports that the 340B hospitals constitute 51 percent of all hospital beds in 2016. See Peter B. Bach & Rachel E. Sachs, *Expansion of the Medicare 340B Payment Program: Hospital Participation, Prescribing Patterns and Reimbursement, and Legal Challenges*, J. AM. MED. ASS'N (2018) (citing Centers for Medicare and Medicaid Services. Cost reports, fiscal-year 2017, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports>).

139. See *340B Brief*, *supra* note 127.

140. See *id.*

141. See *id.*

142. See *id.* Other studies have estimated the difference in the purchase and reimbursement for 340B hospitals in 2017 provided \$19.3 billion in profit. See Bach & Sachs, *supra* note 138 (citing

Eligibility to participate in the 340B Drug Discount Program depends on the facility, not the individual patient.¹⁴³ When an insured patient comes to a 340B covered entity and receives a prescription for an outpatient prescription drug from a physician associated with the 340B program, the pharmacy is allowed to dispense the prescription drug purchased through the 340B program but receive reimbursement through Medicare or commercial insurance at their rates.¹⁴⁴ This allows the covered entity to make a profit on the outpatient prescription drugs purchased under the 340B Drug Discount Program; this is permitted because of their status as a provider serving a large uninsured population.¹⁴⁵

The 340B Drug Discount Program, like Medicaid, calculates the discounted price of prescription drugs based on the average manufacturer price of a prescription drug,¹⁴⁶ not the average manufacturer price of a specific indication of a prescription drug. In order to implement an indication-specific pricing model, the 340B Drug Discount Program would need to modify the way it calculates the cost of prescription drugs. There has also been criticism of the 340B Drug Discount Program continuing to receive mandatory drug discounts in an indication-specific pricing scheme, with people opposing imposing additional discounts when a prescription drug is already being sold at a value-based price.¹⁴⁷ If an indication-specific pricing regime were implemented, it is possible that these discounts would be modified or repealed, undermining the efforts of the program and increasing prescription drug spending.

The high drug discounts in the 340B Drug Discount Program may incentivize inappropriate care or overuse of prescription drugs.¹⁴⁸ This is a result of the revenue 340B-eligible providers receive from the reimbursement for prescription drugs.¹⁴⁹ Some hospitals participating in the 340B Drug Discount Program are abusing the system, gaining immense profits from their prescription drug sales,

The 340B program reached \$19.3 billion in 2017—as hospitals' charity care has dropped, DRUG CHANNELS INST. (May 7, 2018), <https://www.drugchannels.net/2018/05/exclusive-340b-program-reached-193.html>). Because the program is structured such that the covered entity receives the discount directly upon purchase, the program does not cost the taxpayers and the savings directly help the covered entities to offset losses caused by their disproportionate coverage of uninsured patients and focus on local healthcare priorities, including clinics and transportation in rural and low-income areas. See Jim Martin, *We can help rural seniors and veterans by keeping the 340B drug pricing program*, THE HILL (Nov. 4, 2017), <http://thehill.com/opinion/healthcare/358771-we-can-help-rural-seniors-and-veterans-by-keeping-the-340b-drug-pricing>.

143. See *340B Brief*, *supra* note 127.

144. See *id.*

145. See *id.*

146. See *id.*

147. See Bach & Pearson, *supra* note 8, at 2504.

148. *340B Brief*, *supra* note 127.

149. See *id.*

resulting in the system receiving increased public scrutiny.¹⁵⁰ These profits and incentives for abuse could be aggravated by an indication-specific pricing regime. This is true of any fee-for-service program but would be even more likely in a system that already incentivizes inappropriate prescribing.¹⁵¹

While incentivizing prescribing high-value indications, indication-specific pricing would also incentivize overuse of drugs for high-value indications and increase overall drug spending. This could be especially prominent in certain contexts, such as cancer care. Because 340B-eligible hospitals can purchase high-price cancer drugs at deep discounts, there has already been a decrease in cancer care by community oncologists and an increase in cancer care in hospital outpatient departments, including 340B-eligible facilities.¹⁵² If these discounts continue and cancer care continues to be more affordable at 340B-eligible facilities, indication-specific pricing could further exacerbate the increase in cancer care at 340B-eligible facilities. Physicians may also be incentivized to try several different prescription drugs to treat cancer at once, whether necessary or not. Overuse and improper use would magnify an increase in drug spending from indication-specific pricing. These challenges would need to be addressed for an indication-specific pricing model to decrease, not increase, prescription drug prices and spending under the 340B Drug Discount Program.

D. Veterans Health Administration

The Department of Veterans Affairs operates its own integrated healthcare system called the Veterans Health Administration (VA), providing healthcare services to qualified members of the military after they leave active duty.¹⁵³ The VA directly provides services, including prescription drugs, through its network of medical centers, clinics, and pharmacies.¹⁵⁴

Prescription drug manufacturers are required to provide the VA and the

150. See Andrew Pollack, *Dispute Develops Over Drug Discount Program*, N.Y. TIMES (Feb. 12, 2013), <http://www.nytimes.com/2013/02/13/business/dispute-develops-over-340b-discount-drug-program.html>; Ellen Weaver & Lindsay Boyd, *States tell Congress: stop hospital abuse of federal drug discount program*, THE HILL (June 15, 2016), <http://thehill.com/blogs/congress-blog/healthcare/283491-states-tell-congress-stop-hospital-abuse-of-federal-drug>.

151. See Weaver & Boyd, *supra* note 150 (“The Berkeley findings come on top of previous research that revealed that most 340B hospitals don’t actually serve large at-risk populations. One study found that fewer than a third provide charity care exceeding the national average. And last summer, the Government Accountability Office issued a report noting that the program creates an incentive for hospitals to maximize profits by prescribing more—or more expensive—drugs. GAO then tasked Congress with removing these perverse incentives.”).

152. See *340B Brief*, *supra* note 127.

153. See *Veterans Health Administration Brief*, *supra* note 111.

154. See *id.*

Department of Defense a 24 percent discount¹⁵⁵ on the non-federal average manufacturer price.¹⁵⁶ Similar to the Medicaid Best Price Rule, if the prescription drug manufacturer sells their product to another non-federal buyer for less than that amount, they are required to sell to the VA for the lowest price.¹⁵⁷

The VA operates its prescription drug coverage as a national formulary, a list of medicines covered by the VA.¹⁵⁸ The VA provides low or no cost sharing for its beneficiaries and low costs overall.¹⁵⁹ The buying power of the VA allows it to negotiate additional discounts for many of the drugs on the national formulary, especially those drugs with significant competitors.¹⁶⁰ Further, unlike Medicare and Medicaid, which are required to cover all FDA-approved prescription drugs, the VA is not required to cover all FDA-approved prescription drugs; the ability of the VA to decline to include a drug on its national formulary gives it significantly more bargaining power than other federal payers.¹⁶¹ If prescription drug manufacturers do not comply with the mandated discounts to the VA, they are excluded from participating in most federal government health insurance programs.¹⁶² As federal government health insurers compose such a large portion of the pharmaceutical market, prescription drug manufacturers generally comply.¹⁶³

The VA would face barriers to indication-specific pricing of prescription drugs similar to those faced by other federal health insurance programs. Like the other federal programs, the VA calculates its prescription drug prices based on the average manufacturer price of the prescription drug.¹⁶⁴ The average manufacturer price does not differentiate based on the indication for which the prescription drug is prescribed. In order to implement an indication-specific pricing regime, the VA would have to change the way it calculates the price of prescription drugs. However, it may be easier in this context to track and collect the necessary data for charging an indication-specific pricing, as the VA is one integrated system instead

155. See Blumenthal & Squires, *supra* note 122.

156. The non-federal average manufacturer price is defined by statute as “the weighted average price of a single form and dosage unit of the drug that is paid by wholesalers in the United States to the manufacturer, taking into account any cash discounts or similar price reductions during that period, but not taking into account (A) any prices paid by the Federal Government; or (B) any prices found by the Secretary to be merely nominal in amount.” *Veterans Health Administration Brief*, *supra* note 111 (quoting 38 U.S.C. § 8126).

157. See Blumenthal & Squires, *supra* note 122.

158. See *Veterans Health Administration Brief*, *supra* note 111.

159. See *id.*

160. See *id.*

161. See *id.*

162. See *Veterans Health Administration Brief*, *supra* note 111.

163. See *id.*

164. See *id.* (quoting 38 U.S.C. § 8126).

of independent healthcare providers under Medicare.¹⁶⁵ It may be possible to implement an indication-specific pricing system in the VA prescription drug program, but there are still several barriers to indication-specific pricing lowering prescription drug spending in the United States healthcare system.

III. POLICY ARGUMENTS AGAINST INDICATION-SPECIFIC PRICING

The legal and regulatory barriers to implementing an indication-specific pricing scheme in federal government insurance programs are significant and worthy of consideration, but they are not insurmountable.¹⁶⁶ If accomplished, implementing indication-specific pricing in government health insurance programs would have a significant impact on and face additional barriers with the FDA approval system and incentives for physicians, patients, and manufacturers. Section A discusses the barriers presented by the FDA approval system. Section B explains the risks of liability for off-label promotion. Section C presents the arguments regarding whether indication-specific pricing would decrease prescription drug spending, concluding that an indication-specific pricing model would likely not decrease prices or improve consumers' access to prescription drugs. Section D raises ethical arguments against indication-specific pricing and other value-based pricing models.

A. *The FDA Approval System*

The current FDA approval system poses significant barriers to an effective indication-specific pricing regime. Each FDA-approved drug receives a unique National Drug Code (NDC).¹⁶⁷ This NDC is used when tracking and calculating the reimbursement price for prescription drugs. The FDA approves prescription drugs for specific indications, not general use.¹⁶⁸ This is because the safety, effectiveness, and risk-benefit analysis may differ for a prescription drug based on indications.¹⁶⁹ For example, a side effect that is harmless for one indication in one patient may be a significant risk for another indication in a different patient. Thus, when a prescription drug has more than one indication, manufacturers must consider how to gain approval for the new use.

Manufacturers have several options to gain FDA approval for new indications. One possibility is to have the new indication approved as a separate product. This

165. *See id.*

166. *See* Bach, *supra* note 18, at 1630 (“Adopting indication-[specific] pricing is thus technically feasible. Political challenges may be more substantial.”).

167. *See National Drug Code Directory*, *supra* note 78.

168. Ryan Sila, Note, *Incentivizing Pharmaceutical Testing in an Age of Off-Label Promotion*, 93 N.Y.U. L. REV. 941, 946 (2018).

169. *Id.* at 946-48.

could be done by submitting an Investigational New Drug Application¹⁷⁰ to gain FDA approval to research the new indications and then conducting full clinical trials (the traditional process for FDA approval).¹⁷¹ The newly approved indication for the prescription drug would be approved as a unique product.¹⁷² It would receive a unique NDC from the FDA, and it would be billed as a separate product by insurers. Another more common option is for the prescription drug manufacturer to file a supplemental New Drug Application¹⁷³ to update the label and gain approval for this new indication. This results in adding an indication to an already approved prescription drug. Therefore, the product has the same NDC code and must be billed and priced the same under the existing FDA regulatory scheme.

In order to implement an indication-specific pricing model, the FDA and CMS would need to develop a new or modified coding system incorporating the separate indications with approvals and reimbursements. While New Drug Applications would benefit the healthcare system by providing detailed support on the effectiveness of the new indication, there is no incentive for pharmaceutical companies to follow this route. It is time-intensive, labor-intensive, and expensive. Pharmaceutical companies are more likely to file supplemental New Drug Applications, which are quicker and require less support and expenditure. However, this results in a new indication with the same NDC as the existing product. The FDA and CMS would need to develop a system to track the different indications of individual NDC codes for reimbursement purposes. Further, physicians can prescribe these medications without the additional approvals.¹⁷⁴

170. See 21 C.F.R. § 312; *Investigational New Drug (IND) Application*, U.S. FOOD AND DRUG ADMIN. (Oct. 5, 2017), <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/default.htm>.

171. *Id.* If the product is a breakthrough therapy, a cancer drug with no comparable treatment, or certain other types of treatments, the manufacturer may be eligible to gain approval by submitting an application through an Accelerated Approval pathway. See 21 U.S.C. § 356(a) (breakthrough therapies); 21 U.S.C. § 356(b) (fast-track products); 21 CFR 314.510; *Accelerated Approval*, U.S. FOOD AND DRUG ADMIN. (Sept. 15, 2014), <https://www.fda.gov/ForPatients/Approvals/Fast/ucm405447.htm>.

172. *Id.*

173. See 21 CFR § 314; *New Drug Application (NDA)*, U.S. FOOD AND DRUG ADMIN. (Mar. 29, 2016), <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm>; *Off-Label Drug Promotion: Health Policy Brief* HEALTH AFF. (June 30, 2016), https://www.healthaffairs.org/doi/10.1377/hpb20160630.920075/full/healthpolicybrief_159.pdf [hereinafter *Off-Label Drug Promotion Brief*] (“Currently, a manufacturer can expand a drug’s approved indications through a supplemental New Drug Application, but performing the required clinical trials is a costly and time-consuming process, and manufacturers have little incentive to do this for drugs that are already used widely off label.”).

174. See III.B., *infra*.

These challenges are further described in the next Section.

B. *Off-Label Prescribing*

Not all indications for which prescription drugs are used are approved by the FDA.¹⁷⁵ While some prescription drugs are approved for multiple indications, many prescription drugs are only approved for one indication, even if they are commonly used for other indications.¹⁷⁶ Using prescription drugs for uses other than their approved indications is called off-label use.¹⁷⁷ Both off-label prescribing and off-label use are permitted.¹⁷⁸ However, off-label promotion of prescription drugs by prescription drug manufacturers is prohibited.¹⁷⁹ Drug company promotion of a prescription drug for a non-approved use is in contradiction with the approved labeling and qualifies as “misbranding” under the Food, Drug and Cosmetic Act.¹⁸⁰

175. See *Off-Label Drug Promotion Brief*, *supra* note 173, (“A drug is used off label any time it is administered in a way that has not been approved by the FDA . . . Providers might choose to prescribe off label for many reasons.”).

176. See Sachs et al., *supra* note 14, at 9-10 (“There are many drugs like Colcrlys, with multiple FDA-approved indications. But there are also many drugs whose secondary uses are not FDA approved, with large off-label markets.”).

177. *Off-Label Drug Promotion Brief: Health Policy Brief*, *supra* note 173 (“A drug is used off label any time it is administered in a way that has not been approved by the FDA.”).

178. See Aaron S. Kesselheim & Michelle M. Mello, *Prospects For Regulation Of Off-Label Drug Promotion In An Era Of Expanding Commercial Speech Protection*, 92 N.C. L. REV. 1539, 1546 (2014) (“Once a drug is approved, physicians have autonomy to prescribe it for any indication and patient population and at any dose, including those not described in the official labeling materials—so-called ‘off-label’ uses. Off-label uses are often medically appropriate, especially for patients with no other therapeutic alternatives where the drug’s effectiveness is biologically plausible.” (footnote omitted)).

179. See *id.* at 1544 (“The FDCA does not explicitly proscribe off-label drug promotion. Rather, it prohibits introducing any new drug or biological product that has not been approved by the FDA or is misbranded. (citing, *id.* at 1544 n.22, “21 U.S.C. § 331(d) (2012); *id.* § 355(a) (“No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application . . . is effective . . .”); *id.* § 331(a) (forbidding the introduction of adulterated or misbranded food or drugs into commerce); *id.* § 352(a) (defining false or misleading labels as misbranded drugs or devices); *id.* § 352(f) (discussing directions for use and warnings on labels).”).

180. See Kesselheim & Mello, *supra* note 178, at 1547 (“A manufacturer who promotes off-label uses risks criminal liability under the FDCA if its drug is found to be ‘misbranded.’ Drugs can be misbranded for false or misleading labeling information or labeling that does not bear ‘adequate directions for use.’ Since the only legitimate source of information about directions for use is the FDA-approved labeling information, directions provided by the manufacturer for using the drug in an off-label context are not permitted. The combination of the requirements for approval and the misbranding provision provide two avenues for restrictions on off-label promotion: a drug promoted for unapproved uses may be considered to be an “unapproved drug” for that use, or it may be deemed ‘misbranded.’ Under either statutory provision, in the FDA’s view, it can be illegal for a drug’s labeling to discuss uses of the drug that the FDA has not validated as being supported by substantial evidence.” (quoting 21 U.S.C. § 352 (2012); *id.* § 352(f)(1))).

While manufacturers are allowed to make certain statements about non-approved uses (for example in response to a request by a healthcare professional¹⁸¹), manufacturers can only negotiate reimbursement for FDA-approved indications.¹⁸² Even so, insurers in the United States, including Medicare, will generally reimburse providers for prescription drugs even when they are prescribed off-label; however, this could be because insurers cannot tell when drugs are prescribed off-label.¹⁸³ Medicare Part B is required to reimburse for off-label use of oncology drugs when there is specific published evidence supporting their use.¹⁸⁴

Off-label prescribing is relatively common, accounting for approximately 20 percent of all prescriptions in the United States.¹⁸⁵ In some cases, off-label prescribing is beneficial and necessary: some subpopulations (including children and pregnant women) often require off-label prescribing as they are generally not included as subjects in clinical trials, and thus are not included in the FDA approval.¹⁸⁶ Some specialties with few treatments for specific indications, such as oncology, result in off-label uses of prescription drugs becoming the standard of care.¹⁸⁷ Despite the benefits, there is little scientific evidence supporting the effectiveness of over 70 percent of off-label uses of prescription drugs.¹⁸⁸ Permitting drug companies to promote these uses, even allowing them to negotiate reimbursement for their use, may pose great public health risks. Off-label uses lack evidence supporting their safety and effectiveness for treating the non-indicated disease. As off-label prescribing is common absent promotion by manufacturers, permitting such promotion may result in more widespread use of drugs for off-label indications. This would lead to patients gaining access to prescription drugs

181. See *Off-Label Drug Promotion Brief: Health Policy Brief*, *supra* note 173 (“Manufacturers can communicate about off-label uses of their drugs in a number of ways. Companies are permitted to respond to unsolicited requests from health care professionals about unapproved uses and might also support independent continuing medical education activities at which off-label uses are discussed. Since the passage of the Food and Drug Administration Modernization Act (FDAMA) of 1997, companies are also permitted to distribute peer-reviewed journals and reference books that discuss off-label uses, although this practice is subject to certain limitations. In 2014 the FDA expanded this authority to include non-peer-reviewed clinical practice guidelines.”).

182. See Stephen D. Pearson, et al., *Indication-specific pricing of pharmaceuticals in the US healthcare system*, 6 J. COMPARATIVE EFFECTIVENESS RESEARCH 397, 399-400 (2017).

183. See *Off-Label Drug Promotion Brief: Health Policy Brief*, *supra* note 173 (“Payers in the United States, including Medicare, generally reimburse medications used off-label . . . in 2009, 75 percent of U.S. payers reimbursed some off-label uses of prescription drugs.”).

184. See *id.* (“Medicare Part B is required to cover anti-cancer drugs used off-label when published compendia—privately owned pharmaceutical reference guides—support their use.”).

185. THE PEW CHARITABLE TRUSTS, *supra* note 9, at 20.

186. See Patricia J. Zettler, *The Indirect Consequences of Expanded Off-Label Promotion*, 78 OHIO STATE L. J. 1053, 1078 (2017).

187. See *id.*

188. See *id.*

much faster than if manufacturers sought FDA approval through clinical trials or a supplemental New Drug Application. However, as there is a lack of evidence over the safety and effectiveness of the drug for the off-label use and off-label uses are associated with “significantly higher rates of adverse events than on-label uses,”¹⁸⁹ increased off-label use could lead to adverse events and negative health outcomes.¹⁹⁰

Linking the price of a prescription drug to its FDA-approved indications would be possible. However, while the 21st Century Cures Act expanded the ability of prescription drug manufacturers to share information on off-label uses, the FDA has only provided draft guidance, and sharing this information would likely still qualify as prohibited off-label promotion.¹⁹¹ Companies may be able to find ways to promote their prescription drugs notwithstanding the off-label promotion prohibitions. Recently, several companies have succeeded on challenging these restrictions on First Amendment grounds, asserting that this is protected truthful commercial speech.¹⁹² Companies could be extend these First Amendment challenges to the payment context, arguing that pharmaceutical companies should be allowed to negotiate with government health insurance programs using scientific evidence supporting the effectiveness of non-approved indications. The development of commercial speech doctrine does not indicate that this is likely, as courts have not yet extended First Amendment protection to unapproved indications.¹⁹³

Without requiring or incentivizing FDA approval for the additional indications, indication-specific pricing may not be a practical solution. However, if prescription drug manufacturers were incentivized to seek FDA approval for new indications, this would cause a deluge of Investigational New Drug Applications¹⁹⁴ to gain FDA approval to research the new indications; supplemental New Drug

189. *Id.* at 1079.

190. *See id.* at 1078-79.

191. *See Hayes, supra* note 19.

192. *See Zettler, supra* note 186, at 1057 (“Notwithstanding these concerns, courts, increasingly, have seemed willing to find that the First Amendment protects a broader range of off-label promotion than FDA policies have typically permitted.”); Sila, *supra* note 168, at 950 (“[the Second Circuit] it held that the effective prohibition of off-label marketing did not directly advance those interests and in any event was substantially more restrictive than the First Amendment permits.”); *Amarin Pharma, Inc. v. U.S. F.D.A.* 119 F.Supp.3d 196 (S.D.N.Y. 2015); *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012). *See generally Sorrell v. IMS Health Inc.*, 564 U.S. 552 (2011) (explaining that the First Amendment protects companies’ rights to engage in truthful commercial speech).

193. *See Zettler, supra* note 186, at 1071 (“none of the decisions following *Caronia*—in the Second Circuit or elsewhere—have extended *Caronia* to unapproved products.”).

194. *See* 21 C.F.R. § 312; *Investigational New Drug (IND) Application*, U.S. FOOD AND DRUG ADMIN. (Oct. 5, 2017), <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/default.htm>.

Applications¹⁹⁵ to gain FDA approval for the indication; and applications through Accelerated Approval pathways for breakthrough therapies and prescription drugs that treat cancers with no comparable treatment.¹⁹⁶ Seeking approval for these additional indications as new indications for an existing product would make indication-specific pricing a more real possibility.¹⁹⁷ These additional studies and approvals may provide additional data on the safety and effectiveness of certain prescription drugs, especially as data on off-label uses of prescription drugs are often inadequate.¹⁹⁸ Despite the benefits of the additional research that comes with approval, FDA approval is unnecessary for patients to access these medicines and may not improve affordability. Research time and a lengthy approval process greatly delay patient access and undermine the goal of improving affordability and accessibility of prescription drugs.

Indication-specific pricing would face several regulatory and practical barriers in the FDA approval system and with the risk of liability for off-label promotion. Reforms in these two areas would be necessary in order to make indication-specific pricing feasible. Even so, these reforms may not address the end goal of prescription drug reform: decreasing prescription drug prices and spending. The possible economic effects of indication-specific pricing are discussed further in the next Section.

C. Price Effects of Indication-Specific Pricing

Experts disagree on whether an indication-specific pricing regime would decrease prescription drug spending. In general, supporters argue that indication-

195. See 21 CFR § 314; *New Drug Application (NDA)*, U.S. FOOD AND DRUG ADMIN. (Mar. 29, 2016), <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm>; *Off-Label Drug Promotion Brief*, *supra* note 173 (“Currently, a manufacturer can expand a drug’s approved indications through a supplemental New Drug Application, but performing the required clinical trials is a costly and time-consuming process, and manufacturers have little incentive to do this for drugs that are already used widely off label.”).

196. See 21 U.S.C. § 356(a) (breakthrough therapies); 21 U.S.C. § 356(b) (fast-track products); 21 CFR 314.510; *Accelerated Approval*, U.S. FOOD AND DRUG ADMIN. (Sept. 15, 2014), <https://www.fda.gov/ForPatients/Approvals/Fast/ucm405447.htm>.

197. See Sachs et al., *supra* note 14, at 6.

198. See *id.*; Sila, *supra* note 168, at 951 (“critics argue that the prohibition powerfully incentivizes manufacturers to conduct clinical testing of and seek approval for more than just a single indication.”) (citing Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 370 (2007) (explaining that because the FDA requires that “firms conduct rigorous clinical trials before bringing their products to market and before making promotional claims . . . the FDA plays an important structural role in promoting a valuable form of biomedical R&D [research and development] that private firms are undermotivated to perform . . . while internalizing the costs of this R&D to the firms”).

specific pricing would “reduce prices for low-value indications but that prices for high-value indications will not increase.”¹⁹⁹ Many studies do not support this assertion, however. Evidence suggests that an indication-specific pricing model would not result in the desired policy incentives and effects – rational use of prescription drugs, more affordable prices for prescription drugs, and lower overall prescription drug spending. The core goal of indication-specific pricing of prescription drugs, like other value-based pricing regimes, is to make prescription drug prices better represent the value received by the patient.²⁰⁰ While maximizing value is important, it does not solve the problem of high prescription drug prices and spending.

Peter Bach, a physician and researcher at Memorial Sloan Kettering Cancer Center and a prominent supporter of indication-specific pricing in oncology care, argues that indication-specific pricing would likely decrease prescription drug spending.²⁰¹ Dr. Bach has recommended anchoring the prices of a prescription drug to its highest value indication or setting the price based on a preset value per year of life gained.²⁰² He has calculated the changes in prices of multi-indication cancer drugs based both on setting the price of the highest-value indication to the current price and by monthly price based on a cost of \$150,000 per year of life gained.²⁰³ The large variations in value by indication, he argues, demonstrate that indication-specific pricing is necessary to make prescription drug prices rationally related to value.²⁰⁴ However, his methodology presupposes that indication-specific pricing would decrease prescription drug prices, and therefore Dr. Bach’s analysis does not provide support for this conclusion.²⁰⁵

In fact, indication-specific pricing would likely increase prescription drug spending. Amitabh Chandra from the Harvard Kennedy School of Government and Craig Garthwaite from Northwestern University’s Kellogg School of

199. Chandra & Garthwaite, *supra* note 21, at 103 (citing Bach, *supra* note 18, at 1629-30).

200. *But see* Bach, *supra* note 18, at 1629-30 (“The primary reason to pursue this enhancement to the system [implementing indication-specific pricing] is to make it possible to rationalize drug pricing.”).

201. *See* Flume, et al., *supra* note 46 (“Frequent pricing critic Peter Bach recently suggested that paying by indication could save money in cancer using the example of cetuximab, which is much less effective in advanced head and neck cancer (estimated value-based price: \$470) compared with colorectal cancer (estimated value-based price: \$10,320).” (citing Bach, *supra* note 18)).

202. *See* Bach, *supra* note 18, at 1629.

203. *See id.* at 1630.

204. *See id.* at 1629 (“However, the relative findings of large differences in value across indications, and large potential shifts in pricing if the drugs were linked to value, illustrate that a change to indication-based pricing may be a necessary step toward paying rational prices for expensive drugs used to treat cancer and some other conditions, for which efficacy varies across indications.”).

205. *See id.* at 1630 (noting the methodology “Assumes the price of the drug in its most effective setting is the appropriate reference price.”).

Management have argued that indication-specific pricing would not decrease the price of prescription drugs and would therefore not decrease prescription drug spending.²⁰⁶ Instead, they argue that more effective, and supposedly higher value, indications would increase in price, making prescription drugs even more unaffordable (particularly to those who need them most). Their analysis demonstrates that “relative to uniform pricing, indication-[specific] pricing results in higher prices for patients who benefit the most, higher utilization by patients who benefit least, higher overall spending, and higher manufacturer profits.”²⁰⁷ They assert that “setting a price that more closely matches the product’s value to each customer,” is a well understood economic concept called price discrimination.²⁰⁸ Price discrimination, while resulting in a value-based price, can result in manufacturers setting the highest price that each segment of the market is willing to pay.²⁰⁹ Calculating their own indication-specific prices for cancer drugs, Professors Chandra and Garthwaite conclude that prices for high-value indications, both for prescription drugs that are currently expensive and those that are generally affordable, would drastically increase, significantly reducing patient access.²¹⁰

No pure indication-specific pricing regime has yet been implemented, so there is no real-world data to support pricing outcomes in practice. All outcomes are hypothetical and presumptive. The available evidence and incentives support that indication-specific pricing would likely increase prescription drug prices and spending. High-cost prescription drugs may be cost-effective at their current high prices: one study found that Sovaldi was cost-effective at \$84,000 per treatment.²¹¹ Relatedly, high-value prescription drugs that are currently priced low enough to be generally available would likely see drastic price increases.²¹² Indication-specific

206. See generally Chandra & Garthwaite, *supra* note 21.

207. *Id.* at 103-04.

208. *Id.* at 104.

209. See *id.* at 104 (“What would happen if the manufacturer used indication-[specific] pricing—setting a price that more closely matches the product’s value to each customer? This is a practice that economists call price discrimination, and its effects are well understood. In the most extreme version, the manufacturer extracts the most money each patient is willing to pay, leaving no consumer surplus.”).

210. See *id.* at 105 (“Absent indication-based pricing, the manufacturer could not set such a high price without having payers reduce access for patients with low-value indications—the trade-off would not be worth the lost profits. So what would indication-based pricing accomplish? For drugs currently priced so high that they’re unavailable for some indications, it expands access. Drug manufacturers would now be willing to set low prices for low-value indications, since it wouldn’t jeopardize their profits on high-value indications. But the same access-expanding pricing flexibility also allows manufacturers to increase prices for high-value indications. Currently, some treatments are priced low enough to be accessible for a wide range of indications, and it is there that we should expect the biggest price increases.”).

211. Kesselheim et al., *supra* note 12, at 859 (citing Mehdi Najafzadeh et al., *Cost-effectiveness of novel regimens for the treatment of hepatitis C virus*, 162 ANN. INTERN. MED. 407 (2015)).

212. See *id.*

pricing in many cases, especially for diseases with few alternative treatments, may not result in decreased prices and may perpetuate the prohibitively high prices leaving these drugs out of reach to many patients. Even so, some expensive prescription drugs may become more available; this would be the case for prescription drugs that are overpriced beyond their cost-effectiveness.²¹³ The low-value indications would be more available and more utilized, as their prices are lowered to match their comparative value making them more affordable to patients.²¹⁴ This increased access may have counterintuitive results in terms of healthcare outcomes; while increased access to effective treatments would lead to better healthcare outcomes, increased access to low-value indications (which are perhaps not the standard of care or not adequately effective in treating the secondary indication) would likely lead to poorer healthcare outcomes.

Without an experimental implementation of indication-specific pricing of prescription drugs, it is uncertain whether indication-specific pricing would in fact increase or decrease overall prescription drug spending and individual prescription drug prices. However, the incentives are clear. Indication-specific pricing sets higher prices for higher-value indications. Depending on an individual's prescription drug coverage, these higher prices for high-value indications are likely less affordable and less accessible as a result. Conversely, indication-specific pricing sets lower prices for lower-value indications, resulting in them being more affordable, more accessible, and used more by patient populations who receive a comparatively lesser benefit from them.²¹⁵ This could lead to an inefficient allocation of prescription drugs and healthcare resources, overall worse healthcare outcomes, and increased healthcare spending.

D. Ethical Issues of Indication-Specific Pricing

Indication-specific pricing raises several ethical concerns. First and foremost is the ethical distribution of medicines. Indication-specific pricing models suggest that indication-specific pricing in federal government health insurance programs would result in higher prices for more-effective treatments. This regime may demonstrate the value of the medication and incentivize the development of more effective treatments for diseases. In this system, when a patient seeks to buy a more effective medication to treat their disease, it would cost them significantly more money. While the intent of pricing based on value per indication may be to better allocate resources at the health system level, there are challenges to this working at the patient level. What if an individual cannot afford the most effective treatment? There could be prohibitively high out of pocket costs preventing them

213. See Chandra & Garthwaite, *supra* note 21, at 105.

214. See *id.*

215. See Chandra & Garthwaite, *supra* note 21, at 103-04.

from affording the medication that would best treat, or potentially cure, them. Either this individual will go without treatment and get sicker, later costing the healthcare system more money and having a significantly decreased quality of life, or the individual chooses a less expensive, less effective treatment, which may have poorer outcomes for the patient and result in expensive future healthcare to improve their condition. The purpose of decreasing prescription drug prices is not to justify high prices or to make them more rational; the point is that prescription drug prices are too high for patients, and thus reforms need to both rationalize prices but also make prescription drugs more affordable and accessible. Indication-specific pricing may provide ethical and optimal prescriber-side incentives (rewarding physicians for choosing the most effective, most valuable treatment) but it punishes patients who cannot afford effective prescription drugs. This is unethical and unjust.

The inverse pricing scheme has been suggested for the indication-specific model: making the most effective treatment for an indication the most affordable and therefore most accessible to patients. On the patient-side, this is ideal, assuming this low price for a high-value indication is low enough that anyone and everyone who needs it can afford it. But the physician and system incentives are less clear, and potentially against the best interests of patients and the health system as a whole. If the current physician reimbursement schemes continue, particularly in Medicare Part B, this inverse indication-specific pricing model would not incentivize physicians to provide the best course of treatment. In fact, they might be incentivized to provide less effective treatments. Patients may receive a lower standard of care from their physicians because it financially benefits their provider, and as a result the healthcare system will produce poorer outcomes and higher spending. Pharmaceutical companies would also have questionable incentives under this model. Lower prices for effective drugs disincentivizes the development of cures and effective treatments. When pharmaceutical companies identify treatments that may not be more effective than existing treatments or have little benefit to patients, the company would be incentivized to continue research and development and seek approval for several indications. From an innovation and research perspective, this is a positive: decreased off-label prescribing and additional data on prescription drugs prior to approval. However, this incentivizes companies to direct resources away from breakthrough cures and towards less effective, more profitable treatments. Innovation incentives should not support increases in pharmaceutical profits absent improvements in patient care.

The determination of value for indication-specific pricing, or any value-based pricing, also raises ethical issues. What is value? Should determinations of value be based on survival time, improved quality of life, or other outcomes benchmarks? When comparing value determinations, and therefore price determinations, across indications, there are further concerns. Is treating certain

indications considered inherently more valuable than others such that the prices are higher for effective treatments? For example, should all cancer treatments be considered more valuable and therefore inherently more expensive than a treatment for chronic back pain? Taken a step further, should a cancer treatment with little to no benefit in most patients cost more than a prescription drug that treats chronic back pain, removing virtually all symptoms, in 99 percent of cases?

While that thought experiment is an extreme (not to mention unsupported and unlikely) example, these are the kinds of determinations made in value assessments.²¹⁶ Inevitably, value assessments will incentivize companies to develop treatments for certain diseases more than others. This is one of the reasons that rare diseases (which have small populations and therefore small pharmaceutical markets) receive increased attention from the FDA in terms of accelerated approval pathways and incentives for companies that develop treatments. These may not take into account patient perspectives, particularly in terms of approved quality of life. Disability advocates commonly criticize the use of quality adjusted life years (QALYs) as a healthcare metric and raise the potential for disastrous consequences if it is used broadly and incorrectly.²¹⁷ The metric used to determine value in an indication-specific pricing regime would need to be carefully constructed to limit the discriminatory effects. Even with careful consideration, it may be impossible to remove discriminatory effects entirely. It is inevitable that an indication-specific pricing regime will prioritize certain outcome measures while disadvantaging other outcomes – and patients.

IV. ALTERNATIVE REFORMS AND RECOMMENDATIONS FOR LAWMAKERS

The incentive effects of indication-specific pricing of prescription drugs contradict the overall goals of prescription drug reform: decreasing prescription drug spending, decreasing prescription drug prices, and increasing the accessibility and affordability of high-value prescription drugs. It is thus clear that in order to decrease prescription drug spending, other models for prescription drug pricing should be pursued. Section A suggests alternative value-based pricing models that

216. See Peter J. Neumann et al., *Should A Drug's Value Depend On The Disease Or Population It Treats? Insights From ICER's Value Assessments*, HEALTH AFF. BLOG (Nov. 6, 2018), <https://www.healthaffairs.org/doi/10.1377/hblog20181105.38350/full/> (“A central question facing ICER – and by proxy all of us as health plan enrollees, taxpayers, and patients – is whether a drug’s value should depend on not only its “generic benefit” – e.g., as measured by quality adjusted life years (QALYs) gained – but also on which disease or population it treats. For example, should ICER invoke higher (i.e., more lenient) cost-per-QALY gained cost-effectiveness benchmarks in some areas (say, cancer or rare diseases) than others and, if so, on what basis?”).

217. Ari Ne’eman, *Formulary Restrictions Devalue And Endanger The Lives of Disabled People*, HEALTH AFF. BLOG (Oct. 29, 2018), <https://www.healthaffairs.org/doi/10.1377/hblog20181025.42661/full/> (criticizing using QALYs as a cost effectiveness measure in determining which drugs to exclude from formularies).

lawmakers could consider in prescription drug reform instead of indication-specific pricing. Section B introduces alternative policy interventions that lawmakers should explore to decrease prescription drug prices and spending. Section C concludes with recommendations for future legislative action.

A. Other Value-Based Pricing Models for Prescription Drugs

Value should be incorporated in the pricing of prescription drugs. Different value-based pricing models could be explored by lawmakers, but would probably not be more likely to decrease prescription drug spending than indication-specific pricing.

Average weighted pricing for multi-indication prescription drugs could be more feasible to implement than indication-specific pricing but would likely not be more effective.²¹⁸ Average weighted pricing assigns the price of a prescription drug based on the weighted average value of the prices of each indication for the prescription drug.²¹⁹ Unlike a pure indication-specific pricing regime, average-weighted pricing would not face the difficulties of pricing a drug per indication where the system does not track the indication for which a drug is prescribed or recognize differential reimbursement by indication.

However, it is unlikely that an average weighted price would have a significant impact on prescription drug prices or spending. High-value indications that are largely used would likely dominate the pricing calculation, maintaining the high costs of multi-indication prescription drugs. Thus, while average weighted pricing may avoid many of the legal and regulatory barriers related to indication-specific pricing, it would likely provide no benefits in access or affordability to patients and do little or nothing to reduce prescription drug spending.

Outcome-based payments could be another value-based model worth exploring.²²⁰ Instead of directly increasing the cost of high-value indications, outcome-based payments tie the cost of a prescription drug to the outcomes of an individual patient or patient population either by adjusting the initial price to reflect value or providing a rebate based on an individual patient's outcome.²²¹ Several prescription drug companies have entered into outcome-based contracts in the

218. See PEARSON ET AL., *supra* note 18, at 19 (“Lastly, using a single weighted-average price is far more feasible in the current environment than trying to track indication-specific use and applying different discounts to each indication. The latter approach, although a more ‘pure’ form of indication-specific pricing, is more likely to create a price that triggers Medicaid best price provisions; it also presents the greatest potential challenges for sorting out and describing to stakeholders how patients and providers are affected by different prices for different indications.”).

219. See *id.* at 11-12.

220. See Sachs et al., *supra* note 14, at 6.

221. See *id.* at 10.

private sector,²²² and recently the federal government expressed interest in experimenting with outcome-based payment models for prescription drugs for chronic disease treatment.²²³ However, the impact of outcomes-based contracts on prescription drug spending is unclear.²²⁴ One recent outcomes-based contract involving Novartis' Kymriah, a drug used for a type of leukemia, resulted in payment only if the patient received a positive response by the end of the first month of treatment; even so, the value-based, outcome-based payment was \$475,000.²²⁵

This case raises doubt as to whether such contracts in the cancer context would actually save money. If prices are set low enough and very specific outcomes benchmarks are set and tracked, it is possible that these contracts could save money. However, such terms would need to be negotiated with and agreed upon by pharmaceutical companies, which seems unlikely. More research should be done on the broader incentive effects of outcome-based payment models, specifically regarding prescription drug prices, overall prescription drug spending, and patient access to prescription drugs. Outcomes based contracts in practice may incentivize pharmaceutical companies to negotiate extremely low or easy to achieve outcomes benchmarks that do not fully demonstrate effectiveness improved quality of life in a patient. Alternatively, companies may emphasize patient perspectives to seek very subjective and potentially clinically insignificant benchmarks. Such contracts would lead to virtually certain payment to prescription drug companies and may do nothing to lower prices for many drugs if the overall value of the contract is not significantly less than the current price. If these benchmarks are not representative of the value of the drug, these prices would likely increase independent of the effectiveness of the prescription drug. With these assumed incentives, prescription drug prices and overall spending would increase, leading to poorer patient access. Unless aggressive negotiating power is given to federal government insurance programs such that they can overcome these

222. See *id.* at 10-11.

223. See Robert Saunders et al., *Medicare Accountable Care Organization Results For 2016: Seeing Improvement, Transformation Takes Time*, HEALTH AFF. BLOG (Nov. 21, 2017), <https://www.healthaffairs.org/doi/10.1377/hblog20171120.211043/full/> ("effective prescription drug use is essential to effective management of most chronic diseases that have significant population health impacts. . . . As CMMI has recently highlighted, one opportunity is implementing value-based payment reforms for drugs that share overall spending and health outcome accountability with drug manufacturers to advance the movement away from fee-for-service.").

224. See, e.g., ELIZABETH SEELEY & AARON S. KESSELHEIM, *OUTCOMES-BASED PHARMACEUTICAL CONTRACTS: AN ANSWER TO HIGH U.S. DRUG SPENDING?* 1 (Sept. 2017).

225. See Daniel et al., *supra* note 26; *Novartis receives first ever FDA approval for a CAR-T cell therapy, Kymriah(TM) (CTL019), for children and young adults with B-cell ALL that is refractory or has relapsed at least twice*, NOVARTIS (Aug. 30, 2017), <https://www.novartis.com/news/media-releases/novartis-receives-first-ever-fda-approval-car-t-cell-therapy-kymriah-tm-ctl019>.

incentives for prescription drug companies, outcomes-based contracts for prescription drugs would not decrease prescription drug prices and spending.

B. *Other Policies to Lower Prescription Drug Prices*

Other reforms should be considered instead of, or in conjunction with, value-based pricing models. Value-based pricing models have garnered great support and attention from politicians and healthcare professionals, but they only focus on one type of intervention at one point in the pharmaceutical chain – the link between the payer and the pharmaceutical manufacturer. The following list of proposed interventions is by no means exhaustive but raises a broad range of alternative policies lawmakers should consider in prescription drug reform.

Some recommended interventions would affect the interactions between payers and pharmaceutical manufacturers. One popular political talking point is allowing Medicare to negotiate prices for prescription drugs like it does for other healthcare goods and services.²²⁶ However, the Congressional Budget Office has found that Medicare negotiation would have “a negligible effect on federal spending”²²⁷ because each individual Medicare Part D already negotiates with pharmaceutical companies and because Medicare has limited ability, and thus decreased bargaining power, to exclude prescription drugs from coverage.²²⁸ Without the ability to not cover from certain drugs, Medicare Part D plans often must accept high prescription drug prices from companies.²²⁹ Additionally, Medicare negotiation could have a negative impact on the negotiating power of other federal government programs, particularly the 340B Drug Discount Program and the VA.²³⁰ While the federal government could theoretically expand its mandatory discounts to Medicare, this could still threaten the negotiating power of other federal government programs and could incentivize prescription drug manufacturers to increase prices to make up for lost revenue.

Other proposals focus on accessibility and affordability specifically from the patient perspective. Patients generally make copayments when they receive a prescription drug. Scholars have suggested basing beneficiaries’ copayments on the effective price of a prescription drug after rebates instead of the on the list

226. Kesselheim et al., *supra* note 12, at 865.

227. Juliette Cubanski & Tricia Neuman, *Searching for Savings in Medicare Drug Price Negotiations*, KAISER FAM. FOUND. (Jan. 23, 2017), <https://www.kff.org/medicare/issue-brief/searching-for-savings-in-medicare-drug-price-negotiations/>; Congressional Budget Office, *Letter to Senator Ron Wyden* (April 10, 2007), available at <https://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/79xx/doc7992/drugpricenegotiation.pdf>.

228. See Sachs, *supra* note 69, at 2326.

229. See *id.*

230. See Outtersson & Kesselheim, *supra* note 90, at w834.

price²³¹ or reducing copayments by payers or through subsidies.²³² While these approaches may make prescription drugs more affordable at the time of purchase, decreasing patients' out-of-pocket spending, patients' premiums would potentially increase and effect a rise in overall federal government spending on prescription drugs.²³³ Consideration of the magnitude of the potential premium increases and federal government spending increase would have to be made in comparison to increased accessibility to patients at point-of-service.

Broader reforms of the pharmaceutical patent and antitrust regimes may have the most promise in decreasing prescription drug spending and prices. Patent exclusivity keeps the price of prescription drugs high and prevents competitors from entering into the market. Proposals have been made to limit the exclusivity period of patents, particularly limiting "secondary patents for trivial changes of a patented molecule," as well as prohibiting anti-competitive practices, including pay-for-delay agreements where patent holders pay generic companies to delay their entry into the market.²³⁴ Some scholars have even recommended using executive authority to mandate compulsory licensure of prescription drugs based on government-funded research, though this would not be a system-wide solution.²³⁵ Especially with the amount of research that is partially funded by the federal government,²³⁶ there is a social expectation that prescription drugs will be made reasonably accessible and affordable to the public.²³⁷

231. See Rachel Sachs, *Drug Policy: The Year In Review, And The Year Ahead*, HEALTH AFF. (Jan. 4, 2018), <https://www.healthaffairs.org/doi/10.1377/hblog20180103.276023/full/>.

232. Darius N. Lakdawalla et al., *U.S. Pharmaceutical Policy in A Global Marketplace*, HEALTH AFF. w138, w138 (2008).

233. See Sachs, *supra* note 231 ("As scholars have noted, patients' out-of-pocket costs may be based on their drugs' list prices, even if a Part D sponsor has negotiated a lower price. CMS has proposed passing some of those rebates on to patients; this would decrease many beneficiaries' point-of-sale costs significantly, but would potentially increase beneficiary premiums—and increase CMS' direct subsidy costs—overall.).

234. Kesselheim et al., *supra* note 12, at 864.

235. See generally Hannah Brennan et al., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J. L. & TECH. 275 (2016); Rachel Sachs, *March-In Rights Alone Won't Solve Our Drug Pricing Problems*, HARV. BILL OF HEALTH (Jan. 12, 2016), <https://perma-archives.org/warc/HE43-R9X5/http://blogs.harvard.edu/billofhealth/2016/01/12/march-in-rights-alone-wont-solve-our-drug-pricing-problems/>.

236. See Kesselheim et al., *supra* note 12, at 863 ("important innovation that leads to new drug products is often performed in academic institutions and supported by investment from public sources such as the National Institutes of Health. A recent analysis of the most transformative drugs of the last 25 years found that more than half of the 26 products or product classes identified had their origins in publicly funded research in such nonprofit centers.").

237. David Gilman & Nathan Dowden, *Is Value-Based Drug Pricing Compatible with Pharma Innovation?*, NEW ENG. J. MED. CATALYST (Nov. 20, 2017), <https://catalyst.nejm.org/is-value-based-drug-pricing-compatible-with-pharma-innovation/> ("This innovation has occurred within the context of an implicit social contract. The U.S. government substantially subsidizes basic research and the

Critics have argued that decreasing the exclusivity periods on patents would stifle innovation, removing a key financial incentive for pharmaceutical companies to develop new prescription drugs. Studies have challenged this assertion, demonstrating that the revenue gained in the exclusivity period far exceed the costs of pharmaceutical research and development and decreasing the exclusivity period would leave adequate incentives for drug companies.²³⁸ The Lancet Commission on Essential Medicines recommended creating an Essential Medicines Patent Pool which would essentially result in voluntary or compulsory licensure for all essential medicines.²³⁹ These reforms may also challenge future innovation: while pharmaceutical companies may have adequate economic incentives to continue their work, removing some current incentives may result in companies pursuing less risky, innovative research.

One final proposal is greater transparency in the comparative effectiveness and cost-effectiveness of prescription drugs. There is little transparency in the actual prices paid for prescription drugs and there seems to be little intent on the part of the pharmaceutical industry or the federal government to increase this transparency.²⁴⁰ The Patient-Centered Outcomes Research Institute was founded to focus on cost-effectiveness research, but the Affordable Care Act “prohibited the partially government-funded research institution from considering the relative value of drugs and from using [quality-adjusted life years] as a cost-effectiveness measure.”²⁴¹ The governments of several other countries fund assessments of comparative clinical and economic value.²⁴² Currently, only non-governmental

provision of health care, and it waives its ability to negotiate directly with manufacturers about prices. In return, the biomedical industry is allowed to attempt to recoup its R&D investments during a limited post-approval period defined by the Drug Price Competition and Patent Term Restoration Act of 1984 (often called the Hatch–Waxman Act), with the expectation that drug prices will be set at a point that ensures a reasonable level of population access.”)

238. See, e.g., Brennan et al., *supra* note 235, at 328 (explaining that Gilead recouped recouped its expenditure on Sovaldi and Harvoni in two and a half years, likely earning forty times the development costs in that period).

239. Sabine Vogler, et al., *How Can Pricing and Reimbursement Policies Improve Affordable Access to Medicines? Lessons Learned from European Countries*, 15 J. APPLIED HEALTH ECON. & HEALTH POL’Y 307, 316 (2017).

240. HENRY WAXMAN ET AL., GETTING TO THE ROOT OF HIGH PRESCRIPTION DRUG PRICES: DRIVERS AND POTENTIAL SOLUTIONS 30-31 (July 2017)

241. See RALPH MARCELLO ET AL., DELOITTE HEALTH POLICY BRIEF: GETTING TO VALUE: WHAT POLICIES ARE ON THE TABLE TO MANAGE DRUG PRICES? 5 (2016). See also Kesselheim, *supra* note 16, at 866 (“The Patient-Centered Outcomes Research Institute had been expected to serve in this role. It was hailed at its inception as a vehicle to promote robust comparative effectiveness research, but Congress precluded it from considering drug costs as a central focus of its work, shifting instead to patient engagement and decision aids. The institute’s reauthorization in 2019 will provide another opportunity to revisit its mission.”).

242. See Kesselheim et al., *supra* note 12, at 866 (“In the United Kingdom, Germany, Australia, Canada, and several other countries, government-funded technology assessment activities provide support for comparative effectiveness studies and evaluate new products in light of comparative cost-

organizations in the United States, including the Institute for Clinical and Economic Review and others, conduct such assessments.²⁴³ Lawmakers should repeal the law forbidding the government from using comparative effectiveness research to determine the relative value of treatments and inform insurance coverage and prescription drug pricing decisions.²⁴⁴ Advocating for further transparency in prescription drug pricing and the comparative clinical and economic effectiveness will encourage both rational prescription drug pricing and more informed healthcare decision-making. This is true not only for patients (knowing how much they will be paying for prescription drugs) and providers (knowing how much the drugs they prescribed will cost the patient). Greater transparency on comparative effectiveness drug prices, and in particular the discounts on prescription drugs, can aid the government in negotiating prices and improving access to patients.²⁴⁵

C. *Moving Forward: Recommendations for Lawmakers*

Ultimately, some combination of interventions is likely needed to truly control prescription drug spending and make prescription drugs accessible and affordable to all in the United States. High prescription drug prices and spending are complex problems, and reforms at various points in the healthcare delivery system could be effective. Moving forward, lawmakers should look to gain more insight on to how these various pricing regimes and other interventions would affect prescription drug spending and pricing in practice. Specifically, it is necessary to gain a better understanding of the incentive effects of such models.

Both the federal and state government have begun experimenting with alternative prescription drug pricing models. On the federal level, CMS can experiment with different prescription drug payment models, as proposed to do with Medicare Part B in 2015 and again in 2018.²⁴⁶ This plan includes a test of indication-specific pricing of prescription drugs, outcomes-based pricing, and

effectiveness analysis. The information thus generated could be used by government and private payers to help them respond to company-set prices, make determinations about formulary rules and exclusions, and educate physicians and patients about the value of medication choices.”).

243. *Id.* (“patients, physicians, and payers can turn to non-governmental organizations, such as the Institute for Clinical and Economic Review, *The Medical Letter*, the Independent Drug Information Service, Oregon’s Drug Effectiveness Review Project, and *Consumer Reports Best Buy Drugs*, which provide information on value-based choices for select medications The data generated by these groups can support lower drug prices by helping payers organize their formularies and negotiate appropriate rebates, as well as guide prescribers and patients toward more appropriate drug-use decisions.”).

244. See MARCELLO ET AL., *supra* note 241, at 4.

245. Vogler, et al., *supra* note 239, at 315.

246. See *Medicare Part B Brief*, *supra* note 64; Schrag, *supra* note 81, at 2101; Sachs, *supra* note 17.

reducing or eliminating patient cost-sharing.²⁴⁷ CMS should continue to explore interventions and implement an experiment on prescription drug pricing in its programs. The resulting data would be particularly valuable to lawmakers moving forward with reforms.

On the state level, some states are experimenting with value-based pricing models in their government health insurance programs. Massachusetts sought a waiver under Section 1115 of the Social Security Act to experiment with the prescription drug part of its Medicaid program.²⁴⁸ Its model would result in a closed formulary with at least one prescription drug covered in each therapeutic area.²⁴⁹ The proposal also included a component focusing on value: it would exclude drugs with “limited or inadequate benefit until incremental clinical value is proven.”²⁵⁰ This waiver could have resulted in Massachusetts choosing not to cover several types of prescription drugs, such as those prescription drugs approved through FDA’s Accelerated Approval Pathway.²⁵¹ Massachusetts proposed that Medicaid beneficiaries could petition to access non-formulary drugs.²⁵² The federal government initially showed interest in this and similar proposals, with President Trump’s February 2018 budget proposing a study that would allow five states to exclude FDA-approved prescription drugs from their formularies, although it did not include continuing the mandatory rebates by prescription drug manufacturers in these states.²⁵³ Even so, the Trump Administration rejected the Massachusetts proposal, reiterating the requirement that Medicaid programs cover all FDA-approved drugs.²⁵⁴ Such formularies have received criticism from the public for restricting access to drugs, not taking patient perspectives into account,²⁵⁵ using discriminatory value metrics, and devaluing the

247. See CMS proposes to test new Medicare Part B prescription drug models to improve quality of care and deliver better value for Medicare beneficiaries, CTRS. FOR MEDICARE & MEDICAID SERVS. (Mar. 8, 2016), <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-03-08.html>.

248. See Kesselheim et al, *supra* note 16.

249. See *id.*

250. *Id.*

251. See Manatt Phelps & Phillips LLP, *supra* note 118.

252. See *id.*

253. See *id.*

254. See Nicholas Bagley & Rachel E. Sachs, *Limiting State Flexibility in Drug Pricing*, 379 NEW ENG. J. MED. 1002, 1002-03 (2018); MaryBeth Musucemi et al., *Section 1115 Medicaid Demonstration Waivers: The Current Landscape of Approved and Pending Waivers*, KAISER FAM. FOUND. (Sept. 20, 2018), <https://www.kff.org/medicaid/issue-brief/section-1115-medicaid-demonstration-waivers-the-current-landscape-of-approved-and-pending-waivers/view/footnotes/#footnote-273141-22>.

255. Jason Shafrin & Mark Linthicum, *Patent-Centered Formularies: Steps In The Right Direction, But Challenges Remain*, HEALTH AFF. BLOG (Apr. 11, 2018), <https://www.healthaffairs.org/doi/10.1377/hblog20180404.510552/full/>

lives of people with disabilities.²⁵⁶ Taking these perspectives of value into account would be needed for states and the federal government to move forward with formularies emphasizing value.

Other states have also explored pricing regulation at the state level without a Section 1115 waiver. More than eighty pharmaceutical pricing bills were proposed in 2017 in over thirty states.²⁵⁷ New York's bill, for example, passed in April 2017, allows the state to put "limits on prescription drug costs based on their therapeutic benefits."²⁵⁸ Other states should follow and continue to experiment with various interventions to reform prescription drug spending and pricing. This further research and experimentation with various policy interventions will allow data collection so future lawmakers can make informed choices.

Moving forward, lawmakers should continue to make evidence-based proposals that will make prescription drugs more affordable and accessible to patients while allowing for decreased overall prescription drug spending and continued innovation incentives.

CONCLUSION

The skyrocketing prices of prescription drugs and increasing federal drug spending pose significant threats to affordable healthcare in the United States. An indication-specific pricing regime for prescription drugs in federal health insurance programs would neither decrease overall prescription drug spending nor improve accessibility and affordability of prescription drugs for individual patients. The current legal and regulatory framework in Medicare, Medicaid, the 340B Drug Discount Program, and the Veterans Health Administration pose several challenges to implementing any value-based pricing scheme, especially indication-specific pricing. The FDA approval system and the risk of off-label promotion liability also stand in the way of implementing an indication-specific pricing regime in the United States. Additional policy effects and ethical considerations would also have to be made in reforming the prescription drug pricing system in order to protect patients' access to medicines. The barriers to indication-specific pricing may not be insurmountable, but substantial system modifications would have to be made for it to be a realistic option. Even with these

256. Ne'eman, *supra* note 217.

257. See BERMAN ET AL., *supra* note 14, at 1. Particularly innovative bills were passed in Maryland, New York, and Nevada. See *id.* See also Theodore T. Lee et al., *Legal Challenges to State Drug Pricing Laws*, 319 J. AM. MED. ASS'N 865, 865-66 (2018) (discussing legal challenges to state laws to control prescription drug prices); Fran Quigley, *On Drug Pricing, States Step In Where Washington Fails*, N.Y. TIMES (Feb. 27, 2018), <https://www.nytimes.com/2018/02/27/opinion/drug-pricing-states.html> (discussing state efforts on prescription drug price reform).

258. See Thomas J. Hwang et al., *Value-Based Pricing and State Reform of Prescription Drug Costs*, 318 NEW ENG. J. MED. 609, 609 (2017).

modifications, indication-specific pricing would likely not decrease prescription drug prices or overall spending.

As the United States continues to pursue healthcare reform and tackles the problem of unaffordable prescription drug prices, value-based pricing regimes should not be disregarded. Other interventions should be considered to decrease prescription drug prices and spending. Moving forward, lawmakers must explore these potential solutions and focus on affordability and accessibility. The problem of high prescription drug prices and spending is complex and multi-faceted, and any change to the current regime will have impacts on the insurance system, patient access, healthcare system spending, healthcare outcomes, and pharmaceutical innovation.

Any reform to prescription drug pricing and spending must prioritize patient access. Indication-specific pricing may create more problems while failing to increase the accessibility and affordability of drugs. The current system of prescription drug pricing is unethical and unaffordable. Reforms must not perpetuate the problem.

