

Early Access to Unapproved Medicines in the United States and France

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Abstract:

In 2018, President Trump signed a federal “right to try” law, claiming that it would give desperately ill patients earlier access to unapproved medicines, by allowing the patient, doctor, and drug company to arrange for access without federal oversight. Critics of the law argued that it would not meaningfully increase access to experimental medicines, because federal oversight was not the obstacle in the first place. And they were correct. U.S. law already permitted companies to provide terminally ill patients with early access to unapproved medicines. The problem was instead that companies did not take advantage of this option. This Article offers new insights into U.S. law on early access, as well as the new right-to-try law, by offering a comparative perspective using French law. We explore the historical, legal, and cultural differences between France and the United States that may explain differences in their early access systems and why the right-to-try law emerged in one country but not the other. The differing approaches reflect in part differing reactions to arguments grounded in personal autonomy and patients’ rights, when held up against utilitarian arguments for premarket approval and traditions of medical paternalism. Using the French experience, this Article also considers the possibility that the key to increasing use of expanded access in the United States might be financial: making it worthwhile for companies, by allowing them to profit from sales, and making the medicines and associated healthcare services free for patients through insurance coverage.

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TABLE OF CONTENTS

INTRODUCTION	3
I. THE NEW MEDICINE GATEKEEPING MODEL	8
A. THE PREMARKET APPROVAL REQUIREMENT	8
B. PATERNALISM AND UTILITARIANISM IN THE PREMARKET MODEL	11
II. EARLY ACCESS MECHANISMS WITHIN THE GATEKEEPING FRAMEWORK.....	14
A. EVOLUTION IN THE RELATIONSHIP BETWEEN INDIVIDUAL AND STATE	15
B. ACCESS TO INVESTIGATIONAL MEDICINES THROUGH A GATEKEEPER	19
1. EMERGENCE OF EARLY ACCESS MECHANISMS	20
2. COMMITMENT TO THE GATEKEEPING MODEL	23
3. RIGOROUS ASSESSMENT OF INFORMED CONSENT AND MEDICAL PATERNALISM.....	27
4. PRIORITIZING THE GENERATION OF EVIDENCE AND PROGRESS TOWARD APPROVAL	29
III. THE RIGHT-TO-TRY ALTERNATIVE IN THE UNITED STATES	34
A. ELIMINATION OF THE GATEKEEPER.....	35
B. EXPLAINING THE ENACTMENT OF RIGHT-TO-TRY IN THE UNITED STATES.....	39
IV. INCREASING USE OF EXPANDED ACCESS IN THE UNITED STATES.....	44
A. ADDRESSING BARRIERS TO COMPANY PARTICIPATION IN EXPANDED ACCESS	44
B. ADDRESSING THE FINANCIAL STRUCTURE OF EXPANDED ACCESS.....	49
C. BARRIERS TO PROVIDER AND PATIENT PARTICIPATION IN EXPANDED ACCESS	53
CONCLUSION	54

INTRODUCTION

In spring 2014, a first-grader with cancer became a poster child for the growing “right to try” movement in the United States. When Josh Hardy was nine months old, doctors diagnosed him with a malignant, highly aggressive, and rare form of kidney cancer.¹ After successful treatment, he faced recurrences in 2008 and again in 2009, before being declared “cancer-free for two years” in May 2013.² But in the fall of 2013, doctors diagnosed him with myelodysplastic syndrome, bone marrow failure stemming from years of chemotherapy and radiation treatments.³ Josh received a bone marrow transplant in early 2014, but weakening of his immune system led to a life-threatening adenovirus infection.⁴ After receiving the standard of care for this infection—cidofovir—led to kidney failure, Josh was out of options. There were no other approved drugs to treat the infection.

Josh’s physicians at St. Jude Children’s Hospital in Tennessee turned to an unapproved drug, brincidofovir, made by Chimerix Inc., a small company based in North Carolina.⁵ The company was in the middle of a phase 3 clinical trial—the last trial needed for regulatory approval—but they were studying the use of this drug in preventing cytomegalovirus (CMV) reactivation in adult stem cell transplant recipients, a different indication.⁶ The company had also just released promising results from a small study using brincidofovir to treat early adenovirus infections in stem cell transplant patients.⁷ Without a doubt, the federal government would have permitted Chimerix to provide Josh the drug on a “compassionate use” basis under its “expanded access” regulations.⁸ Under these regulations, the U.S. Food and Drug Administration (FDA) permits a company to provide an unapproved drug to a patient with a serious or life-threatening condition who is *not* enrolled in its clinical trials, if certain conditions are met. The company must be willing to provide the drug, however, and it has to ask FDA for permission before proceeding. Chimerix turned the doctors and family down, however, saying

1. Kenneth I. Moch, *Ethical crossroads: expanded access, patient advocacy, and the #SaveJosh social media campaign*, 1 MED. ACCESS @ POINT OF CARE e119 (2017), <https://journals.sagepub.com/doi/pdf/10.5301/maapoc.0000019> [https://perma.cc/34KB-MREY]. Moch was Chief Executive Officer of Chimerix during the events described in the article.

2. Elena Gerasimov, *Saved Josh: The Gears of a Successful Patient Advocacy Campaign*, KIDS V. CANCER 1–2 (Mar. 9, 2016), <https://www.kidsvcancer.org/wp-content/uploads/2016/01/Hardy-Case-Study-final-March-9-2016.pdf> [https://perma.cc/C4D2-UQTY].

3. *Id.*; Moch, *supra* note 1, at e122.

4. Moch, *supra* note 1, at e122.

5. Gerasimov, *supra* note 2, at 3.

6. Moch, *supra* note 1, at e121.

7. Moch, *supra* note 1, at e121. Statistical significance had not been achieved, but the study showed numerical benefit in virologic response, treatment failures, and mortality.

8. *See infra* Section 2. Commitment to the Gatekeeping Model.

that it wanted to focus on enrolling patients in the ongoing CMV trial to complete the research needed for approval.⁹ The family turned to social media, which led to a barrage of phone calls and emails to the company from the public and from state and federal legislators, media headlines such as “Company denies drug to dying child,” and death threats against family members of the company’s Chief Executive Officer.¹⁰

Facing this onslaught, Chimerix worked with FDA to design and launch a twenty-patient study of the drug for the treatment of adenovirus infections in immunocompromised patients, in which Josh would be the first enrolled patient.¹¹ On March 12, 2014, he received his first dose.¹² Nineteen days later the virus was undetectable, and ten days later Josh left the hospital.¹³ This opened the floodgates. Three days after announcing the trial, the company received six more requests for the drug, and within six months the company had enrolled eighty patients in its twenty-patient study.¹⁴ Although the drug eliminated Josh’s viral infection, his cancer eventually returned, and he died in September 2016.¹⁵

The story made national news, and for the next few years it played a role in a larger public debate about the rights of dying patients to try experimental medicines to save their own lives and the proper role of the federal government—if any—in limiting those rights. Just one month before the Josh Hardy firestorm hit social media, the Goldwater Institute published a paper arguing that every state should enact a “right to try” measure, which it had drafted, to “allow terminal

9. Gerasimov, *supra* note 2, at 2–3.

10. Moch, *supra* note 1, at e125; see Elizabeth Cohen, *Company Denies Drug to Dying Child*, CNN HEALTH (Mar. 11, 2014), <https://www.cnn.com/2014/03/10/health/cohen-josh/index.html> [<https://perma.cc/CSB4-86DW>].

11. Moch, *supra* note 1, at e125. Because the drug was unapproved and the company had decided against providing expanded access, a formal clinical trial designed to support approval of the drug for Josh’s condition was the only legal mechanism by which Josh could receive the drug.

12. *Id.*

13. *Id.*; David Kroll, *Josh Hardy Going Home After Getting Chimerix Anti-Viral Drug*, FORBES (Jul. 17, 2014), <https://www.forbes.com/sites/davidkroll/2014/07/17/josh-hardy-going-home-after-getting-chimerix-anti-viral-drug> [<https://perma.cc/A48J-KR82>].

14. Moch, *supra* note 1, at e126. Although the drug eventually failed its phase 3 trial in CMV, Chimerix is still studying the drug’s antiviral activity. See Press Release, Chimerix, Chimerix Presents Results from Post-hoc Analysis of Phase 3 Study (Feb. 22, 2019), <https://ir.chimerix.com/news-releases/news-release-details/chimerix-presents-results-post-hoc-analysis-phase-3-study> [<https://perma.cc/42LU-WV63>]; Jessica Merrill, *Chimerix Sees Options For Brincidofovir Despite Disappointing CMV Data*, PINK SHEET (Feb. 22, 2016), <https://pink.pharmaintelligence.informa.com/PS079135/Chimerix-Sees-Options-For-Brincidofovir-Despite-Disappointing-CMV-Data>.

15. Cathy Dyson, “Now He is Healed”; *Mourning the Death of 10-Year-Old Josh Hardy*, FREDERICKSBURG FREELANCE STAR (Sept. 22, 2016), https://www.fredericksburg.com/news/local/now-he-is-healed-mourning-the-death-of-10-year-old-josh-hardy/article_3da24a7a-ee8b-5c74-89a8-f58adeb0ff31.html [<https://perma.cc/862X-PL22>].

patients access to investigational drugs that have completed basic safety testing.”¹⁶ This was not a new idea: U.S. policymakers and courts had heard similar arguments for decades.¹⁷ But the arguments gained traction this time, and after more than two-thirds of the states enacted right-to-try laws, the federal government followed suit.¹⁸ Under the federal right-to-try law, a patient, doctor, and drug company can proceed to treatment with an unapproved medicine *without* seeking permission first from the federal government. Expanded access, in contrast, requires FDA’s permission.

But the problem for Josh was not federal law in the first place. His problem was that Chimerix refused to provide brincidofovir on a compassionate basis outside of a conventional clinical trial. And Chimerix was not an outlier. Drug companies often decline to provide experimental medicines to dying patients who do not qualify for ongoing trials.¹⁹ The federal right-to-try law addressed a few reasons companies may decline requests—specifically, concerns about liability exposure and concerns that adverse events will affect the medicine’s approval or labeling—but seemingly as an afterthought. It was not a fully fleshed-out attempt to improve access to investigational drugs so much as an attempt to cut FDA out of the process. And because FDA was not the problem in the first place, there remains a serious question whether the law will have any effect on access to experimental medicines.

Many scholars have explored the ethical arguments for providing early access to unapproved medicines on a compassionate basis.²⁰ There is also a rich body of

16. Christina Corieri, *Everyone Deserves the Right to Try: Empowering the Terminally Ill to Take Control of Their Treatment*, GOLDWATER INSTITUTE 1 (Feb. 11, 2014), https://goldwaterinstitute.org/wp-content/uploads/cms_page_media/2015/1/29/Right%20To%20Try.pdf [<https://perma.cc/XW4Y-SA9H>].

17. See *infra* Section 0.

18. See Jacqueline Howard, *What you need to know about right-to-try legislation*, CNN HEALTH (May 29, 2018), <https://www.cnn.com/2018/03/22/health/federal-right-to-try-explainer/index.html> [<https://perma.cc/LH9Y-KM8F>] (noting that thirty-eight states had passed right-to-try laws).

19. Gail A. Van Norman, *Expanding Patient Access to Investigational Drugs: Single Patient Investigational New Drug and the “Right to Try”*, 3 JACC: BASIC TO TRANSLATIONAL SCI. 280, 287 (2018) (“Although companies have developed internal pathways by which individual patients can achieve access to investigational drugs, the majority of such requests are denied.”); Lewis A. Grossman, *FDA and the Rise of the Empowered Consumer*, 66 ADMIN. L. REV. 627, 632 (2014) (“The pharmaceutical industry has never been enthusiastic about expanded access programs for unapproved, investigational therapies.”).

20. E.g., Eline Bunnik, Nikkie Aarts & Suzanne van de Vathorst, *The Changing Landscape of Expanded Access to Investigational Drugs for Patients with Unmet Medical Needs: Ethical Implications*, 10 J. PHARMACY POL’Y & PRAC., Feb. 21, 2017, at 1; Eline Bunnik, Nikkie Aarts & Suzanne van de Vathorst, *Little to Lose and No Other Options: Ethical Issues in Efforts to Facilitate Expanded Access to Investigational Drugs*, 122 HEALTH POL’Y 977 (2018); Arthur Caplan, *Is It Sound Public Policy to Let the Terminally Ill Access Experimental Medical Innovations?*, 7 AM. J. BIOETHICS, Jun. 1, 2007, at 1; Arthur Caplan & Kenneth Moch, *Rescue Me: The Challenge of*

legal and public policy literature on these issues and on the history of expanded access in the United States.²¹ This Article offers fresh insights on early access schemes, by providing a comparative perspective using French law. Both the United States and France use a regulatory gatekeeper for new medicines, requiring premarket approval based on testing data. Both legal systems have evolved in the last half century to permit access before approval in some cases: under “expanded access” in the United States and “temporary authorization for use” (ATU) in France. Functionally, the early access schemes are similar, preserving a gatekeeping mechanism and respecting the basic premises and goals of the new medicine preapproval paradigm. But the schemes differ in their genesis and specifics, and they operate within fundamentally different healthcare finance systems. We explore the historical, legal, and cultural differences between the two countries that may explain these differences. These same differences help explain why the right-to-try law—which rejects the basic premises and goals of the preapproval paradigm—emerged in the United States but is unlikely to emerge in France.

This Article makes two claims. First, the differences between the two countries’ approaches to early access and right-to-try reflect in part differing reactions to arguments grounded in personal autonomy and patients’ rights, when held up against utilitarian arguments for premarket approval and traditions of medical paternalism. New drug approval schemes are utilitarian, using the barrier

Compassionate Use in the Social Media Era, HEALTH AFFAIRS BLOG, Aug. 27, 2014, <https://www.healthaffairs.org/doi/10.1377/hblog20140827.041027/full/> [https://perma.cc/RDR3-L5ES]; Daniele Carrieri, Fedro A. Peccatori & Giovanni Boniolo, *The Ethical Plausibility of the “Right to Try” Laws*, 122 CRITICAL REV. ONCOLOGY/HEMATOLOGY 64, 66 (2018); Audrey Chapman, *Proposal for Patient Obligations for Access to Unapproved Interventions: Both Too Much and Not Enough*, 14 AM. J. BIOETHICS, Oct. 17, 2014, at 25; Kasper Raus, *An Analysis of Common Ethical Justifications for Compassionate Use Programs for Experimental Drugs*, 17 BMC MED. ETHICS, Oct. 18, 2016, at 1; Udo Schüklenk & Christopher Lowry, *Terminal illness and access to phase 1 experimental agents, surgeries, and devices: reviewing the ethical arguments*, 89 BRITISH MED. BULL. 7, 9 (2009); Mary Jean Walker, Wendy A. Rogers & Vikki Entwistle, *Ethical Justifications for Access to Unapproved Medical Interventions: An Argument for (Limited) Patient Obligations*, 14 AM. J. BIOETHICS, Oct. 17, 2014, at 3, 4.

21. E.g., Rebecca Dresser, *The “Right to Try” Investigational Drugs: Science and Stories in the Access Debate*, 93 TEX. L. REV. 1631 (2015); Elizabeth Weeks Leonard, *The Public’s Right to Health: When Patient Rights Threaten the Commons*, 86 WASH. U. L. REV. 1335, 1343–44 (2009); Michael J. Malinowski, *Throwing Dirt on Doctor Frankenstein’s Grave: Access to Experimental Treatments at the End of Life*, 65 HASTINGS L. J. 615 (2014); Seema Shah & Patricia Zettler, *From a Constitutional Right to a Policy of Exceptions: Abigail Alliance and the Future of Access to Experimental Therapy*, 10 YALE J. HEALTH POL’Y LAW & ETHICS 136, 178–79 (2010); Eugene Volokh, *Medical Self-Defense, Prohibited Experimental Therapies, and Payment for Organs*, 120 HARV. L. REV. 1813 (2007); Patricia J. Zettler, *The Implications of Post-Phase I and Off-Label Treatment Use of Experimental Drugs: How Expansive Should Expanded Access Be?*, 18 KAN. J.L. & PUB. POL’Y 135 (2009); Patricia J. Zettler & Henry T. Greely, *The Strange Allure of State “Right-to-Try” Laws*, 174 JAMA INTERNAL MED. 1885 (2014).

to entry as leverage to force the production of robust scientific data to support new medicines. They are also paternalistic, because the approval decision in any particular case requires judgment calls about the value and significance of specific benefits, which stray well beyond the science and trump whatever judgment call a particular patient might have made. Both countries enacted early access schemes in response to arguments from patient groups newly empowered in the AIDS era, who were seeking greater control over their own medical care and the right to accept the risk of using unproven medicines when facing death. Arguments grounded in autonomy principles and rights-based jurisprudence have had more salience in the United States than in France, however, driving some differences between expanded access and ATUs. And right-to-try laws found traction in the United States due to a seeming alliance between patients making arguments grounded in autonomy and rights-based jurisprudence and groups advocating for reduction in the size and power of the federal government.

Second, the right-to-try law is unlikely to increase access to unapproved medicines, and we use the French experience to hypothesize changes to the U.S. expanded access scheme that *would* increase access. Most importantly, we consider the possibility that the key to increasing use of expanded access in the United States might be financial: making it worthwhile for companies to supply unapproved medicines, by allowing them to profit from sales, and making the medicines and associated healthcare services free for patients through insurance coverage. The French minimize the fiscal impact of these choices by also imposing price controls, however, and it is unclear whether U.S. policymakers and the public would accept the full French approach. Adopting a partial solution, such as permitting profit but not mandating insurance coverage, or vice versa, may be ineffective, raise new issues, or both.

This Article proceeds as follows. Section I explains the basic approach to medicine regulation in both countries—premarket review of scientific data by an expert agency—and how the modern premarket review model differs from an earlier model of postmarket enforcement power. It also explains the tradeoff inherent in premarket approval paradigms—that requiring data delays patient access to potential treatments—and discusses the paternalism and utilitarianism in the premarket review model.

Section II explains how shifts in thinking about the relationship between individual and government on matters of health led to refinement of the French and U.S. gatekeeping frameworks with laws that permit access to medicines before approval. It explains how these arrangements responded to autonomy and patient rights arguments but are broadly consistent with the approach and goals of the new drug approval paradigm. Further, it explains how the differences between the two schemes reflect broader sociocultural and legal differences tied to the weight given to autonomy and patients' rights arguments and views on medical paternalism.

Section III describes the U.S. right-to-try law, comparing it to expanded access, and exploring the social and cultural differences between the countries that made this law possible in the United States.

Section IV addresses steps that U.S. policymakers may need to take to increase use while preserving, rather than sidestepping, the basic regulatory framework in place for new medicines. It borrows heavily from the successful French early access scheme in exploring the possibility that the impediments are mainly financial, though it also considers other changes that might be needed.

I. THE NEW MEDICINE GATEKEEPING MODEL

In both the United States and France, a new medicine must be approved as safe and effective by a regulator—FDA and the Agency for Medicines and Health Product Safety (ANSM), respectively—before it can be placed on the market for use by patients.²²

A. The Premarket Approval Requirement

The premarket approval requirement reflects two basic assumptions: first, that society has a profound interest in the generation of high-quality evidence about the effectiveness and safety of new medicines, and second, that the evidentiary standard should serve as a barrier to entry, enforced by an agency composed of scientific experts.²³ These assumptions come from hard lessons in history. Congress enacted the basic statute requiring premarket safety review of drugs in

22. There are two pathways to market for an innovative new medicine in the United States: approval of a new drug application submitted under § 355(b)(1) of the Federal Food, Drug, and Cosmetic Act, or, if the drug is biological, a biologics license application submitted under section 351(a) of the Public Health Service Act. 21 U.S.C. § 355(b)(1) (2018); 42 U.S.C. § 262(a) (2018). There are four pathways to market in France: (1) approval by the French National Agency for Medicines and Health Product Safety (ANSM) under Article L.5121-8 of the French Public Health Code; (2) for certain types of medicine, centralized approval by the European Commission following review by the European Medicines Agency; (3) simultaneous approval for France and other individual EU Member States (chosen by the company) under a decentralized procedure, in which one country takes the lead in review of the application; and (4) approval through “mutual recognition,” in which a company asks France to respect the decision of another EU Member State that has approved the medicine. *See* CODE DE LA SANTÉ PUBLIQUE [PUBLIC HEALTH CODE] art. L.5121-8 (Fr.); Regulation No. 726/2004 of the European Parliament and of the Council of 31 March 2004 Laying Down Community Procedures for the Authorisation and Supervision of Medicinal Products for Human and Veterinary Use and Establishing a European Medicines Agency, 2004 O.J. (L 136) 1, 5–6, 33 (EC) [hereinafter Regulation 726/2004]; Directive 2001/83 of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Medicinal Products for Human Use, 2001 O.J. (L 331) 67 (EC) [hereinafter Directive 2001/83]; EUR. COMM’N, THE RULES GOVERNING MEDICINAL PRODUCTS IN THE EUROPEAN UNION vol. 2A, ch. 1, § 3.2 (2019).

23. *See* Erika Lietzan, *Access Before Evidence and the Price of FDA’s New Drug Authorities*, 53 U. RICH. L. REV. 1243, 1293–95 (2019).

1938 on the heels of a tragedy in which an inadequately tested sulfanilamide preparation killed more than one hundred people, including many children.²⁴ Without a premarket review requirement, FDA was left to pursue the company after the fact for misbranding the drug.²⁵ Changes to the statute in 1962 converted the premarket review requirement into a premarket approval requirement with a robust effectiveness standard, following a tragedy in which more than 10,000 children in forty-six countries were born with severe deformities after their mothers used thalidomide during pregnancy.²⁶

The new approach shifted the burden of proof to companies seeking to market medicines. This ensures the production of high-quality data to support use and prescribing decisions.²⁷ It also gives the regulator—the gatekeeper—more power. The ability to grant or withhold permission to enter the market provides powerful leverage during the research process. And enforcement of the premarket approval requirement is far more efficient than any regime that places the burden on the government to begin proceedings and prove there is something wrong after a medicine enters the market.²⁸

In both countries, proof of safety and effectiveness takes the form of data from laboratory and animal testing as well as human (“clinical”) trials.²⁹ Developing these data is an iterative process. After trials in relevant animals show that a new

24. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938); DANIEL CARPENTER, REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT THE FDA 85–92 (2010).

25. U.S. Dep’t. of Agric., Letter from the Secretary of Agriculture Transmitting in Response to Senate Resolution No. 194 a Report on Elixir Sulfanilamide-Massengill, S. Doc. No. 75-124 at 1, 9 (“[T]he only basis of action under the Food and Drugs Act against the interstate distribution of the ‘elixir’ was the allegation that the word implies an alcoholic solution, whereas the product was a diethylene glycol solution . . . [and] [t]o protect the public from drugs which, like the ‘elixir’ are dangerous because of their inherent toxicity, it is the Department’s recommendation that legislation be enacted to provide . . . [l]icense control of new drugs.”).

26. CARPENTER, *supra* note 24, at 213–97.

27. Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOM. & TECH. L. REV. 345, 370–71 (2007); Amy Kapczynski, *Dangerous Times: The FDA’s Role in Information Production, Past and Future*, 102 MINN. L. REV. 2357 *passim* (2018).

28. See Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1797 (1996).

29. See 21 U.S.C. § 355(d) (2018) (standard for approval of a new drug in the United States); 42 U.S.C. § 262(a) (2018); 21 C.F.R. § 601 (2020) (standard for approval for a biological product in the United States); CODE DE LA SANTÉ PUBLIQUE [PUBLIC HEALTH CODE] art. L.5121-9 (Fr.) (grounds for denying approval of a medicine in France); *id.* art. L.5121-20 (indicating that more detailed rules, including those governing trials, will be set forth in decrees). A company does not repeat the process for each country in which it seeks approval. Although some regulators may require trials that others do not—such as trials in a local population—companies are usually able to use the same pivotal safety and effectiveness data. The actual applications will be different, reflecting each regulator’s content and format requirements, including with respect to the types of analysis performed and the types of detailed reports written.

drug is safe to begin testing in humans, the applicant begins with small safety tests and moves gradually to larger and larger trials.³⁰ Phase 1 trials entail the initial introduction of the investigational medicine in humans and focus on questions of absorption, distribution, metabolism, excretion, and side effects of increasing dose.³¹ These trials sometimes also generate early evidence of effectiveness, if the subjects are patients rather than healthy volunteers.³² Phase 2 trials assess the effectiveness of the medicine in patients, as well as common short-term side effects and risks.³³ The pivotal trials providing statistically robust proof of effectiveness—phase 3 trials—often involve thousands of patients and clinical trial sites around the world.³⁴

The three-phase approach dates to the 1960s and is somewhat obsolete.³⁵ Today, there are few hard-and-fast rules about clinical trial design. A company's premarket clinical development program will usually include trials that can be classified as phase 1, phase 2, or phase 3. But some companies start with a "phase 0" trial to examine administration of a micro-dose to a very small group of volunteers, and companies often run trials that combine elements of phase 1 and phase 2, or phase 2 and phase 3.³⁶ Regardless of the design of the overall research program, the goal is the same. Regulators look for randomized, controlled, double-blinded, prospective, interventional trials, which are the gold standard for approval of a new medicine.³⁷ If these trials are large enough, they can support a conclusion that the tested drug is effective, meaning that it causes the therapeutic benefit measured.³⁸

30. See Lietzan, *Access Before Evidence*, *supra* note 23, at 1246–47.

31. *E.g.*, 21 C.F.R. § 312.21(a) (2020).

32. *E.g.*, *id.* Most phase 1 trials use healthy volunteers, but phase 1 trials of oncology drugs and other drugs with narrow therapeutic indices that are intended for life-threatening conditions are often conducted in patients. The decision whether to recruit healthy volunteers or patients is made on a case-by-case basis, considering a variety of factors relating to the safety of the trial participants and the quality of the data being generated. *E.g.*, Jie Shen et al., *Design and Conduct Considerations for First-in-Human Trials*, 12 CLINICAL & TRANSLATIONAL SCI. 6 (2019).

33. *E.g.*, 21 C.F.R. § 312.21(b) (2020).

34. *E.g.*, 21 C.F.R. § 312.21(c) (2020).

35. New Drugs for Investigational Use: Proposed Exemptions, 27 Fed. Reg. 7,990, 7,990–91 (Aug. 10, 1962).

36. *E.g.*, FDA, GUIDANCE FOR INDUSTRY, INVESTIGATORS, AND REVIEWERS: EXPLORATORY IND STUDIES (Jan. 2006), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/exploratory-ind-studies> [<https://perma.cc/NVS4-43BG>].

37. Vinay Prasad & Vance W. Berger, *Hard-Wired Bias: How Even Double-Blind Randomized Controlled Trials Can Be Skewed from the Start*, 90 MAYO CLINIC PROC. 1171, 1171 (2015) ("Well-designed, adequately-powered randomized controlled trials . . . are rightfully considered the highest form of evidence on which to base treatment and diagnostic decisions, minimizing potential biases, particularly confounding, that plague nonrandomized evidence.").

38. Thomas R. Frieden, *Evidence for Health Decision Making — Beyond Randomized Controlled Trials*, 377 NEW ENG. J. MED. 465, 465 (2017); *see also* FDA, GUIDANCE FOR INDUSTRY: E9 STATISTICAL PRINCIPLES FOR CLINICAL TRIALS I, 10–12 (Sept. 1998),

Whether the data support a finding of effectiveness, and whether the applicant has conducted all reasonably applicable safety testing, are scientific judgments. The new medicine frameworks in France and the United States appropriately give these calls to expert agencies composed of scientists. By assigning the job of application review to agencies staffed by scientists, the frameworks ensure that the data supporting each new medicine face at least one formal structured assessment grounded in science.³⁹

B. Paternalism and Utilitarianism in the Premarket Model

No medicine is, however, perfectly safe or always effective in the patients for whom it is labeled. Patients are heterogeneous, and clinical responses vary.⁴⁰ Side effects are inevitable; medicines are biologically active, and the relationship between a patient's body and a chemical product can be complex.⁴¹ As a result, when approving a new medicine for the market, the most a regulator can ask for is proof that a medicine's benefits outweigh its risks.⁴²

It is, however, impossible to be certain about this.⁴³ No premarket research and development program can generate complete information about a medicine's clinical profile.⁴⁴ In clinical trials the experimental medicine is administered under tightly controlled conditions, to ensure that the resulting data can be interpreted. In

<https://www.fda.gov/media/71336/download> [<https://perma.cc/4F73-86D8>].

39. See Robert M. Temple, *Commentary on "The Architecture of Government Regulation of Medical Products,"* 82 VA. L. REV. 1877, 1898 (1996) ("[A]part from contributing independent review, the existence of the regulator helps maintain the safety assessment enterprise, as public standards, applicable to all parties, assure a level playing field and discourage excessive corner-cutting.").

40. E.g., Richard L. Kravitz, Naihua Duan & Joel Braslow, *Evidence-Based Medicine, Heterogeneity of Treatment Effects, and the Trouble with Averages*, 82 MILLBANK Q. 661, 699 (2004) ("Even if the treatment is delivered uniformly, the outcomes will still vary because, as noted earlier, individual patients differ according to their preexisting risk without treatment, responsiveness to treatment, vulnerability to side effects, and health state preferences or utilities."); see also Anup Malani, Oliver Bombom & Mark van der Laan, *Accounting for Heterogeneous Treatment Effects in the FDA Approval Process*, 67 FOOD & DRUG L. J. 23, 24 (2012) ("It is common for drugs to have different effects in different patients, a phenomenon statisticians call 'heterogeneity in treatment effects.'").

41. See FDA, STRUCTURED APPROACH TO BENEFIT-RISK ASSESSMENT IN DRUG REGULATORY DECISION-MAKING 1, 1 (Feb. 2013) (recognizing that "all drugs have some ability to cause adverse effects").

42. E.g., FDA, BENEFIT-RISK ASSESSMENT IN DRUG REGULATORY DECISION-MAKING: DRAFT PDUFA VI IMPLEMENTATION PLAN (FY 2018-2022), 1, 3 (2018) ("Simply put, for a drug to be approved for marketing, FDA must determine that the drug is effective and that its expected benefits outweigh its potential risks to patients.").

43. See generally Lietzan, *Access Before Evidence*, *supra* note 23, at 1297-98.

44. FDA, STRUCTURED APPROACH, *supra* note 41, at 9 ("Although drug regulatory decisions are informed by an extensive body of evidence on the safety and efficacy of a proposed product, in many cases, FDA must draw conclusions from imperfect data.").

the real world, patients may have other diseases and conditions, are more biologically heterogeneous, and may take other medicines.⁴⁵ Also, premarket testing involves administration of the experimental medicine to fewer people and for less time than would happen in the real world.⁴⁶ As a result of these and other limitations, the risks and benefits of a new medicine may turn out to be different than suggested by premarket testing. Some adverse reactions could be more frequent or more severe than expected. Some may have been too rare to emerge in clinical trials, and some might emerge only after long-term use.⁴⁷ The medicine may be less effective or ineffective in patient groups that were not included in the trials.⁴⁸

Approval really means only that the data gathered so far show that the medicine's benefits outweigh its risks.⁴⁹ There is, therefore, a tradeoff at the heart of any premarket approval paradigm. On the one hand, although it is impossible to eliminate all uncertainty about a proposed new medicine, more testing will generally provide more certainty. On the other hand, additional testing delays the regulatory decision, and thus market entry. If the regulator still approves the medicine at the end, the additional testing delayed access to a medicine with a positive benefit-risk ratio. Patients who could have benefitted from the medicine had to wait. And if the medicine treated a serious or life-threatening disease, some patients may have missed the opportunity to use the medicine.⁵⁰

45. *E.g.*, *id.* at 9 (noting that trials are designed to show the benefit of a medicine compared with a control and that some patients may be “excluded to improve the ability to detect a benefit that can be attributed to the drug”). *See generally* Kravitz, *supra* note 40.

46. Frieden, *supra* note 38, at 465 (noting various limitations of randomized controlled trials, including that they have limited duration and sample size).

47. *E.g.*, Comm. on the Assessment of the U.S. Drug Safety Sys., The Inst. of Med., The Future of Drug Safety: Promoting and Protecting the Health of the Public 1, 106 (Alina Baci, Kathleen Stratton & Sheila P. Burke, eds. 2007) (“Safety information can emerge from clinical trials, but rare events may not surface at all; if they do, it is at a rate so low that one cannot distinguish a drug-caused event from one expected by chance (background incidence).”).

48. *E.g.*, Kravitz, *supra* note 40, at 667 (“By convenience, [randomized controlled trials] are usually characterized by narrow inclusion criteria and recruitment. Under these conditions, the heterogeneity of treatment effects may be dramatically underestimated, and even assiduous investigators can be misled into thinking that their results are more generalizable than they actually are.”).

49. *See generally* Lietzan, *Access Before Evidence*, *supra* note 23, at 1297–98. FDA takes a “population” approach to assessing benefit-risk, meaning that it focuses on the entire patient population for whom the medicine will be labeled. *See* Mark Van Der Laan, Anup Malani & Oliver Van Der Benbom, *Improving the FDA Approval Process* (John M. Olin Law & Econ., Working Paper No. 580 (2d Series), Public Law and Legal Theory, Working Paper No. 367, 2011). Approval therefore includes the possibility of an undesirable outcome, and negative benefit-risk balance, for any particular individual in the population.

50. *See* Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, *Innovation in the pharmaceutical industry: new estimates of R&D costs*, 47 J. HEALTH ECON. 20, 23 (2016) (reporting average time from synthesis to human testing of 31.2 months and an average time from start of

How much information is enough for a decision on the risk-benefit profile of a new medicine depends on the relative weight given to two goals: (1) earlier release of new medicines to patients and (2) reduction of uncertainty about the effects of those medicines. Scholars, doctors, patients, regulators, and policymakers may disagree about the tradeoff here.⁵¹ A patient facing death may care more about the cost of delay and less about the risk that a drug is unsafe or ineffective.⁵² And the benefit-risk assessment for any particular medicine reflects value judgments that stray well beyond science—such as how *much* a particular side effect matters and how *much* extending life for a month matters. As FDA says, these decisions occur “at the intersection of law, science, medicine, policy, and judgment.”⁵³

As a result, the modern medicine approval paradigm is partly paternalistic.⁵⁴ A medicine may not be sold for use by a patient—even if the benefits exceed the

clinical testing to approval of 96.8 months).

51. For example, there is debate about whether regulators set the evidentiary bar too *low* for approval of drugs intended to treat cancer. Regulators often approve these drugs on the basis of trials using surrogate measurements—such as tumor shrinkage or progression-free survival—because these measurements are easier and quicker to measure than the true endpoint of interest, overall survival. Some argue that the association between surrogate outcomes and clinically meaningful outcomes is weak and that FDA should wait for robust clinical outcomes data, rather than approving new medicines on the basis of small increases in questionable surrogate measurements. *E.g.*, Robert Kemp & Vinay Prasad, *Surrogate endpoints in oncology: when are they acceptable for regulatory and clinical decisions, and are they currently overused?*, 15 BMC MED., Jul. 21, 2017, at 1; Vinay Prasad et al., *The Strength of Association Between Surrogate End Points and Survival in Oncology: A Systematic Review of Trial-Level Meta-Analyses*, 175 JAMA INTERNAL MED. 1389 (2015).

52. See Richard A. Epstein, *The Erosion of Individual Autonomy in Medical Decisionmaking: Of the FDA and IRBs*, 96 GEO. L.J. 559, 579 (2008) (noting that the risk of approving drugs that turn out not to be safe and effective may be less concerning to patients facing imminent death, because delay could be catastrophic); Michael D. Greenberg, *AIDS, Experimental Drug Approval, and the FDA New Drug Screening Process*, 3 N.Y.U. J. LEGIS. & PUB. POL’Y 295, 298 (2000) (“Terminally ill patients lacking effective conventional treatments confront a risk-benefit determination very different from that of the general public. Such patients have far greater incentives than the larger public to gather their own information and to take risks.”); Christina Sandefur, *Safeguarding the Right to Try*, 49 ARIZ. ST. L. J. 513, 536 (2017) (arguing that “the FDA system presumes that the public should not have access to medicine until federal officials certify it as both safe and effective to their satisfaction” but “dying patients face a different risk/benefit calculus than other people”).

53. FDA, STRUCTURED APPROACH, *supra* note 41, at 2.

54. See Richard Epstein, *Regulatory Paternalism in the Market for Drugs: Lessons from Vioxx and Celebrex*, 5 YALE J. HEALTH POL’Y & ETHICS 741, 758 (2005) (“The implicit paternalism of allowing FDA supremacy assumes that a distant bureaucracy, which has its own institutional biases, will be a better guardian of all potential users than the people themselves. It is often said that the ability to take risks and bear their consequences is one of the marks of a self-reliant population.”); Michael D. Greenberg, *Information, Paternalism, and Rational Decision-Making: The Balance of FDA New Drug Approval*, 13 ALB. L. J. SCI. & TECH. 663, 671–76 (2003) (discussing and critiquing the “regulatory paternalism” of the drug approval process); Marie-Louise Lamau, *Le recours au principe d’autonomie en éthique clinique*, 234 REVUE D’ÉTHIQUE ET DE THÉOLOGIE MORALE 63 (2005) (discussing medical paternalism in France).

risks from the perspective of the patient, and even if avoiding delay is more important to the patient than knowing more about the drug—until a regulator agrees to permit it, based on its own assessment of benefits and risks. The approval paradigm is also utilitarian, because it focuses on maximizing overall welfare.⁵⁵ The decision to require premarket approval based on evidence that may take a decade to generate focuses on the needs of the population as a whole.⁵⁶ It places the need for high quality evidence over the preferences of individual patients, who may want access to potentially beneficial medicines before that evidence has been generated. Policymakers have decided that the public as a whole is better off if market entry is denied until robust evidence has been produced. The use of controls in premarket clinical trials similarly places the needs of the study—quality data for the benefit of future patients—above the needs of any particular patient enrolled in the study.⁵⁷

II. EARLY ACCESS MECHANISMS WITHIN THE GATEKEEPING FRAMEWORK

Over the last half century, policymakers in France and the United States have refined the regulatory gatekeeping model as the broader relationship between the individual and state on matters of personal health has evolved. As a practical matter, a patient today has access to more personal health information than a patient fifty years ago, as well as more information about diseases and potential medical interventions. As a matter of political economy, a patient today has more influence over laws and public policy relating to his health. And as a legal matter, a patient today has more decision-making authority over personal health matters, which can constrain others in the healthcare system—for example, when courts have recognized “rights” that the government must respect. These developments are intertwined and linked by a thread: elevation of individual agency and autonomy in matters of personal health.⁵⁸ Empowerment of the patient has collided with the paternalism and utilitarianism of the gatekeeping model, leading to the

55. Utilitarian theory is most associated with the writings of Jeremy Bentham. JEREMY BENTHAM, *AN INTRODUCTION TO THE PRINCIPLES OF MORALS AND LEGISLATION* (J.H. Burns & H.L.A. Hart eds., Clarendon Press 1996) (1823). This approach would be considered “rule” utilitarian, in the sense that it assumes this rule can produce better results (more overall well-being) than any other approach. A different, also utilitarian, approach would say that greater overall well-being will be achieved if every individual maximizes his or her own utility.

56. Walker, *supra* note 20, at 4 (“Regulation of new medical interventions draw on population-focused rather than individual approaches to ethics—taking account of the potential for harm of unrestricted access . . . and of the opportunity costs should ineffective interventions be approved.”).

57. Schüklenk & Lowry, *supra* note 20, at 9 (quoting Anthony Fauci, head of the National Institute of Allergy and Infectious Diseases during the AIDS epidemic, that the randomized controlled trial “routinely asks physicians to sacrifice the interests of their particular patients for the sake of the study”).

58. See generally Grossman, *Empowered Consumer*, *supra* note 19 (making this argument).

refinement of gatekeeping frameworks at the heart of this Article: creation of mechanisms giving patients access to medicines *before* approval.⁵⁹

A. Evolution in the Relationship between Individual and State

Patients have access to more information today. In 1954, only sixty-five percent of U.S. households owned a television set; today, more than three quarters of households own a desktop or laptop computer, and seventy-seven percent have a broadband Internet subscription.⁶⁰ Patients can use the Internet to access information about diseases, approved medicines, other types of interventions, ongoing research, and ongoing clinical trials.⁶¹ Significant advances in medicine have also occurred over the same half century, meaning that the information available is deeper and richer. Improvements in diagnostic technology have reshaped our understanding of the human body in both healthy and pathological states, enhancing our understanding of disease and making possible new areas of pharmacological intervention.⁶² Profound advances in genetics, virology, and immunology have transformed the field of microbiology. And the biotechnology revolution has worked hand in hand with improved imaging capability and an explosion in computing capability to revolutionize our understanding of human disease and our therapeutic options, making possible, for example, molecular engineering.⁶³ Patients today know more because information technology has

59. Others have recounted the U.S. history in detail. *E.g.*, Lewis A. Grossman, *AIDS Activists, FDA Regulation, and the Amendment of America's Drug Constitution*, 42 AM. J. L. & MED. 687 (2016); Zettler, *Implications*, *supra* note 21. To our knowledge, no one has considered the parallels in French history.

60. *U.S. Census Bureau History: Public Broadcasting*, U.S. CENSUS BUREAU (Oct. 2015), https://www.census.gov/history/www/homepage_archive/2015/october_2015.html [https://perma.cc/R53L-9LHW]; CAMILLE RYAN & JAMIE M. LEWIS, U.S. CENSUS BUREAU, COMPUTERS AND INTERNET USE IN THE UNITED STATES: 2015 (2017), <https://www.census.gov/content/dam/Census/library/publications/2017/acs/acs-37.pdf> [https://perma.cc/GQQ3-5YK4].

61. The reality of access varies. Some patients own multiple computers and handheld devices, for example, while others may need to walk to a public library on days they do not work. Some information—such as reports in peer-reviewed medical and scientific journals—resides behind a paywall, limiting its access to patients with resources or access through an employer. Some patients and caregivers have ample time for research, others much less. Some patients have the training to understand scientific and statistical literature, while others do not.

62. Electron microscopy evolved from permitting rudimentary diagnosis of kidney disease and tumors in the 1960s to identifying a wide range of subtle cellular changes characteristic of diseases. Ronald E. Gordon, *Electron Microscopy: A Brief History and Review of Current Clinical Application*, in 1180 HISTOPATHOLOGY 119 (Christina E. Day ed., 2014). Since the earliest nuclear magnetic resonance images of humans were published in the 1970s, the field has undergone dramatic change—with improvements in hardware (such as the introduction of superconducting magnets and the invention of phased array radiofrequency coils) as well as the development of a variety of rapid imaging and contrast enhanced cardiac imaging. Robert R. Edelman, *The History of MR Imaging as Seen through the Pages of Radiology*, 273 RADIOLOGY S181 (2014).

63. See generally Ronald Evens & Kenneth Kaitin, *The Evolution of Biotechnology and Its*

improved *and* because there is more information.⁶⁴

The changing information landscape coincided with a rights revolution that began in the 1960s.⁶⁵ The rights revolution included a series of rights-affirming judicial decisions ranging over a wide field relating to medicine and health—for example, limiting the grounds on which the government may involuntarily commit an adult,⁶⁶ recognizing the rights of prisoners to avoid the unwanted administration of antipsychotic drugs,⁶⁷ assuming a right to refuse lifesaving hydration and nutrition,⁶⁸ and identifying several health-related prerogatives related to contraception and abortion within a “right to privacy.”⁶⁹ In the late 1970s, a group of terminally ill cancer patients persuaded a federal court that the right to privacy included a right to purchase an unapproved new drug, amygdalin, from sellers in other countries.⁷⁰ These decisions embraced autonomy principles, finding that the

Impact on Health Care, 34 HEALTH AFF. 210 (2015).

64. See Grossman, *Empowered Consumer*, *supra* note 19, at 639 (citing changes in the “health information environment” contributing to patient empowerment); JAY KATZ, *THE SILENT WORLD OF DOCTOR AND PATIENT* (1984) (explaining how information politics fueled movement for patient autonomy and reform in the doctor-patient relationship). Also, an increase in the prevalence of chronic disease may be prompting patients to take advantage of the information explosion and insist on more collaborative long-term relationships with their doctors. See JANINE BARBOT, *LES MALADES EN MOUVEMENT: LA MEDECINE ET LA SCIENCE A L’EPREUVE DU SIDA* (2002); SEBASTIEN DALGALARRONDO, *SIDA: LA COURSE AUX MOLECULES* (2004).

65. The rights revolution included legislative changes as well as the judicial decisions noted in text. Max N. Helveston, *Judicial Deregulation of Consumer Markets*, 36 CARDOZO L. REV. 1739, 1745 (2015) (“Large legislative expansions of consumers’ rights occurred in the 1960s and early 1970s, which saw the enactment of statutes like the Consumer Product Safety Act, the Consumer Credit Protection Act, and state consumer protection acts.”).

66. *O’Connor v. Donaldson*, 422 U.S. 563, 576 (1975) (“[A] State cannot constitutionally confine without more a nondangerous individual who is capable of surviving safely in freedom by himself or with the help of willing and responsible family members or friends.”).

67. *Washington v. Harper*, 494 U.S. 210, 229 (1990) (“The forcible injection of medication into a nonconsenting person’s body represents a substantial interference with that person’s liberty.”).

68. *Cruzan v. Dir., Mo. Dep’t. of Health*, 497 U.S. 261, 281 (1990) (“It cannot be disputed that the Due Process Clause protects an interest in life as well as an interest in refusing life-sustaining medical treatment.”).

69. *E.g.*, *Griswold v. Connecticut*, 381 U.S. 479 (1965) (finding that Connecticut law prohibiting the use of contraceptives was unconstitutional); *Roe v. Wade*, 410 U.S. 113, 153 (1973) (“This right of privacy, whether it be founded in the Fourteenth Amendment’s concept of personal liberty and restrictions upon state action, as we feel it is, or, as the District Court determined, in the Ninth Amendment’s reservation of rights to the people, is broad enough to encompass a woman’s decision whether or not to terminate her pregnancy.”).

70. The resulting injunction did not survive appeal, however, and the Tenth Circuit disagreed with the trial court’s view of the privacy cases. FDA had asserted that Laetrile (amygdalin) required premarket approval, which meant that the plaintiffs could not receive shipments of the compound from sources outside the United States. In 1977, a federal district court ruled that Laetrile qualified for a statutory exemption from the approval requirement. It also ruled in the alternative that FDA’s decision—“denying the right to use a nontoxic substance in connection with one’s own personal health-care”—had infringed the constitutional “right of privacy.” *Rutherford v. United States*, 438 F.

patient should make the healthcare decisions relating to his or her own body.⁷¹

A series of free speech rulings affirmed the right of consumers to receive information,⁷² many related to the availability and cost of medical treatments.⁷³ During these same decades, FDA's policies governing the communication of information about medicines to patients evolved. For example, in the 1970s the agency permitted companies to advertise their prices directly to consumers.⁷⁴ In the 1980s it allowed direct-to-consumer (DTC) advertising disclosing the uses of prescription drugs.⁷⁵ And in the 1990s it issued guidance paving the way for DTC broadcast advertising.⁷⁶ These developments made it possible for patients to

Supp. 1287 (W.D. Okla. 1977). After the Supreme Court reversed the statutory ruling, *United States v. Rutherford*, 442 U.S. 544 (1979), the Tenth Circuit declined to consider the constitutional argument, writing that the privacy cases protect “the decision by the patient whether to have a treatment or not,” but that “his selection of a particular treatment, or at least a medication, is within the area of governmental interest in protecting public health.” *Rutherford v. United States*, 616 F.2d 455, 457 (10th Cir. 1980).

71. Grossman, *Empowered Consumer*, *supra* note 19, at 637 (“One important aspect of the rights revolution that blossomed in the 1970s was the notion of ‘patients’ rights.”). Although the patients’ rights movement came of age in the 1970s, the notion that patients’ rights play a role in law is much older. *E.g.*, *Schloendorff v. Soc’y of N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914) (“[E]very human being of adult years and sound mind has a right to determine what shall be done with his own body . . .”).

72. *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council*, 425 U.S. 748, 756 (1976) (holding that protection of speech is afforded “to the communication, to its source and to its recipients both”).

73. *E.g.*, *Bigelow v. Virginia*, 421 U.S. 809 (1975) (reversing conviction of Virginia newspaper editor for printing an advertisement from an organization in New York that would help women locate clinics and hospitals in New York for low-cost abortions); *Va. State Bd. of Pharmacy*, 425 U.S. at 748 (1976) (holding that state bans on advertising prescription drug prices violated the First and Fourteenth Amendments); *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002) (finding that federal law that prohibited advertising and promotion of compounded medicines violated the First Amendment); *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998) (holding that FDA’s restrictions on use of textbooks and journal reprints to promote unapproved uses of approved drugs violated the First Amendment), *vacated sub nom. Wash. Legal Found. v. Henney*, 202 F.3d 331 (D.C. Cir. 2000) (vacating on mootness grounds because government changed its interpretation of the statutory provisions); *United States v. Caronia*, 703 F.3d 149, 168 (2d Cir. 2012) (construing the misbranding provisions of the drug statute as “not prohibiting and criminalizing the truthful off-label promotion of FDA-approved prescription drugs,” in order to avoid construction that “would unconstitutionally restrict free speech”); *Amarin Pharma, Inc. v. FDA*, 119 F. Supp. 3d 196 (S.D.N.Y. 2015) (finding manufacturer likely to succeed on the merits of claim that the threat of enforcement action chilled it from sharing information with doctors about an unapproved use of its drug).

74. *Reminder Labeling and Reminder Advertisements for Prescription Drugs*, 40 Fed. Reg. 58,794 (Dec. 18, 1975).

75. *Direct-to-Consumer Advertising of Prescription Drugs; Withdrawal of Moratorium*, 50 Fed. Reg. 36,677 (Sept. 9, 1985). FDA had not banned this advertising, but companies had generally refrained. After two advertisements ran in 1983, FDA called for a moratorium to consider the rules that should apply. It withdrew the moratorium in 1985.

76. *Guidance for Industry on Consumer-Directed Broadcast Advertisements; Availability*, 64

assume a greater role in decisions about their own care, though some believe that DTC advertising needs greater oversight.⁷⁷ The agency now requires that some prescription drugs have labeling for patients, in addition to the usual labeling for prescribers.⁷⁸ A district court rejected the argument that patient labeling for estrogen interfered with the practice of medicine,⁷⁹ reflecting a cultural shift away from medical paternalism.⁸⁰

Similar changes affected the relationships of patients in France to their healthcare providers and to the state, but these changes came later in time and were more limited in scope. Patient groups in France grew more empowered, especially during the AIDS crisis of the 1990s.⁸¹ A rights revolution, embracing patients' rights, occurred in France as it did in the United States. But because France is a civil law country, not a common law country, the rights revolution has mainly taken the form of statutory changes. In 2002, a Patients' Rights Law profoundly changed the relationship between a patient and his or her doctor, laying out the patient's rights and the doctor's responsibilities, and reforming malpractice

Fed. Reg. 43,197 (Aug. 9, 1999). These advertisements were already legal, but it had been unclear how to comply with the agency's advertising regulations in the new medium. The guidance explained how, effectively making the advertisements possible.

77. See Grossman, *Empowered Consumer*, *supra* note 19, at 657–62 (discussing emergence of direct-to-consumer advertising in connection with patients becoming active participants in their own treatment decisions); U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-03-177, *PRESCRIPTION DRUGS: FDA OVERSIGHT OF DIRECT-TO-CONSUMER ADVERTISING HAS LIMITATIONS* 1, 16 (2002) (“[A]bout 8.5 million consumers received a prescription after viewing a DTC advertisement and asking their physician for the drug in 2000.”); Bo Wang & Aaron S. Kesselheim, *The Role of Direct-to-Consumer Pharmaceutical Advertising in Patient Consumerism*, 15 *AMA J. OF ETHICS* 960, 960 (2013) (arguing that “the lack of firm regulatory guidelines governing” direct-to-consumer advertising “may lead to suboptimal treatment decisions and health and economic outcomes”). The information revolution has also facilitated the spread of misinformation about medicine and disease. Erin Connolly, *Cleaning Up “Fake News” in Health Care*, *MEDICAL BAG* (Nov. 21, 2018), <https://www.medicalbag.com/home/more/ethics/cleaning-up-fake-news-in-health-care> [<https://perma.cc/7TJY-7A8E>].

78. Grossman, *Empowered Consumer*, *supra* note 19, at 652–57 (discussing patient labeling requirements introduced in the 1970s).

79. *Pharm. Mfrs. Ass'n v. Food & Drug Admin.*, 484 F. Supp. 1179 (D. Del. 1980), *aff'd per curiam*, 634 F.2d 106 (3d Cir. 1980); see also Grossman, *Empowered Consumer*, *supra* note 19, at 653–54.

80. See generally DAVID J. ROTHMAN, *STRANGERS AT THE BEDSIDE: A HISTORY OF HOW LAW AND BIOETHICS TRANSFORMED MEDICAL DECISION MAKING* (1991) (discussing transformation in the practice of medicine in the United States due in part to the redefinition of the role of the physician and the rejection of paternalism).

81. Paul Véron & François Violla, *De quelques difficultés entourant l'action de groupe en matière de santé*, 127 *REVUE LAMY DROIT DES AFFAIRES* 45 (2017); Philippe Amiel, *Les associations de patients et la recherche clinique académique et industrielle*, 199 *BULLETIN DE L'ACADEMIE NATIONALE DE MÉDECINE* 589 (2015) (discussing the growth of the patients' rights movement in France especially in the 2000s).

liability for doctors.⁸² While the seminal U.S. litigation relating to the right to refuse lifesaving hydration and nutrition concluded in 1990,⁸³ France did not enact legislation governing palliative care and giving individuals the *choice* to refuse life support measures until 2005.⁸⁴ And the French courts grappled with the issue only last year, when a patient injured in a motorcycle accident received life support for years without brain activity.⁸⁵ Finally, although patients in France today have more information, a greater sense of autonomy, and a more egalitarian relationship with their doctors than did their counterparts fifty years ago, they have less comparatively than patients in the United States today.⁸⁶

B. Access to Investigational Medicines through a Gatekeeper

In both countries, the shifting relationship between patients and the state put pressure on the gatekeeping model for new medicines.⁸⁷ Policymakers responded

82. Loi 2002-303 du 4 mars 2002 relative aux droits des malades et à la qualité du système de santé, JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE [J.O.] [OFFICIAL GAZETTE OF FRANCE], Mar. 5, 2002, p. 4118. *See generally* Florence G'Sell-Macrez, *Medical Malpractice and Compensation in France, Part I: The French Rules of Medical Liability since the Patients' Rights Law of March 4, 2002*, 86 CHI.-KENT L. REV. 1093 (2011). Historically, the relationship between a patient and private physician was governed by contract (and liability under the contract was governed by the Civil Code), while the relationship between a patient and physician in a public hospital was governed by "administrative" (public) law. *Cf.* GÉRARD MÉMETEAU, TRAITÉ DE LA RESPONSABILITÉ MÉDICALE (1996); René Savatier, *La responsabilité médicale en France (aspects de droit privé)*, 28 REVUE INTERNATIONALE DE DROIT COMPARÉ 493 (1976). But the 2002 law created a new unified scheme for medical malpractice liability. *See* G'Sell-Macrez, *supra*. French prosecutors had also sometimes brought criminal charges against healthcare professionals in the past. For example, they took action in the 1850s after physicians investigating the contagiousness of secondary syphilis had "inoculated" a non-syphilitic ten-year-old boy with pus taken from a patient suffering from secondary syphilis. *See* Alex Dracoby, *Ethics and Experimentation on Human Subjects in Mid-Nineteenth-Century France: The Story of the 1859 Syphilis Experiments*, 77 BULL. HIST. MED. 332, 360–61 (2003) (describing the trial of Antoine Gailleton and Joseph-Frédéric Guyenot).

83. *See* Cruzan v. Dir., Mo. Dep't. of Health, 497 U.S. 261, 281 (1990).

84. Loi 2005-370 du 22 avril 2005 relative aux droits des malades et à la fin due vie, J.O., Apr. 23, 2002, p. 7089; *see* Antoine Baumann et al., *Ethics review: End-of-life legislation—the French model*, 13 CRITICAL CARE 204 (2009) (explaining that the new law "authorizes the withholding or withdrawal of treatments when they appear 'useless, disproportionate or having no other effect than solely the artificial preservation of life'").

85. *See* Aurelien Breeden, *French Court Clears Way to End Life Support for Man in Vegetative State*, N.Y. TIMES, June 28, 2019, <https://www.nytimes.com/2019/06/28/world/europe/france-vincent-lambert-life-support.html> [<https://perma.cc/8NCG-T2HF>]; *see also* Aline Cheynet de Beaupré, *Entre la vie et la mort : juger la fin de vie*, 3 LES CAHIERS DE LA JUSTICE 413 (2017) (discussing recent changes to the 2005 law); Paul Véron & François Vialla, *Arrêt des traitements : deux premières applications de la loi du 2 février 2016*, 5 L'ACTUALITE JURIDIQUE. DROIT ADMINISTRATIF 301 (2017) (discussing early application of this law).

86. *See infra* Section 0.

87. Anna B. Laakman, *Customized Medicine and the Limits of Federal Regulatory Power*, 19 VAND. J. ENT. & TECH. L. 285, 321–22 (2016) ("The rise of an increasingly influential patient

in part with mechanisms allowing patients access to new medicines *before* approval for the commercial market.⁸⁸

1. *Emergence of Early Access Mechanisms*

Early access mechanisms emerged during the worst years of the AIDS crisis and responded to the fact that better informed and newly empowered patients were willing to take greater risks in exchange for earlier access to new medicines. In the United States, however, policymaking discussions also included proponents of deregulation—groups who opposed gatekeeping altogether, on philosophical grounds.

Even before the AIDS crisis, FDA had permitted seriously ill patients access to experimental drugs.⁸⁹ The agency proposed formalizing early access in 1983, two years after the first major news coverage of AIDS.⁹⁰ FDA called the mechanism a “treatment IND.”⁹¹ Recent scholarship has argued persuasively that

empowerment movement has forced the FDA to significantly revise its review and approval processes.”).

88. Policymakers also responded with mechanisms that moved the market entry decision earlier in time. A few examples follow. The French “fast track” program reduces the timeline for regulatory approval of clinical trials for certain important medicines. ANSM, CLINICAL TRIALS ON MEDICINAL PRODUCTS SUBMITTED TO THE ANSM AS PART OF THE FAST TRACK PROCEDURE, Oct. 10, 2018, https://www.ansm.sante.fr/var/ansm_site/storage/original/application/42df327468624f1ce1862ef562c1cc30.pdf [https://perma.cc/DJU6-GS7A]. U.S. law permits accelerated approval of a medicine intended for treatment of serious or life-threatening illness, based on data that do not *show* clinical benefit but rather *predict* it. 21 C.F.R. § 314.500 (2020). European law permits a one-year renewable “conditional marketing authorization”—before comprehensive clinical data have been generated—for certain medicines intended to treat a seriously debilitating or life-threatening disease. Regulation 726/2004, *supra* note 22, at 10; Commission Regulation No. 507/2006 of 29 March 2006 on the Conditional Marketing Authorisation for Medicinal Products for Human use Falling Within the Scope of Regulation (EC) No. 726/2004 of the European Parliament and of the Council, 2006 O.J. (L 92) 6, 8 (EC). *See generally* Jorge Martinalbo et al., *Early Market Access of Cancer Drugs in the EU*, 27 ANNALS ONCOLOGY 96 (2016) (describing conditional marketing authorization, authorization under exceptional circumstances, and accelerated assessment in Europe). French law similarly provides for conditional approval of medicines. CODE DE LA SANTÉ PUBLIQUE [PUBLIC HEALTH CODE] art. R.5121-36-1 (Fr.).

89. *See generally* Grossman, *AIDS Activists*, *supra* note 59, at 699–700 (describing single patent exceptions, compassionate use INDs, open label INDs, and the “Group C” program under which the National Cancer Institute furnished investigational cancer drugs to physicians before their approval); *see also* Greenberg, *AIDS*, *supra* note 52, at 316 (describing compassionate use INDs before the AIDS crisis); Zettler, *Implications*, *supra* note 21, at 150 (describing the Group C program).

90. Lawrence K. Altman, *Rare Cancer Seen in 41 Homosexuals*, N.Y. TIMES, July 3, 1981, <https://www.nytimes.com/1981/07/03/us/rare-cancer-seen-in-41-homosexuals.html> [https://perma.cc/8XF9-WKHE]; *see* Proposed New Drug, Antibiotic, and Biologic Drug Product Regulations, 48 Fed. Reg. 26,720 (June 9, 1983).

91. When a company requests permission to perform clinical trials, it submits an investigational new drug application, or “IND.” Calling the mechanism a “treatment IND” signaled

the proposal was an attempt to partially dismantle the premarket gatekeeping mechanism, advanced by conservatives and libertarians in positions of influence during the Reagan Administration.⁹² At one point FDA even proposed shifting the burden to the agency to reject requests for access.⁹³ The AIDS crisis exploded on the heels of this proposal, however, and many AIDS advocates who sought early access nevertheless supported the basic premarket approval paradigm, rejecting any hint of a lower standard of proof for drugs intended to treat AIDS.⁹⁴ With their influence, the final rule was more moderate.⁹⁵

In subsequent years, critics complained that FDA's approach to providing early access lacked clear criteria and submission requirements, leading to inconsistent policies, inequitable access, and preferential access for some categories of patients.⁹⁶ Policymakers and courts also continued to hear arguments for early access that combined patient empowerment rhetoric with arguments from rights-based jurisprudence. In 2003, for instance, Abigail Alliance—a public interest group named after a young woman who died of cancer after being denied access to an experimental medicine—asked FDA to permit the commercial sale of drugs after phase 1 trials, contingent on continued progress toward approval.⁹⁷ It

that although the medicine was experimental, the purpose of the use was treatment rather than experimentation.

92. Grossman, *AIDS Activists*, *supra* note 59, at 701.

93. *Id.* at 702–04. FDA also proposed allowing companies to charge for the drugs. *See* Investigational New Drug, Antibiotic, and Biological Drug Product Regulations; Treatment Use and Sale, 52 Fed. Reg. 8,850 (Mar. 19, 1987) (permitting companies to charge for investigational medicines but allowing FDA to withdraw permission for sale if the price was “manifestly unfair”).

94. Grossman, *AIDS Activists*, *supra* note 59, at 706 (arguing that accelerated approval on the basis of surrogate, rather than clinical, endpoints was controversial within the AIDS community, because it seemed to embrace a lower standard of proof for commercial distribution); *id.* at 714 (pointing out that AIDS activists focused on “bodily freedom” and used the rhetoric of “choice” rather than unrestricted experimentalism). In addition to influencing the development of accelerated approval, AIDS activists played a role in the development of a “parallel track” early access mechanism specific to HIV/AIDS drugs. *Id.* at 718–26; Zettler, *Implications*, *supra* note 21, at 149–50. The parallel track program was meant to enable AIDS patients to enroll in uncontrolled parallel studies, once promising new AIDS drugs began enrollment for Phase 2 trials. *See* Expanded Availability of Investigational New Drugs Through a Parallel Track Mechanism for People with AIDS and Other HIV-Related Disease, 57 Fed. Reg. 13,250 (Apr. 15, 1992). It has not been used much; as of 2005, only one drug (stavudine) had been made available through parallel track. Zettler, *Implications*, *supra* note 21, at 150.

95. Grossman, *AIDS Activists*, *supra* note 59, at 693. *See* Investigational New Drug, Antibiotic, and Biological Drug Product Regulations; Treatment Use and Sale, 52 Fed. Reg. 19,466 (May 22, 1987).

96. Expanded Access to Investigational Drugs for Treatment Use, 71 Fed. Reg. 75,147, 75,149 (Dec. 14, 2006) (noting the criticisms). For example, some argued that physicians in academic medical centers tended to be more aware of FDA's early access policies and procedures and that patients treated outside of these centers were therefore unlikely to have access. *Id.*

97. Zettler, *Implications*, *supra* note 21, at 154. By then Congress had also enacted provisions broadly describing expanded access to investigational drugs for treatment use. Food and Drug

then turned to the courts, arguing that the U.S. Constitution provides a right of access to experimental drugs and asking the court to enjoin FDA from preventing the sale of investigational drugs to terminally ill patients.⁹⁸ Although Abigail Alliance lost its case,⁹⁹ FDA revised its regulations to clarify its early access scheme and improve access, and the resulting “expanded access” regulations remain in place today.¹⁰⁰

The French history is different, reflecting pressure from patient groups during the AIDS crisis, but no broader movement to eliminate the gatekeeper. There was no legislative basis for access to unapproved medicines before 1992.¹⁰¹ Patients who had enrolled in clinical trials could sometimes continue treatment while the marketing application was pending, but other patients could not access the unapproved medicine.¹⁰² As in the United States, during the early years of the AIDS crisis patient groups pressed for changes that would allow them medicines still in trials.¹⁰³ In 1990, two years after enactment of the first comprehensive French law governing clinical trials,¹⁰⁴ the government decreed that a company

Administration Modernization Act of 1997, Pub. L. No. 105-115, § 402 (1997) (adding section 561 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb). And it had directed the National Institutes of Health to establish a publicly accessible registry listing ongoing clinical trials of drugs for serious or life-threatening diseases and conditions. *Id.* § 113 (codified at 42 U.S.C. § 282(j)).

98. Zettler, *Implications*, *supra* note 21, at 154–55. Private litigation to force companies to provide access has mostly failed, no matter the legal theory. Shah & Zettler, *supra* note 21, at 152–63 (providing an overview of efforts to obtain access through litigation and noting only one successful contractual claim, which was grounded in an express promise, in *Dahl v. HEM Pharmaceuticals Corp.*, 7 F.3d 1399 (9th Cir. 1993)); *cf.* William M. Janssen, *A “Duty” to Continue Selling Medicines*, 40 AM. J. L. & MED. 330 (2014) (reviewing and dismissing theories for a legal duty to continue selling a medicine once that medicine has been made available, such as a common law duty to initiate a rescue or continue a rescue once initiated). Nor do U.S. or European regulators have any basis to order companies to provide early access. *E.g.*, Expanded Access to Investigational Drugs for Treatment Use, 71 Fed. Reg. at 75,150 (“under its existing authority, FDA cannot compel a drug manufacturer to provide access to investigational drugs for treatment use”).

99. *Abigail All. for Better Access to Developmental Drugs v. Von Eschenbach*, 495 F.3d 695 (D.C. Cir. 2007).

100. Charging for Investigational Drugs Under an Investigational New Drug Application, 74 Fed. Reg. 40,872 (Aug. 13, 2009) (codified at 21 C.F.R. pt. 312, subpart I).

101. Quiterie de Launet, Agnès Brouard & Christian Doreau, *Les autorisations temporaires d’utilisation (ATU): 50 ans d’histoire de l’évolution de la réglementation des médicaments en France*, 341 REVUE D’HISTOIRE DE LA PHARMACIE 47, 49 (2004).

102. *Id.*

103. *Id.* Groups like Act Up Paris mobilized to gather and share information about the disease and potential treatments, and eventually prominent patient advocates secured seats at the table with government researchers. DIDIER LESTRADE, *ACT UP: UNE HISTOIRE* (2000).

104. Loi 88-1138 du 20 décembre 1988, dite loi Huriet, relative à la protection des personnes qui se prêtent à des recherches biomédicales, J.O., Dec. 22, 1988, p. 16025. The *Loi Huriet* provided a legal framework for clinical trials in France, including the ethical principles of informed consent that apply, and it thus addressed the reluctance of French regulators to authorize trials as well as the liability concerns of doctors and companies—reluctance and concerns that trace their legacy to the Nuremberg Charter after World War II. *See* Anne Laude, *La réforme de la loi sur les recherches*

could in some cases sell investigational medicines to patients unable to enroll in trials.¹⁰⁵ Legislation enacted in 1992 added a new section to the Public Health Code, largely tracking the decree.¹⁰⁶ Further reflection on the AIDS crisis led to later proposals for mechanisms that would allow wider and faster access to unapproved medicines.¹⁰⁷ The resulting law, passed in May 1996, amended the Public Health Code and created the “temporary authorization for use” (ATU) framework in place today.¹⁰⁸

2. Commitment to the Gatekeeping Model

In both countries, early access requires the approval of a regulator. This reflects the basic innovation of twentieth century medicines law and the realization that the public’s interest is best served when scientific and public health authorities have gatekeeping power instead of only the lesser power to take enforcement action after the fact.¹⁰⁹ The standards are similar, reflecting the common themes and origins of the two medicine approval systems. Expanded access in the United States requires a showing that (1) the patient has a serious or immediately life-threatening disease or condition for which there is no comparable or satisfactory alternative therapy; (2) the potential benefit for the patient(s) justifies the potential risks,¹¹⁰ and the potential risks are not unreasonable in the context of the disease

biomédicales, 2009 RECUEIL DALLOZ 1150.

105. Décret 90-872 du 27 septembre 1990 portant application de la loi Huriet, J.O., Sept. 29, 1990, p. 11862, 11868.

106. Loi 92-1279 du 8 décembre 1992, modifiant le livre V du code de la santé publique et relative à la pharmacie et au médicament, J.O., Dec. 11, 1992, p. 16888, 16891 (adding § L.601-2 to the Public Health Code).

107. de Launet, *supra* note 101, at 51.

108. Loi 96-452 du 28 mai 1996, portant diverses mesures d’ordre sanitaire, sociale et statutaire, J.O., July 6, 1996, p. 7912, 7913. The provisions now appear in Article L.5121-12 of the Public Health Code.

109. Both countries grant most requests, but each denies some. See Jonathan P. Jarow et al., *Expanded Access of Investigational Drugs: The Experience of the Center of Drug Evaluation and Research Over a 10-Year Period*, 50 THERAPEUTIC INNOVATION & REG. SCI. 705 (2016) (indicating that FDA rejected roughly thirty-two requests for expanded access between 2005 and 2014). The fact that a regulator generally approves applications for early access does not mean the gatekeeping function is meaningless. First, the approval may follow back-and-forth about appropriate dosing and regimen, among other things. Steve Usdin, *FDA to Facilitate Access to Unapproved Drugs*, BIOCENTURY (Dec. 14, 2018), <https://www.biocentury.com/article/299854/how-fda-plans-to-help-patients-get-expanded-access-to-unapproved-drugs> [https://perma.cc/2TU7-QCJU]. Second, marketing applications are also generally approved, and few would argue the preapproval authority is meaningless. Gatekeeping is powerful because it shifts the burden of proof to the party seeking to make a medicine available, it ensures the standard is met before the medicine is made available, and it makes enforcement easier for the government. See *supra* Section 0.

110. When weighing the benefits and risks, FDA will consider the rationale for the intended use of the drug, the criteria for patient selection, pharmacology and toxicology information showing the drug is reasonable safe at the dose intended, and the clinical procedures, laboratory tests, and

being treated; and (3) providing the drug will not interfere with clinical trials that could support marketing approval.¹¹¹ In France, the ANSM provides temporary authorization for use, for a limited time and subject to renewal, if (1) the medicine is intended to treat a rare or serious condition, (2) there is no suitable alternative, and (3) there is a presumption of safety and effectiveness.¹¹² In both countries these general criteria apply to every request for early access, and additional standards must be satisfied depending on whether access will be provided to an individual or a group of patients.

Both countries permit early access for individual patients. In the United States, the general criteria for expanded access must be satisfied, *and* (1) the treating doctor must determine that the probable risk to the patient from the drug is not greater than the probable risk from the disease, and (2) FDA must determine that the patient cannot obtain the drug any other way (for instance, by enrolling in a clinical trial).¹¹³ The agency ordinarily looks for completed phase I trials at doses similar to those proposed for the patient, together with preliminary evidence suggesting effectiveness.¹¹⁴ In some cases, however, FDA will permit a single patient access based on preclinical (animal) data or even mechanism of action.¹¹⁵ In France, the ANSM will issue a “nominative” ATU at the request of a doctor, if the basic criteria for ATUs are met, *and* (1) the patient cannot participate in clinical trials, and (2) the benefits to the patient are expected to outweigh the risks.¹¹⁶ Generally the ANSM requires that there be a submitted or pending application for marketing approval, or at least an ongoing clinical trial in France, but it may make exceptions.¹¹⁷ Both agencies approve these single-patient requests rapidly: often

monitoring planned. 21 C.F.R. § 312.305 (2020).

111. 21 C.F.R. § 312.305(a) (2020).

112. *Autorisations temporaires d'utilisation*, ANSM, [https://www.ansm.sante.fr/Activites/Autorisations-temporaires-d-utilisation-ATU/Qu-est-ce-qu-une-autorisation-temporaire-d-utilisation/\(offset\)/1](https://www.ansm.sante.fr/Activites/Autorisations-temporaires-d-utilisation-ATU/Qu-est-ce-qu-une-autorisation-temporaire-d-utilisation/(offset)/1) [<https://perma.cc/EGW9-YFUC>]; *see generally* CODE DE LA SANTÉ PUBLIQUE [PUBLIC HEALTH CODE] art. L.5121-12 (setting rules governing use for therapeutic purposes of medicines without marketing authorization in France); ANSM, NOTICE TO APPLICANTS FOR MARKETING FOR TEMPORARY AUTHORISATION FOR USE (ATU) (July 2015) (hereinafter ATU NOTICE); *see also* Directive 2001/83, *supra* note 22, at 74 (“A Member State may, in accordance with legislation in force and to fulfil special needs, exclude from the provisions of this Directive medicinal products supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of an authorised health-care professional and for use by an individual patient under his direct personal responsibility.”).

113. 21 C.F.R. § 312.310(a) (2020).

114. Expanded Access to Investigational Drugs for Treatment Use, 71 Fed. Reg. 75,147, 75,151 (Dec. 14, 2006).

115. *Id.*

116. ATU NOTICE, *supra* note 112, at § 1.1.

117. *Id.* at § 1.1. Indeed, the ANSM may grant access to an unapproved medicine in a desperate case even if the company is not performing clinical trials to support approval. CODE DE LA SANTÉ PUBLIQUE [PUBLIC HEALTH CODE] art. L.5121-12, § III.A.5.

within hours and at most within a few days.¹¹⁸

Widespread use in the United States requires a “treatment IND” or “treatment protocol.”¹¹⁹ The ordinary standards for expanded access apply. If the medicine is intended to treat a serious disease or condition, FDA will look for data from phase 3 trials showing safety and effectiveness, but in some cases it will accept compelling data from phase 2 trials.¹²⁰ If the medicine is intended to treat an immediately life-threatening disease, FDA will consider whether “the available scientific evidence, taken as a whole, provides a reasonable basis to conclude that the investigational drug may be effective for the expanded access use and would not expose patients to an unreasonable and significant risk of illness or injury.”¹²¹ This will “ordinarily consist of clinical data from phase 3 or phase 2 trials,” but it could comprise “more preliminary clinical evidence.”¹²² Widespread use in France requires a “cohort ATU” proposed by the company developing the drug.¹²³ The general standards for ATUs apply. Unlike FDA, though, the ANSM also expects the medicine to be the subject of a pending or imminent marketing application.¹²⁴ (In this regard, the cohort ATU differs from a nominative ATU, which may be issued earlier in the life of an investigational medicine and can last for years.) This means that “early access” via the cohort ATU in France may not be as *early* in a particular medicine’s research and development timeline as “early access” via treatment INDs in the United States. The industry reports that new medicines become available through the ATU mechanism in France roughly 210 days earlier than they otherwise would become available.¹²⁵ The cohort ATU also contains much of the same information as a full-blown marketing application, including

118. E.g., Lesley R. Navin, *DDI Webinar Series: An Overview of FDA’s Expanded Access Process and the New Individual Patient Expanded Access Application*, FDA 40, <https://www.fda.gov/media/98959/download> [<https://perma.cc/BT59-9TWM>]; ATU NOTICE, *supra* note 112, at § 5.2.

119. 21 C.F.R. § 312.320 (2020). Use will fall under a treatment IND if it is organized by an entity separate from the drug company (which will need the company’s cooperation). Otherwise use falls under a treatment protocol that the company adds to its file at FDA.

120. 21 C.F.R. § 312.320(a)(3) (2020).

121. *Id.*

122. *Id.*

123. See generally CODE DE LA SANTÉ PUBLIQUE [PUBLIC HEALTH CODE] art. L.5121-12 (setting rules governing use for therapeutic purposes of medicines without marketing authorization in France); ATU NOTICE, *supra* note 112; Regulation 726/2004, *supra* note 22, at art. 83.

124. A company submits its cohort ATU application when it submits its marketing application or, in some cases, before the marketing application (provided that it files the marketing application within a fixed period of time). ATU NOTICE, *supra* note 112, at § 6.1; see also Regulation 726/2004, *supra* note 22, at art. 83.

125. LES ENTREPRISES DU MÉDICAMENT, CHANTIER 3: L’ÉVALUATION ET L’EFFICACITÉ ADMINISTRATIVE POUR UN ACCÈS À L’INNOVATION PLUS RAPIDE (May 10, 2019), <https://www.leem.org/chantier-3-levaluation-et-lefficacite-administrative-pour-un-acces-innovation-plus-rapide> [<https://perma.cc/2CQN-WGDC>].

draft labeling for the final product and the analytical, preclinical, and clinical data that will ultimately support approval.¹²⁶

Unlike the ANSM, FDA will also permit expanded access for an “intermediate-size” population.¹²⁷ The agency explains that this may be necessary if patients cannot participate in ongoing trials—because they do not meet enrollment criteria, because enrollment has ended, or even because the trial site is not geographically accessible.¹²⁸ The regulations also describe use of this arrangement when a drug is not under development at all—for instance, because the disease is so rare that the sponsor cannot recruit trial subjects.¹²⁹ For intermediate-size groups to enjoy early access, the ordinary standards for expanded access must be met. In addition, there must be (1) enough evidence of safety to justify a clinical trial at the same dose and duration in the same number of people, and (2) preliminary clinical evidence of effectiveness, or of a plausible pharmacologic effect, sufficient to make expanded access use a reasonable therapeutic option for the patients.¹³⁰ French law has no equivalent scheme.

These early access mechanisms resonate with the shifting relationship between the individual and the state. Arguments for early access grounded in autonomy principles tended to reason that individuals should have access to medicines of their choosing provided that they are fully aware of the risks and choosing freely.¹³¹ Rights-based jurisprudential arguments similarly focused on the notion that individual rights should rarely be subordinated to the interests of the larger society.¹³² Various scholars have pointed out, however, that limiting early access to patients with serious or life-threatening conditions is hard to square with these rationales.¹³³ After all, if the autonomy principle applies, it surely justifies early access for all patients and not simply the dying.¹³⁴ Moreover, some

126. ATU NOTICE, *supra* note 112, at § 6.1.

127. 21 C.F.R. § 312.315 (2020).

128. 21 C.F.R. § 312.315(a)(2) (2020).

129. 21 C.F.R. § 312.315(a)(1) (2020). Unlike U.S. law, though, French law permits use of the ATU for medicines that treat not only serious diseases but rare diseases. ATU NOTICE, *supra* note 112, at § 1.1.

130. 21 C.F.R. § 312.315(b) (2020).

131. See Schüklenk & Lowry, *supra* note 20, at 10 (discussing this argument).

132. Manik Chahal, *Off-trial Access to Experimental Cancer Agents for the Terminally Ill: Balancing the Needs of Individuals and Society*, 36 J. MED. ETHICS 367, 368 (2010) (“Though risk is evident, according to rights-based theory, competent terminal patients should have the right to choose for themselves what risks they are willing to take, and what actions make life worth living for them.”)

133. E.g., Raus, *supra* note 20, at 1, 7 (identifying and responding to autonomy rationale).

134. Leonard, *supra* note 21, at 1352 (arguing that if expanded access is grounded in an autonomy rationale there is no basis for distinguishing between terminally ill patients and other patients); see also Caplan, *Sound Public Policy*, *supra* note 20, at 2 (arguing that the ethical case for access does not single out the terminally ill as a class deserving of special standing). And, of course, it can be difficult to reach consensus about what exactly constitutes a life-threatening or terminal condition. Caplan, *Sound Public Policy*, *supra* note 20, at 2 (noting that there is no societal consensus

point out that the autonomy rationale may be hard to square with the imposition of any gatekeeping mechanism at all.¹³⁵ These are fair points, and indeed some who argue from the autonomy rationale would eliminate the gatekeeper altogether.¹³⁶ That the expanded access and ATU schemes do not align perfectly with the autonomy rationale suggests that policymakers considered other principles. The next two subsections explain how the early access schemes in France and the United States reflect additional competing principles.

3. Rigorous Assessment of Informed Consent and Medical Paternalism

In bioethics, informed consent is consent to a medical intervention, freely given, based on a complete understanding of the intervention, its risks and benefits, and available alternatives.¹³⁷ Some argue that uncertainty during premarket testing means that consent is inherently less informed than it would be later.¹³⁸ Those arguing from the autonomy principle may respond that a patient can consent to uncertainty as much as to risk. A more compelling concern might be that the very patients for whom early access is considered—those with serious or life-threatening illnesses—may be less likely to give truly informed consent.¹³⁹ These patients may be easily swayed by family members who want them to keep fighting, for example, and they may not be emotionally or intellectually prepared to

on the criteria for classification of a patient as terminally ill and that physicians are “notoriously poor” at predicting the probability of death).

135. Cf. Caplan, *Sound Public Policy*, *supra* note 20, at 2 (arguing that the ethical case for access does not explain why patients should have to wait for phase 1 trial results); Leonard, *supra* note 21, at 1379 (arguing that if a patient’s right to control what he puts in his body is the paramount consideration, there is no basis for requiring any clinical trials or even the prescription requirement).

136. E.g., Epstein, *Erosion*, *supra* note 52, at 574 (“Citizens, as autonomous individuals, should be free to make these decisions for themselves.”); see also Richard A. Epstein, *Against Permittitis: Why Voluntary Organizations Should Regulate the Use of Cancer Drugs*, 94 MINN. L. REV. 1 (2009) (suggesting elimination of FDA’s gatekeeping role altogether, on autonomy grounds).

137. See Andrea A. Conti, From informed consent to informed dissent in health care: historical evolution in the twentieth century, 88 ACTA BIOMEDICA 201 (2017) (describing the principle of informed consent); Joan H. Krause, Reconceptualizing Informed Consent in an Era of Health Care Cost Containment, 85 IOWA L. REV. 261, 267–72 (1999) (providing brief overview of the principle and history of informed consent).

138. Carrieri, Peccatori & Boniolo, *supra* note 20, at 68 (noting argument that there is insufficient information for informed consent). Indeed, some would argue that the uncertainty makes rational decision-making impossible; see also Schüklenk & Lowry, *supra* note 20, at 14 (noting this argument).

139. Schüklenk & Lowry, *supra* note 20, at 12 (noting argument that the dying are unable to make fully autonomous choices); see also Jonathan J. Darrow et al., *Practical, Legal, and Ethical Issues in Expanded Access to Investigational Drugs*, 372 NEW ENG. J. MED. 279, 284 (2015) (noting that “most patients do not have the training or experience to evaluate the combined pharmacologic, clinical, and statistical information on experimental therapies that is available to them” and that “[r]isk comprehension among the general public is low, is not strongly correlated with self-perceived ability to understand risk, and may be more impaired in sicker patients”).

understand the risks and benefits.¹⁴⁰ Some literature suggests that these patients are prone to therapeutic optimism—an excess of optimism about an intervention’s potential benefits and a tendency to dismiss the potential for harm.¹⁴¹ Those arguing from the autonomy principle respond that our regulatory framework views patients with serious, life-threatening, even terminal illnesses as competent to enroll in phase 1 and phase 2 clinical trials.¹⁴² This is true even though these subjects often suffer from therapeutic misconception—the mistaken belief that the trial’s purpose is to treat their disease.¹⁴³

Both early access schemes take informed consent seriously. In the United States, the treating doctor is considered an “investigator” (just like an investigator in a normal clinical trial), which triggers the duty to ensure review by an institutional review board (ethics committee), focused on the protection of human subjects.¹⁴⁴ FDA’s informed consent regulations also apply, requiring that the doctor ensure that the patient understands the drug is investigational and that there may be uncertainty about its safety and effectiveness.¹⁴⁵ In France, the treating

140. See Malinowski, *supra* note 21, at 645 (arguing that the terminally ill should be considered a “vulnerable group” for informed consent purposes).

141. See Bunnik, Aarts & van de Vathorst, *Little to Lose*, *supra* note 20, at 979; Raus, *supra* note 20, at 7.

142. See John A. Robertson, *Controversial Medical Treatment and the Right to Health Care*, 6 HAST. CTR. REP. 15, 17 (2006) (suggesting these same patients should be able to consent to administration of the same medicines “in a nonresearch setting under a physician’s supervision”).

143. Caplan, *Sound Public Policy*, *supra* note 20, at 2 (“Some patients enrolled in Phase One safety studies believe themselves to be involved in therapeutic experimentation. And almost nothing that any one can do by way of informed consent can disabuse them of this hope.”); Monica H. Schaeffer et al., *The Impact of Disease Severity on the Informed Consent Process in Clinical Research*, 100 AM. J. MED. 261 (1996) (finding that severely ill patients enrolling in phase 1 trials retain the least information from informed consent documents). In other words, these patients believe that investigators focus on the goal of treating them, rather than on strict compliance with the protocol and trial design elements intended to maximize the usefulness and quality of the resulting data. Pat McConville, *Presuming Patient Autonomy in the Face of Therapeutic Misconception*, 31 BIOETHICS 711, 712 (2017); Zettler, *Implications*, *supra* note 21, at 169 (“Even when patients are told they are participating in a research study that is not intended to benefit them personally in any way, patients tend to exhibit a robust therapeutic misconception.”). See also Carrieri, *supra* note 20, at 68 (noting arguments against right-to-try laws given “ethical concern of therapeutic misconception”).

144. 21 C.F.R. § 312.305(c) (2020). This review is meant to ensure that the rights and welfare of human subjects are protected, including by determining that informed consent is obtained in accordance with and to the extent required by federal requirements. FDA, GUIDANCE FOR INDUSTRY: EXPANDED ACCESS TO INVESTIGATIONAL DRUGS FOR TREATMENT USE — QUESTIONS AND ANSWERS I, 5 (Oct. 2017), <https://www.fda.gov/media/85675/download> [<https://perma.cc/6FVZ-MPN6>] (hereinafter EXPANDED ACCESS GUIDANCE). FDA has detailed regulations governing institutional review boards, including their organization, their functions and manner of operation, and the records and reports they must keep. See 21 C.F.R. pt. 56 (2020).

145. FDA, EXPANDED ACCESS GUIDANCE, *supra* note 144, at 6. These detailed regulations cover general requirements for informed consent, exceptions from these requirements, the elements of informed consent, and documentation of informed consent. 21 C.F.R. §§ 50.20-50.27 (2020).

doctor must similarly confirm that the patient has provided informed consent.¹⁴⁶ And although both legal systems envision consent involving the patient *or*, if appropriate, the patient's legally authorized representative, French law *also* allows every patient to designate a trusted person ("personne de confiance") to help with medical decisions.¹⁴⁷

Although both early access schemes assume that seriously ill and dying patients can make informed decisions about risk and benefit, they are paternalistic in the sense that the regulator plays a direct role in treatment decisions for individual patients.¹⁴⁸ When an individual patient seeks early access in the United States, FDA considers *that* patient's disease, medical history, and prior treatments.¹⁴⁹ It compares the benefits and risks for that patient, and it could in theory reach a different decision than the doctor and patient.¹⁵⁰ The French regulator similarly considers the benefits and risks for individual patients who seek early access. FDA and the ANSM have a more paternalistic role with respect to early access arrangements than with respect to medicines approved for the market. When regulators approve a new medicine, they make the benefit-risk call focusing on the entire intended patient population, and individual treatment decisions are left to doctors.¹⁵¹ But they oversee individual treatment decisions in early access arrangements.

4. Prioritizing the Generation of Evidence and Progress Toward Approval

Early access schemes could interfere with the utilitarian goal of the premarket approval requirement: the generation of high-quality evidence to support market entry and prescribing decisions.¹⁵² A company providing early access spends

146. ATU NOTICE, *supra* note 112, at § 5.5 (nominative ATU); *id.* at § 6.4 (cohort ATU).

147. CODE DE LA SANTÉ PUBLIQUE [PUBLIC HEALTH CODE] art. L.1111-6; *see also* HAUTE AUTORITÉ DE SANTÉ, LA PERSONNE DE CONFIANCE (Apr. 2016), https://www.has-sante.fr/upload/docs/application/pdf/2016-03/da_personne_confiance_v9.pdf [<https://perma.cc/LV39-897Q>].

148. Dresser, *supra* note 21, at 1641–43; Benjamin P. Falit & Cary P. Gross, *Access to Experimental Drugs for Terminally Ill Patients*, 300 JAMA 2793, 2793 (2008) ("Minimization of harm to terminally ill patients is a primary goal of governmentally imposed restrictions on access.").

149. 21 C.F.R. § 312.305(b)(2)(iii) (2020).

150. In practice, this rarely happens. *See supra* note 109.

151. A doctor may prescribe an approved medicine for any use, including a use for which the medicine is *not* approved. Legal Status of Approved Labeling for Prescription Drugs; Prescribing for Uses Unapproved by the Food and Drug Administration, 37 Fed. Reg. 16,503, 16,503 (Aug. 15, 1972) ("[T]he physician may, as part of the practice of medicine, lawfully . . . vary the conditions of use from those approved in the package insert, without informing or obtaining the approval of the Food and Drug Administration."); CODE DE LA SANTÉ PUBLIQUE [PUBLIC HEALTH CODE] art. R.4127-8 (Fr.) (providing that, within the limits of current scientific knowledge, a doctor is free to prescribe the medicine that he considers most appropriate under the circumstances).

152. *See* Caplan & Moch, *Rescue Me*, *supra* note 20 ("In the case of many experimental therapies, there is a clear and growing moral dilemma which society will ultimately need to address:

resources that could instead support ongoing clinical trials and a marketing application. Smaller companies may find it financially prohibitive to supply patients seeking early access while also supplying and funding clinical trials, particularly if the manufacturing process is complex or the raw materials expensive.¹⁵³ Diverting resources could slow a medicine's progress to approval and thus delay access for other patients. If the patient seeking early access suffers from a different disease, diverting resources may delay treatment of patients with a disease that the medicine is more likely to treat safely and effectively.¹⁵⁴

Early access programs may also siphon patients away from trials, interfering with enrollment.¹⁵⁵ This will happen if patients eligible for the trial are also allowed

Do attempts to help individuals in immediate need place at risk the pursuit of evidence-based regulatory approval that will make a product available as quickly as possible to the largest number of affected and soon-to-be affected individuals?").

153. Tim K. Mackey & Virginia J. Schoenfeld, *Going "Social" to Access Experimental and Potentially Life-Saving Treatment: An Assessment of the Policy and Online Patient Advocacy Environment for Patient Access*, 14 BMB MED. 17, 20 (2016) (noting that "[l]ogistics for investigational drug availability are also challenging, since these drugs are typically manufactured in small lot sizes that can be impacted by manufacturing complications and/or limited availability of active pharmaceutical ingredient/raw materials"); Jerry Menikoff, *Beyond Abigail Alliance: The Reality Behind the Right to Get Experimental Drugs*, 56 KAN. L. REV. 1045, 1063 (2008); Michael Cipriano, *Gottlieb's "Right to Try" Sentiment: Law Fails to Address Difficulties Faced by Drugmakers*, PINK SHEET (Jul. 30, 2018), <https://pink.pharmaintelligence.informa.com/PS123596/Gottliebs-Right-To-Try-Sentiment-Law-Fails-To-Address-Difficulties-Faced-By-Drugmakers> (noting that then-Commissioner Gottlieb pointed out repeatedly that the problem with right-to-try was that companies would not make their drugs available and that with cell-based therapies in particular the "cost of goods isn't trivial"); Kristina Fiore, *Desperate Families Pursue "N-of-1" Trials for Ultra-Rare Diseases*, MEDPAGE TODAY (Aug. 21, 2019), <https://www.medpagetoday.com/special-reports/exclusives/81725> [<https://perma.cc/VH3R-FGXS>] (noting that one small company providing early access to a gene therapy product in 2019 reported a total cost, for four infusions to a single patient, of "hundreds of thousands of dollars").

154. The drug could work in both diseases, to be sure. Abigail Burroughs, for whom the "Abigail Alliance" organization is named, suffered from head and neck cancer and sought (unsuccessfully) access to Erbitux (cetuximab), which was being tested for colon cancer. Complaint at 6–7, *Abigail All. for Better Access to Developmental Drugs v. McClellan*, Case No. 1:03cv01601, 2004 WL 3777340 (D.D.C. 2004). And today the medicine is approved for both. Still, even if the medicine will work in patients seeking expanded access for a different disease, diverting resources for those patients may slow access for future patients with the first disease the company chose to study.

155. Whether an early access program will discourage participation in ongoing clinical trials may depend on the drug, the disease it is meant to treat, alternative treatments in the market, and the design of the trial. Thousands of patients participated in controlled clinical trials of the lipid-lowering statins, after their approval, to assess their effect on cardiovascular mortality and morbidity, even though these patients faced potential randomization to a potentially inferior alternative therapy. Amicus Brief for Economists John E. Calfee et al. at 14, *Abigail All. for Better Access to Developmental Drugs v. Von Eschenbach*, 495 F.3d 695 (D.C. Cir. 2007). But low enrollment in the trials of Zidovudine (azidothymidine) in the 1980s suggests that the risk of under-enrollment may be meaningful if the trials are placebo-controlled, particularly if the disease is serious and otherwise untreatable. Leonard, *supra* note 21, at 1361 (noting that patients who were HIV-positive but who did not yet have AIDS would not enroll in clinical trials of AZT in the later 1980s because they were

early access, as they may want to avoid the risk of being randomized to the control group.¹⁵⁶ Interfering with enrollment could slow—or even prevent—the medicine’s progress to market. This will delay or prevent access for future patients, unless those patients also proceed through early access—at which point the premarket approval requirement would become a sham. Slowing the trials not only delays approval for future patients, but also delays the production of robust evidence on which to base treatment decisions.¹⁵⁷ Doctors and patients relying on expanded success during the delay base these decisions on poorer quality evidence.¹⁵⁸

The French and U.S. schemes address these concerns in three ways, although they differ in the specifics.

First, neither regulator permits early access unless the arrangement will not threaten the completion of trials designed to support approval of the medicine. FDA requires that in all cases of expanded access the agency first find that the proposed use “will not interfere with the initiation, conduct, or completion of clinical trials that could support . . . approval.”¹⁵⁹ An ATU in France may not interfere with the trials that would provide “essential, accurate answers” to questions about the medicine’s benefit-risk ratio.¹⁶⁰

Second, they partially restrict access to the programs. Limiting an early access program to patients ineligible for clinical trials prevents the program from cannibalizing the pool of potential trial participants. But views on this vary. On the one hand, some suggest equity supports providing early access programs to trial-

otherwise able to obtain AZT and feared placebo in the trial).

156. Although officials at FDA prefer a placebo control where ethically permissible, in the case of a serious illness patients in a control arm will receive available treatment as a control. Generally controlled trials are viewed as ethical if there is equipoise, meaning genuine uncertainty regarding the comparative therapeutic merits of each arm. Benjamin Freedman, *Equipoise and the Ethics of Clinical Research*, 317 NEW ENG. J. MED. 141 (1987). Patients may nevertheless decline to enroll due to concerns about receiving an active control rather than the experimental medicine. Menikoff, *supra* note 153, at 1063 (2008) (noting concerns about early access programs affecting enrollment because patients fear randomization); Leonard, *supra* note 21, at 1361.

157. Vinay Prasad & Vance Berger, *Hard-Wired Bias: How Even Double-Blind Randomized Controlled Trials Can Be Skewed from the Start*, 90 MAYO CLINIC PROC. 1171, 1171 (2015) (“Well-designed, adequately powered randomized controlled trials . . . are rightfully considered the highest form of evidence on which to base treatment and diagnostic decisions, minimizing potential biases, particularly confounding, that plague nonrandomized of evidence.”).

158. Consider the example of high-dose chemotherapy followed by autologous bone marrow transplant, which was under investigation for treatment of breast cancer. Patients had access to the treatment while the trial was underway, not because of an early access program but because FDA had already approved the chemotherapy agent for another use. This led to low enrollment in the trials, which delayed the eventual finding that the procedure offered no benefit over less risky alternatives. Shah & Zettler, *supra* note 21, at 178–79; see also Dresser, *supra* note 21, at 1650.

159. 21 C.F.R. § 312.305(a)(3) (2020).

160. ATU NOTICE, *supra* note 112, at § 1.1.

ineligible patients, because these patients are denied access to trials through no fault of their own.¹⁶¹ Some add that, essentially for utilitarian reasons, regulators must deny early access to patients who could enroll in clinical trials.¹⁶² On the other hand, some have argued that controlled trials are inherently coercive and thus ethical only if trial-eligible patients may obtain access outside the trials.¹⁶³ And sometimes requiring that patients be ineligible for trials is a sham, because eligible patients can render themselves ineligible.¹⁶⁴ This second, more expansive view, that early access should be open to all, has not prevailed, perhaps because it risks compromising a medicine's progress to market. Some have also pointed out that opening early access schemes to all patients can raise equity issues if patients with greater resources choose early access to avoid the risks of randomization.¹⁶⁵ Both regulators limit single-patient access to trial-ineligible patients. In the United States, single patients are eligible for early access only if they cannot obtain the drugs in clinical trials.¹⁶⁶ The ANSM will issue an ATU for a single patient only if that patient cannot participate in a clinical trial.¹⁶⁷ For intermediate-size patient groups, FDA will also entertain arguments that the patients are theoretically trial-eligible but *unable* to enroll (for instance, because of geographic proximity to trial sites and lack of resources, over which they have little control).¹⁶⁸ Widespread early access in both countries is available for patients with the disease that the company is studying in controlled trials for marketing approval.¹⁶⁹

Third, the regulators mitigate the effect of early access on progress to approval by limiting these arrangements to drugs that are nearly finished with premarket research and development. French law embraces this solution more than U.S. law does. The ANSM will not approve a cohort ATU unless the medicine is the subject of a pending or imminent marketing application.¹⁷⁰ In contrast, widespread use under a treatment IND or treatment protocol in the United States usually requires ongoing or completed controlled clinical trials, but can be based on more

161. Raus, *supra* note 20, at 3 (describing the argument).

162. *E.g.*, Falit & Gross, *supra* note 148, at 2794 (arguing that “authorities must deny access to experimental drugs for patients who are eligible for clinical trials” and “individuals should be adequately deterred from gaming the system by, for instance, initiating therapy with an alternative compound that renders them ineligible for a study”).

163. Schüklenk & Lowry, *supra* note 20, at 20 (noting argument).

164. Walker, *supra* note 20, at 11.

165. *Cf.*, Schüklenk & Lowry, *supra* note 20, at 8 (noting argument that it is coercive to require the terminally ill to risk randomization for the sake of future patients).

166. 21 C.F.R. § 312.310(a)(2) (2020).

167. ATU NOTICE, *supra* note 112, at § 1.1.

168. 21 C.F.R. § 312.515(a) (2020); *see* Carrieri, Peccatori & Boniolo, *supra* note 20, at 66 (suggesting an ethical argument for access in this situation).

169. 21 CFR 312.320(a)(1)(i) (2020); ATU NOTICE, *supra* note 112, at § 6.1.

170. Regulation 726/2004, *supra* note 22, at art. 83.

preliminary data in appropriate situations.¹⁷¹ For individuals, both regulators will permit access well before phase 3 trials, and FDA will do so even based only on animal testing.¹⁷² And, again, in the United States, an “intermediate-size” group can benefit from early access even if the medicine is not being developed at all.¹⁷³ This is impossible in France.

Limiting early access schemes to patients who are ineligible for trials, or to drugs that are nearing premarket approval, is hard to square with autonomy arguments. These limitations reflect instead the influence of utilitarian arguments that the public’s interest in the development of high-quality evidence for proposed new medicines outweighs any individual interests in earlier access.¹⁷⁴ The U.S. expanded access scheme is less limited in these respects than the French ATU scheme, perhaps reflecting greater policymaking deference to autonomy arguments. In the end, though, FDA will still refuse access if it will interfere with trials that could support approval.

Some suggest that the effect of early access on the public’s interest can be partially mitigated by the collection of evidence from early access arrangements, which can inform the regulator’s understanding of the medicine, for the benefit of other patients. Although views vary on the ethics of using data from early access for research,¹⁷⁵ both schemes require the collection and submission of data. When an individual patient receives expanded access in the United States, either the treating doctor or the company must send FDA a written summary of the results.¹⁷⁶

171. 21 C.F.R. § 312.320(a)(1) (2020); 21 C.F.R. § 312.320(a)(2) (2020).

172. Expanded Access to Investigational Drugs for Treatment Use, 71 Fed. Reg. 75,147, 75,151. For example, in 2019 a 25-year-old woman from Iowa received an experimental antisense oligonucleotide (ASO) targeted at the gene mutation responsible for her rare form of amyotrophic lateral sclerosis (ALS). The company developing the ASO had completed *in vitro* and animal testing, but no trials in humans. Fiore, *supra* note 153; Stella Daskalakis, *Jaci Hermstad Receives Seventh ASO Infusion as her Mother Honors Her in New York*, KTIV.COM (Oct. 23, 2019), <https://ktiv.com/2019/10/23/jaci-hermstad-receives-seventh-aso-infusion-as-her-mother-honors-her-in-new-york/> [<https://perma.cc/NA7M-QFAA>].

173. 21 C.F.R. § 312.315(a)(1) (2020). It is unclear whether expanded access has ever been provided on this basis. Expanded access is also available if the drug is approved but no longer marketed, or if the drug contains the same active moiety as an approved but unavailable drug. *Id.* at (a)(3).

174. Leonard, *supra* note 21, at 1343–44; Carrieri, Peccatori & Boniolo, *supra* note 20, at 68 (noting that early access has “direct negative implications for [randomized clinical trials] and general public health interests”). Permitting earlier access for the subset of the population with serious conditions, as both regulators do, also arguably increases overall utility, because this group has a different risk-benefit tradeoff than does the population at large.

175. Walker, *supra* note 20, at 11–12 (reasoning that early access programs might be ethical if they contribute to our understanding of the experimental medicines in question); *but see* Bunnik, Aarts & van de Vathorst, *Little to Lose*, *supra* note 20, at 981 (noting disagreement about whether it is morally acceptable to collect research data within expanded access programs).

176. 21 C.F.R. § 312.310(c)(2) (2020).

Adverse events must be reported to the agency,¹⁷⁷ and the safety data must be included in any marketing application submitted.¹⁷⁸ Safety data from expanded access could even support the approval decision.¹⁷⁹ The effectiveness data from expanded access, however, are lower in quality than effectiveness data from randomized controlled trials, and they might not support—let alone justify—a finding of effectiveness under the U.S. drug statute.¹⁸⁰ In France, patient monitoring and data collection under an ATU are governed by a protocol for therapeutic use and information collection, drawn up by the company and the ANSM.¹⁸¹ The company also has adverse event reporting obligations.¹⁸² And with a cohort ATU, the ANSM receives information about the characteristics of the patients, the effectiveness of the medicine, and adverse events resulting from its use.¹⁸³ The company must analyze the medicine’s benefit-risk ratio in light of this information.¹⁸⁴

III. THE RIGHT-TO-TRY ALTERNATIVE IN THE UNITED STATES

Expanded access in the United States and ATU in France are broadly consistent with the approach and goals of the new medicine approval paradigm. They similarly assume that a scientific agency should serve as the gatekeeper—here, deciding whether a particular patient (or group of patients) may access a

177. 21 C.F.R. § 312.305(c)(4) (2020).

178. 21 C.F.R. § 314.50(d)(5)(iv) (2020) (requiring that an application include a “description and analysis of any other data or information relevant to an evaluation of the safety and effectiveness of the drug product obtained or otherwise received by the applicant from any source, foreign or domestic”).

179. Approval of Epidiolex (cannabidiol) in 2018 was supported in part by safety data from nearly 700 patients who received the product through expanded access. Sean M. O’Connor & Erika Lietzan, *The Surprising Reach of FDA Regulation of Cannabis, Even After Descheduling*, 68 AM. U. L. REV. 823, 917–18 (2018). See also Kate Rawson, *Expanded Access Data Can Support Approval Decisions*, FDA Says, PINK SHEET (Nov. 21, 2018), <https://pink.pharmaintelligence.informa.com/PS124296/Expanded-Access-Data-Can-Support-Approval-Decisions-US-FDA-Says> (citing other examples).

180. Expanded Access to Investigational Drugs for Treatment Use, 74 Fed. Reg. 40,900, 40,905 (Aug. 13, 2009) (“Because expanded access programs are typically uncontrolled exposure (with limited data collection), it is very unlikely that an expanded access IND would yield effectiveness information that would be useful to FDA in considering a drug’s effectiveness.”); Jan Borysowski, Hans-Jörg Ehni & Andrzej Górski, *Ethics Review in Compassionate Use*, 15 BMC MED., Jul. 24, 2017, at 3 (“Indeed, the value of data collected during the conduct of compassionate use is limited, especially compared to that of randomized controlled trials, the contemporary gold standard of drug efficacy and safety studies”).

181. CODE DE LA SANTÉ PUBLIQUE [PUBLIC HEALTH CODE] art. R.5121-70; ATU NOTICE, *supra* note 112, at § 1.1.

182. ATU NOTICE, *supra* note 112, at § 7.2.2.1, CODE DE LA SANTÉ PUBLIQUE [PUBLIC HEALTH CODE] art. R.5121-166.

183. ATU NOTICE, *supra* note 112, at § 6.2.

184. *Id.* at § 6.9.

medicine. And their design reflects the premise that the paramount goal of a medicine regulatory system remains the generation of high-quality evidence to support a scientific decision on approval for the market. In 2018, the U.S. Congress passed a law taking a fundamentally different approach.¹⁸⁵ The right-to-try law permits access to unapproved medicines without the prior involvement of FDA, rejecting the premarket review mechanism that has characterized new medicines frameworks since the mid-twentieth century in favor of limited *post hoc* enforcement power.

A. Elimination of the Gatekeeper

Congress added a new section to the U.S. drug statute, exempting certain drugs provided to certain patients from the gatekeeping provisions of that statute and from FDA’s regulations implementing those provisions. The patient must be diagnosed with a life-threatening disease or condition—generally meaning the likelihood of death is high unless the course of disease is interrupted.¹⁸⁶ (In contrast, expanded access is available when the disease is “serious or immediately life-threatening,” which is broader, because “serious” diseases are included.¹⁸⁷) The patient must have exhausted approved treatment options and must be unable to participate in a clinical trial involving the drug.¹⁸⁸ The drug itself must be the subject of a pending marketing application or a clinical trial intended to form the primary basis of a claim of effectiveness in an application, and it must have completed phase 1 trials.¹⁸⁹ (In contrast, FDA can authorize expanded access at any time during premarket trials, including phase 1 trials, or even earlier.¹⁹⁰) If all these criteria are met, the drug may be provided to the patient.

The federal government does not play a role in determining whether these conditions are met. Neither the company nor the doctor seeks permission from FDA.¹⁹¹ If anyone (apart from the company) plays a gatekeeping role, it is state-licensed doctors. However, FDA must have already given permission for the phase 1 trials, and this limits the pool of permitted compounds to those that the government has deemed safe enough to test in humans. But a patient exercising

185. Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act, Pub. L. No. 115-176, 132 Stat. 1372 (2018) (largely codified at 21 U.S.C. § 360bbb-0a).

186. 21 U.S.C. § 360bbb-0a(a)(1)(A) (2018) (referring to the definition of “life threatening” that appears in 21 C.F.R. § 312.81)). A disease is also life-threatening if it has a potentially fatal outcome and the endpoint for preapproval clinical trials is (or in this case, would be) overall survival. 21 C.F.R. § 312.81(a)(2) (2020).

187. *See supra* Section 0. A disease is considered serious if it is associated with morbidity that has a substantial impact on day-to-day functioning. 21 C.F.R. § 312.300(b) (2020).

188. 21 U.S.C. § 360bbb-0a(a)(1)(B) (2018).

189. 21 U.S.C. § 360bbb-0a(a)(2) (2018).

190. *See supra* Section 0.

191. 21 U.S.C. § 360bbb-0a(b) (2018) (exempting eligible drugs from 21 C.F.R. pt. 312).

the “right to try” does not need to ask the government’s permission. Instead, before the drug can be provided to the patient, a physician in good standing with the appropriate licensing board must determine that the patient has exhausted approved treatment options and cannot participate in a clinical trial. (In contrast, in expanded access situations, FDA makes this determination.¹⁹²) The right-to-try law specifies no actor to enforce the other two threshold eligibility requirements—that the patient’s disease is life-threatening, and that the patient provided informed consent. (In contrast, in expanded access, FDA determines whether the patient’s disease qualifies, holds the investigator responsible for securing informed consent, and requires ethics committee review.¹⁹³)

FDA’s role here is, at best, after the fact. The agency would have to learn of the procedure in the first instance and then, believing that the patient had not provided informed consent or did not suffer from a life-threatening disease, claim that the patient had not been eligible for right-to-try access. If either is true, the drug was *not* exempt from FDA’s gatekeeping authorities, and FDA could take enforcement action. (It would charge the company with introduction of a new drug into interstate commerce without an approved marketing application or effective IND.¹⁹⁴) But the agency will not learn about right-to-try treatments until the company’s annual summary of right-to-try uses, and the statute does not require those summaries to identify investigators or patients.¹⁹⁵ Even if the agency knew each patient’s identity, it is not clear how FDA could conclude that a patient did not provide informed consent, because the law also says that FDA’s regulations on the protection of human subjects, including the informed consent requirements, do not apply.¹⁹⁶ Presumably FDA would have to find that the relevant state law standard was met, but a court would not defer to its interpretation of that state law. So, these limitations may turn out to be a sham.¹⁹⁷

192. 21 C.F.R. § 312.305(a)(1) (2020) (“FDA must determine that . . . there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition”).

193. *E.g.*, 21 C.F.R. § 312.305(a)(1) (2020) (“FDA must determine that the patient or patients to be treated have a serious or immediately life-threatening disease or condition . . .”); 21 C.F.R. § 312.305(c)(4) (2020) (holding the investigator responsible for ensuring informed consent).

194. 21 U.S.C. § 355(a) (2018).

195. FDA plans to issue regulations implementing the annual summary requirement. Michael Cipriano, *Expanded Access Program Improving, But Sponsor Concerns Linger*, PINK SHEET (Sept. 10, 2019), <https://pink.pharmaintelligence.informa.com/PS140818/Expanded-Access-Program-Improving-But-Sponsor-Concerns-Linger>; *OMB Reviewing FDA Proposal for Right to Try Reporting Requirements*, FDA WEEK (Apr. 3, 2020).

196. FDA’s regulations requiring institutional review board (ethics committee) review also do not apply. 21 U.S.C. § 360bbb-0a(b) (2018).

197. To be fair, state law will usually impose its own informed consent obligation on treating doctors. And it may require that access proceed through the same kind of ethics review as FDA would have required. *See* Jeannie Baumann, *Experimental Drug Requests Rising Faster Than Previously Thought*, BLOOMBERG LAW (Nov. 18, 2019), <https://news.bloomberglaw.com/pharma-and-life-sciences/experimental-drug-requests-rising-faster-than-previously-thought> (noting California law

The right-to-try law also strips FDA of its ability to impose conditions on access.¹⁹⁸ For example, in ordinary expanded access situations, the sponsor of the trial (usually the drug company) must notify FDA of any serious and unexpected adverse reaction within 15 days.¹⁹⁹ It also notifies investigators working with the drug. These rules do not apply to drugs made available under right-to-try. The right-to-try law does require each company's annual summary to identify "any known serious adverse events,"²⁰⁰ but FDA's detailed adverse event rules do not apply,²⁰¹ and agency officials believe the data in these annual summaries will be of low quality.²⁰² FDA's rules relating to maintaining control of the investigational medicine also do not apply,²⁰³ nor do its recordkeeping rules.²⁰⁴ And the agency has no power to call a halt to the process when patients are subject to unreasonable risk of injury or when the doctors lack the training and experience necessary to administer the drug.²⁰⁵

Only three FDA regulations relating to investigational medicines still apply: a regulation governing labeling,²⁰⁶ a regulation prohibiting promotion,²⁰⁷ and the regulation limiting how much the company can charge (only the direct costs of making the medicine available).²⁰⁸ And the agency will have to enforce these rules

requires that an institutional review board review each access request).

198. 21 U.S.C. § 360bbb-0a(b) (2018) (exempting eligible drugs from sections 502(f), 503(b)(4), 505(a), and 505(i) of the Federal Food, Drug, and Cosmetic Act as well as section 351(a) of the Public Health Service Act, and parts 50, 56, and 312 of title 21 of the Code of Federal Regulations).

199. 21 C.F.R. § 312.32(c) (2020).

200. 21 U.S.C. § 360bbb-0a(d)(1) (2018).

201. *See* 21 C.F.R. § 312.32 (2020) (ordinary adverse event reporting framework, which does not apply).

202. Derrick Gingery, *Unlicensed Stem Cell Clinics are 'Surrogate' for Right to Try, USFDA's Marks Says*, PINK SHEET (Nov. 21, 2018), <https://pink.pharmaintelligence.informa.com/PS124294/Unlicensed-Stem-Cell-Clinics-Are-Surrogate-For-Right-To-Try-US-FDAs-Marks-Says>.

203. *Compare* 21 C.F.R. § 312.61 (2020) ("The investigator shall not supply the investigational drug to any person not authorized under this part to receive it."), *with* 21 U.S.C. § 360bbb-0a(b) (2018).

204. *Compare* 21 C.F.R. § 312.62(a) (2020) ("An investigator is required to maintain adequate records of the disposition of the drug, including dates, quantity, and use by subjects. If the investigation is terminated, suspended, discontinued, or completed, the investigator shall return the unused supplies of the drug to the sponsor, or otherwise provide for disposition of the unused supplies of the drug"), *with* 21 U.S.C. § 360bbb-0a(b) (2018).

205. *Compare* 21 C.F.R. § 312.42(b)(1) (2020), *with* 21 U.S.C. § 360bbb-0a(b) (2018).

206. 21 C.F.R. § 312.6 (2020). This requires that (1) the package label state the drug is limited to investigational use, and (2) the label and labeling not bear any false or misleading statement and not represent that the drug is safe and effective for the purpose for which it is being investigated.

207. 21 C.F.R. § 312.7 (2020). This prohibits (1) representing in a promotional context that the drug is safe and effective for the purpose for which it is being investigated, (2) commercial distribution of the drug, and (3) "unduly" prolonging the investigation after generating sufficient data to support approval.

208. 21 C.F.R. § 312.8(d)(1) (2020). There is confusion on this point. *E.g.*, Adam Feuerstein,

after the fact, when it receives the company's annual summary.

The drug industry did not support the law.²⁰⁹ The law subverts an eighty-year-old approach to medicine regulation, and its underpinnings may be deeply uncomfortable for the scientific and regulatory personnel at larger companies that operate within, understand, and agree with the basic approach to medicines regulation in this country.²¹⁰ Representatives of the Goldwater Institute insist that the scheme is being used,²¹¹ but speakers at a recent conference could identify only one company using the “right to try.”²¹² Many companies have said they will

Here comes the right-to-try profiteers: The FDA is powerless to stop them, STAT NEWS (June 20, 2018), <https://www.statnews.com/2018/06/20/right-to-try-opportunism> [<https://perma.cc/8NH2-TUDK>] (stating that medicines can be sold “at a profit” and quoting one CEO who was considering charging \$300,000 per treatment).

209. See Stephen Barlas, “Right-To-Try” Legislation Moving Through Congress, But Drug Companies and Some Patient Groups Want Changes, 42 PHARMACY & THERAPEUTICS 739, 739 (2017) (“The Biotechnology Innovation Organization (BIO), the trade group that represents many smaller biopharmaceutical companies, especially those involved in biologics, also opposes the bill.”); *id.* at 741 (“Research pharmaceutical companies are not enthusiastic about the bill.”); *Early Access Programs: Points to Consider*, BIO 2–4 (Apr. 16, 2010), <https://www.bio.org/sites/default/files/legacy/bioorg/docs/files/20100416.pdf> [<https://perma.cc/4PVJ-LCQY>] (“A patient’s right to treatment based on his or her autonomous decision-making ability does not supersede a company’s ethical responsibility to develop and market safe and effective products as fast as possible In some circumstances, . . . by allowing early access, the company risks market approval of the product. Thus, the question often confronting companies is whether to put an entire project at risk – and therefore jeopardize availability of a drug for a larger patient population – in order to provide early access to a product for an individual or small group of patients.”)

[https://perma.cc/4PVJ-LCQY] (“A patient’s right to treatment based on his or her autonomous decision-making ability does not supersede a company’s ethical responsibility to develop and market safe and effective products as fast as possible In some circumstances, . . . by allowing early access, the company risks market approval of the product. Thus, the question often confronting companies is whether to put an entire project at risk – and therefore jeopardize availability of a drug for a larger patient population – in order to provide early access to a product for an individual or small group of patients.”)

210. Criticism of the state right-to-try laws and the federal proposal was robust. Rebecca Dresser, “Right to Try” Laws: The Gap between Experts and Advocates, 45 HASTINGS CTR. REP. 9, 9 (2015) (“Scientists and policy experts are virtually unanimous in criticizing right to try laws.”); Christopher Morrison, *Critics Say “Right to Try” Wrong for Patients*, 36 NATURE BIOTECHNOLOGY 294, 294 (2018) (noting the opposition of “a diverse group” of critics including “many patient advocacy groups, the biotech industry, and FDA officials”).

211. Michael Cipriano, *Right to Try Conversation Should be Redirected Toward Reimbursement of Unapproved Drugs, Experts Say*, PINK SHEET (Jan. 29, 2019), <https://pink.pharmaintelligence.informa.com/PS124659/Right-To-Try-Conversation-Should-Be-Redirected-Toward-Reimbursement-Of-Unapproved-Drugs-Experts-Say> (quoting Goldwater representative that companies are using it).

212. Sue Sutter, *Expanded Access Advocates Seek Reimbursement Mandate, Manufacturer Incentives from Congress*, PINK SHEET (Feb. 11, 2020), <https://pink.pharmaintelligence.informa.com/PS141654/Expanded-Access-Advocates-Seek-Reimbursement-Mandate-Manufacturer-Incentives-From-Congress> (noting that “Epitopoietic Research Corporation has approved 10 requests for access to Gliovac (ERC1671), a cell-based immunotherapy for glioblastoma multiforma and gliosarcoma,” under a right-to-try program). See also *ERC-USA Initiates Therapy Under Right to Try Law with First Patient in California Using Investigational Compound ERC1671 for Treatment of Glioblastoma*, GLOBENEWSWIRE (Jan. 8, 2019), <https://www.globenewswire.com/news-release/2019/01/08/1682156/0/en/ERC-USA-Initiates-Therapy-Under-Right-to-Try-Law-With-First-Patient-In-California-Using-Investigational-Compound-ERC1671-for-Treatment-of-Glioblastoma.html> [<https://perma.cc/U8ZF-ND4F>]

continue to provide experimental medicines under traditional expanded access programs or simply focus on seeking approval.²¹³

B. Explaining the Enactment of Right-to-Try in the United States

The right-to-try mechanism differs conceptually from the early access mechanisms in the United States and France. The early access mechanisms assume that generating high-quality phase 3 data and securing regulatory approval remain paramount goals, and thus retained the regulator’s gatekeeping role. Proponents of the right-to-try law explicitly rejected this utilitarianism, saying that “the most troubling argument in favor of the FDA’s veto power is that the agency is always mindful of the effect expanded access may have on the clinical-trial process.”²¹⁴ Its legislative sponsors openly explained that the law was meant to reduce FDA’s power and, instead, empower patients to choose potentially life-saving therapies.²¹⁵ These arguments suggest that enactment of the right-to-try law in the United States can be explained by three things.

First, the United States has a robust history and tradition of valuing personal autonomy, including autonomy in personal medical decisions. Proponents of the “right to try” invoked this tradition, putting forward arguments that found their roots in the writing of John Stuart Mill and Gerald Dworkin—that the state may interfere with the choices of an autonomous individual only to prevent harm to others.²¹⁶ The individual, they argued, has a moral right—perhaps a constitutional right, some argued²¹⁷—to try to save his or her own life. Further, the state cannot

213. Derrick Gingery, *Unlicensed Stem Cell Clinics*, *supra* note 202 (noting that Johnson & Johnson has declined to use right-to-try and that Brainstorm Cell Therapeutics, developing Nurown for ALS, announced in June 2018 that it would use right-to-try and then changed its mind); Sue Sutter, *Why The Right-to-Try Law is Not Right for Some Biotech Companies*, PINK SHEET (June 13, 2018), <https://pink.pharmaintelligence.informa.com/PS123274/Why-The-RightToTry-Law-Is-Not-Right-For-Some-Biotech-Companies> (noting that Alnylam and Sarepta said they would not use it because they are focusing on approval).

214. Corieri, *supra* note 16, at 16.

215. Letter from Sen. Ron Johnson, Chairman, Senate Committee on Homeland Security and Governmental Affairs, to Scott Gottlieb, Comm’r, FDA (May 31, 2018), <https://www.hsgac.senate.gov/media/majority-media/johnson-to-fda-agency-should-comply-with-right-to-try-law> [<https://perma.cc/Q3T8-BVJ9>] (“[T]his legislation is fundamentally about empowering patients to make decisions in cooperation with their doctors and the developers of potentially life-saving therapies . . . [and it] intends to diminish the FDA’s power over people’s lives, not increase it.”).

216. Corieri, *supra* note 16, at 21–22; *see also* Bruce J. Winick, *On Autonomy: Legal and Psychological Perspectives*, 37 VILL. L. REV. 1705, 1712 (1992) (discussing John Stuart Mill’s “harm principle,” that “the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others” in the context of various healthcare decisions); *see generally* JESSICA FLANIGAN, PHARMACEUTICAL FREEDOM: WHY PATIENTS HAVE A RIGHT TO SELF-MEDICATE (2017).

217. *E.g.*, Volokh, *supra* note 21, at 1829–30; Corieri, *supra* note 16, at 21.

“reasonably demand” to decide what risks an informed and competent individual may take when facing death.²¹⁸ Respect for personal autonomy means leaving this decision to the patient. In the United States, the strong consumer empowerment movement and a political-legal commitment to the unencumbered flow of information acclimated patients to a high degree of involvement in their healthcare decisions. This aligns with the U.S. emphasis on personal autonomy and provided fertile ground for the right-to-try movement.²¹⁹

Second, many in the United States favor a reduced role for government, especially the federal regulatory apparatus. Two strands of thinking are at play here. To begin with, the federalist system of governance generally reserves to the states matters relating to medicine and health.²²⁰ This leads to skepticism about, and hostility towards, a federal agency intervening when a state-regulated doctor decides the best course forward for a patient. The state right-to-try laws trace their lineage to laws enacted forty years ago, when patients—frustrated with FDA’s failure to approve Laetrile for the treatment of cancer—persuaded the states to legalize its sale within their borders.²²¹ There is also a robust deregulatory movement in the United States only tangentially related, if at all, to state’s rights. Thirty years ago during the AIDS crisis, some were prepared to repeal the effectiveness standard or even eliminate FDA’s gatekeeping role altogether.²²² Patient groups were divided over the ultimate objective: some merely sought early access but embraced the goal of full approval under the approval standard, while others focused on, as one scholar recently put it, getting “drugs into bodies.”²²³ In the 1990s, the latter groups found common cause with deregulatory forces. The same thing happened with the right-to-try initiative, the origins of which lie with the Goldwater Institute, a conservative and libertarian public policy think tank in Arizona. This organization drafted a model right-to-try law in February 2014, which it then distributed to the states.²²⁴ A majority of states passed right-to-try laws in the years that followed.²²⁵ The proliferation of state laws snubbing the

218. Schüklenk & Lowry, *supra* note 20, at 11 (describing the argument).

219. The law passed with a “sense of the senate” provision stating that the law “expands the scope of individual liberty and agency among patients.” Pub. L. No. 115-176 § 3, 132 Stat. 1372 (2018).

220. Patricia J. Zettler, *Pharmaceutical Federalism*, 92 IND. L. J. 845 (2018).

221. Grossman, *AIDS Activists*, *supra* note 59, at 693.

222. *Id.* at 712.

223. *Id.* at 706.

224. Zettler & Greely, *Strange Allure*, *supra* note 21, at 1885.

225. The state laws varied somewhat in their details. Most state laws authorized doctors to prescribe—and companies to provide and charge for—investigational medicines that had completed phase I trials. Some also provided the doctor and company with protection from liability arising from the injury. *E.g.*, 2015 OR. LAWS ch. 819 (codified at OR. REV. STAT. § 127.990 (2019)). Despite these state laws, federal law continued to prohibit the shipment of unapproved medicines across state lines to patients. 21 U.S.C. § 355(a) (2018). Some supported the federal right-to-try legislation for this

federal government eventually provided the catalyst for the federal law.²²⁶ Enactment of the right-to-try law thus reflects an alignment between patients' rights groups and deregulatory libertarians, the seeds of which had been planted during the Reagan Administration. Like AIDS advocates in the 1990s who were presented with proposals to dismantle FDA, patients eventually realized that the right-to-try proposal was not in their interests; it was mainly an attack on FDA regulatory power and was not designed—or, as explained in the next Section, likely—to increase their access to unapproved drugs.²²⁷ But by then it was too late.

Third, healthcare delivery in the United States is colored by widespread fear, and even denial, of mortality. Popular culture venerates youthfulness and vigor, while respectful representations of the elderly and dying are virtually absent.²²⁸ Patients and their caregivers are slow to discuss palliative care and slower still to seek hospice.²²⁹ Physicians are often reluctant to begin end-of-life care discussions with their patients.²³⁰ Discussions of terminal illness are cast in metaphors of war, and death itself characterized as “loss” of a “battle”—creating a sense of failure in

reason: to give effect to the clear policy preference of the states. *E.g.*, Ellen A. Black, *State “Right to Try” Acts: A Good Start, but a Federal Act is Necessary*, 45 SW. L. REV. 719, 755 (2016) (arguing that “a federal right to try act, such as the Right to Try Act of 2015, is necessary to enable the implementation of state right to try acts”).

226. This pattern is not uncommon. *See* Diane R. H. Winters, *The Benefits of Regulatory Friction in Shaping Policy*, 71 FOOD & DRUG L. J. 228 (2016) (discussing other examples).

227. Carrieri, Peccatori & Boniolo, *supra* note 20, at 67 (noting that “[right to try] laws appear to be a largely symbolic attack to the governmental authority of the FDA, masked by libertarian ethos of conferring more rights to patients”); Barlas, *supra* note 209, at 741 (noting that the bill was “presented as a boon to terminally ill individuals” but was in fact “opposed by so many groups representing them”).

228. Kirk Combe & Kenneth Schmader, *Naturalized Myths of Aging: Reading Popular Culture*, 4 J. AGING & IDENTITY 79 (1999) (concluding that “the majority of Americans have generally negative attitudes towards elders and the aging process,” and that the “ageism” that “permeates our culture” is in large part due to popular culture’s impact on common opinion); *see, e.g.*, Stacy L. Smith, Marc Choueiti & Katherine Pieper, *Over Sixty, Underestimated: A Look at Aging on the Silver Screen in Best Picture Nominated Films*, USC ANNENBERG SCH. FOR COMM’N & JOURNALISM (Feb. 2017), https://www.annenberg.usc.edu/sites/default/files/Over_Sixty_Underestimated_Report_2_14_17_Final.pdf [<https://perma.cc/U77K-G5XD>] (finding that seniors are “scarce” in films and finding a prevalence of negative verbal and nonverbal references to age).

229. *E.g.*, Lisa Jane Brighton & Katherine Bristowe, *Communication in Palliative Care: Talking about the End of Life, Before the End of Life*, 92 POSTGRADUATE MED. J. 466 (2016); Aline Sarraon-Eck et al., *Understanding the Barriers to Introducing Early Palliative Care for Patients with Advanced Cancer: A Qualitative Study*, 22 J. PALL. MED. 508 (2019).

230. Kay Manning, *Doctors Slow to Have End-of-Life Conversations*, CHI. TRIB. (Dec. 6, 2016), <https://www.chicagotribune.com/lifestyles/health/sc-end-of-life-health-1207-20161205-story.html> [<https://perma.cc/V5ZM-QXDX9>]; Barbara Feder Ostrov, *Most Doctors Unsure How to Discuss End-of-Life Care, Survey Says*, KAISER HEALTH NEWS (Apr. 14, 2016), <https://khn.org/news/most-doctors-unsure-how-to-discuss-end-of-life-care-survey-says> [<https://perma.cc/S2AL-B7EB>]; Mieke Visser, Luke Deliens & Dirk Houttekier, *Physician-Related Barriers to Communication and Patient- and Family-Centered Decision-Making Towards the End of Life in Intensive Care: A Systemic Review*, 18 CRITICAL CARE 604 (2014).

death and a corresponding sense of obligation to fight.²³¹ This fuels not only an immense body of research focusing on longevity, but also a powerful technological imperative—to save life at any cost, to exhaust all possibilities that medical science has to offer.²³² This aligns with a powerful norm in the United States: the duty to seek to rescue.²³³ Together, these factors create fertile ground for a law that appears to give more options to the desperately ill.

In contrast, two aspects of the French legal and cultural landscape make the “right to try” an unlikely fit.

First, the French healthcare system remains paternalistic. The law only recently recognized the patient’s right to information about his or her own health.²³⁴ Patients have less access to information about medical products than in the United States and fewer options to purchase medical products without the involvement of a healthcare professional. There is no direct-to-consumer advertising of prescription drugs in France.²³⁵ Under the “monopole officinal,” only authorized pharmacies may sell medicines. No medicines are sold over the counter in the sense that they are sold in the United States—freely at a gas station or in a grocery store, without the involvement of a pharmacist.²³⁶ And although each country has responded to drug safety tragedies by giving its medicines regulator more power, the French response—to crises from the Stalinon affair in

231. *E.g.*, Carrieri, Peccatori & Boniolo, *supra* note 20, at 68 (noting U.S. “social norms and expectations of maintaining a ‘fighting spirit’”).

232. *E.g.*, Malinowski, *supra* note 21, at 632 (noting the “compulsion to exhaust all medical science resources”).

233. Caplan & Moch, *Rescue Me*, *supra* note 20.

234. *See supra* note 82 (discussing the 2002 Patients’ Rights Law).

235. Only the United States and New Zealand permit direct-to-consumer advertising of prescription drugs that includes a description of the uses of the products. C. Lee Ventola, *Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic*, 36 PHARMACY & THERAPEUTICS 669 (2011).

236. *But see* AUTORITÉ DE LA CONCURRENCE, AVIS N° 19-A-08 DU 4 AVRIL 2019 RELATIF AUX SECTEURS DE LA DISTRIBUTION DU MÉDICAMENT EN VILLE ET DE LA BIOLOGIE MÉDICALE PRIVÉE 204–206 (Apr. 4, 2019), <https://www.autoritedelaconcurrence.fr/sites/default/files/2019-05/19a08.pdf> [<https://perma.cc/4D9G-EY2K>] (discussing reorganization of the pharmacy monopoly and recommending that certain health products be allowed for sale outside pharmacies); *French Health Minister Opposed to Selling Over-the-Counter Drugs in Supermarkets*, THE LOCAL (Apr. 5, 2019), <https://www.thelocal.fr/20190405/french-health-minister-opposed-to-selling-over-the-counter-drugs-in-supermarkets> [<https://perma.cc/KUP7-3R9C>] (noting that French antitrust authority wants to liberalize the monopole officinal and has recommended permitting sale of certain medicines, such as ibuprofen, at supermarkets).

the 1950s²³⁷ to the recent Mediator scandal²³⁸—has also included greater responsibilities for and elevation of the role of *pharmacists* through the lifecycle of drugs, from manufacture through delivery to patients.²³⁹ Although there has been a modest patient empowerment movement in France, medical paternalism—and with it a passive attitude of deference to doctors and pharmacists—still tends to trump patient autonomy arguments in French culture and law.

Second, French culture and law remain deeply committed to the notion of equality—in this context, equality of access, treatment, and outcome—tracing its roots to the principles of political equality that fueled the Revolution of 1789 and ideals of socioeconomic equality that took root in 1792 (which drove, for example, the abolition of the entire tax system of the Old Regime).²⁴⁰ This special tradition has played a powerful role in French politics and culture ever since. It counsels against laws and policies that might lead to differing results depending on socioeconomic status, including solutions that allow a patient's initiative and personal connections to provide treatment options others lack.²⁴¹ It also tends to lead to pro-regulatory sentiment, because regulation can serve the end of ensuring equality in treatment. Patients have a less aggressive sense of empowerment in France, and those who might want access for themselves without ANSM's involvement are less likely to find powerful allies interested in reducing the role

237. In this crisis, an anti-infective drug caused nearly 100 deaths and led to reexamination of the French system for drug safety monitoring. See generally Christian Bonah & Jean-Paul Gaudillière, *Faute, accident ou risque iatrogène? La régulation des événements indésirables du médicament à l'aune des affaires Stalinon et Distilbène*, 3 REVUE FRANÇAISE DES AFFAIRES SOCIALES 123 (2007) (describing the Stalinon affair and subsequent changes in French drug regulation).

238. Mediator (benfluorex) reached the market in 1976 as an adjunctive therapy for hyperlipidemia and diabetes with obesity. It was a fenfluramine, and the class was eventually associated with serious cardiovascular risks and generally withdrawn from the market, but Mediator remained on the market in Europe until 2009. The company marketing the drug, Servier, had argued that benfluorex was pharmacologically different from fenfluramine and dexfenfluramine. By 2009, French doctors had prescribed the drug off label for obesity for decades. Some believe the drug had caused as many as 2,000 deaths before its withdrawal, and an exhaustive report from the French Inspection Générale des Affaires Sociales (IGAS) blamed not only the company but also the regulator, the medical and scientific communities, and the regulatory framework. Asher Mullard, *Mediator Scandal Rocks French Medical Community*, 377 THE LANCET 890 (2011).

239. Mathieu Guerriaud, *Pharmacien responsable, une exception française au service de la sécurité de la sécurité du médicament*, in Mathieu Guerriaud, Clotilde Jourdain-Fortier & Isabelle Moine-Dupuis, *LE DROIT DES AFFAIRES PHARMACEUTIQUES, VERS LA CARACTÉRISATION D'UNE LEX PHARMACEUTICA* (LexisNexis, forthcoming).

240. See Christian Morrison & Wayne Snyder, *The Income Inequality of France in Historical Perspective*, 4 EUR. REV. ECON. HIST. 59, 70–76 (2000) (discussing changes in 1792 and trends towards greater income equality over time).

241. Changes made to French law in 2002 illustrate this. As noted *supra* note 82, historically, the liability of a private physician was governed by the Civil Code, while the liability of a physician in a public hospital was governed by public law. But under the Patients' Rights Law of 2002, all health liability issues are now governed by the Public Health Code, which ensures that patients are treated equally under the law.

of the regulatory state.

IV. INCREASING USE OF EXPANDED ACCESS IN THE UNITED STATES

Supporters of the right-to-try law said that it addressed two impediments to use of expanded access in the United States: (1) a burdensome regulatory framework that either precluded, or at least discouraged, expanded access arrangements, and (2) the failure of companies to participate in expanded access.²⁴² But the regulatory framework was not the problem. The new law does not permit access to any more drugs than FDA's expanded access regulations already do, and in some important respects it is narrower. Moreover, the agency rarely refuses requests for expanded access.²⁴³ In addition, as discussed below, the modest changes made to address company reluctance were probably insufficient. The right-to-try law is unlikely to increase use of unapproved medicines.²⁴⁴ If policymakers want to increase use of the expanded access regime, they will need to address the actual impediments to its use. This requires thinking about reasons companies do not provide access, reasons patients do not request expanded access, and reasons prescribers refuse to participate in access arrangements.

A. Addressing Barriers to Company Participation in Expanded Access

The primary problem has been that drug companies decline to provide requested drugs. Supporters of the right-to-try law tried to address this. To begin with, some companies may be concerned about products liability exposure arising out of adverse events during expanded access.²⁴⁵ Under the right-to-try law, a company faces no liability arising out of any act or omission with respect to medicine provided to patients.²⁴⁶ And some companies may be concerned adverse

242. See generally Corieri, *supra* note 16.

243. See *supra* note 109; see also U.S. Gov't Accountability Office, GAO-18-157T, Testimony Before the Subcommittee on Health, Committee on Energy and Commerce, House of Representatives: FDA's Expanded Access Program 1, 2 (Oct. 3, 2017) ("[O]f the nearly 5,800 expanded access requests that were submitted to FDA from fiscal year 2012 through 2015, FDA allowed 99 percent to proceed.").

244. E.g., Steven Joffe & Holly Fernandez Lynch, *Federal Right-to-Try Legislation—Threatening the FDA's Public Health Mission*, 378 NEW ENG. J. MED. 695, 696 (2018) (arguing that "the bill would probably have minimal effects . . . because it targets alleged barriers to early access that aren't actually rate-limiting"); Amy Kapczynski, *Dangerous Times: The FDA's Role in Information Production, Past and Future*, 102 MINN. L. REV. 2357, 2375–76 (2018) ("The law's provisions mainly target the FDA, despite the fact that the Agency has not been the main barrier to access. It will therefore likely do little to help patients.").

245. Shah & Zettler, *supra* note 21, at 182–83 (discussing company concerns about liability); see also Zettler, *Implications*, *supra* note 21, at 170 (suggesting "sponsors may face traditional tort liability if adverse events occur").

246. Pub. L. No. 115-176, § 2(b)(1), 132 Stat. 1372 (2018) (not codified).

outcomes will affect the medicine's labeling or approval, or even trigger an order to stop ongoing trials.²⁴⁷ The right-to-try law limits FDA's use of the data arising out of the patient's use of the medicine: the agency cannot use a clinical outcome from use under the right-to-try law to delay approval of the medicine unless the sponsor requests that use or the agency finds that using the clinical outcome is critical to determining the medicine's safety.²⁴⁸ The exception is essential from a public health perspective, but it also effectively nullifies the provision; if FDA needs to use the data, it can and will. Still, concerns about regulatory outcomes and liability exposure probably do not fully explain the reluctance of companies to participate in expanded access. Recent scholarship suggests that concerns about adverse regulatory outcomes and liability exposure are not well-founded.²⁴⁹ It is likely that at least the larger and more sophisticated companies knew this.

The real impediment to company participation in expanded access in the United States might be financial: there is a hypothetical risk of liability and no real financial upside to participation.²⁵⁰ Experimental drugs are not covered by private payers or government insurance programs.²⁵¹ The patient must bear the cost of the

247. *E.g.*, Menikoff, *supra* note 153, at 1061–62 (noting that FDA officials report companies with concerns that unexpected toxicity in a patient receiving early access will lead to a clinical hold).

248. 21 U.S.C. § 360bbb-0a(c)(1) (2018).

249. One study published in 2017 considered regulatory actions taken by FDA on 261 molecular entities from 2010 through 2016, finding “no instance in which expanded access . . . lead to a negative regulatory action for drug approval” and only one instance in which a safety event had “what might be interpreted as a negative effect on product labeling.” Jonathan P. Jarow & Richard Moscicki, *Impact of Expanded Access on FDA Regulatory Action and Product Labeling*, 51 THERAPEUTIC INNOVATION & REG. SCI. 787 (2017); *see also* Bunnik, Aarts & van de Vathorst, *Little to Lose*, *supra* note 20, at 980 (“In practice, serious adverse events in expanded access programs have rarely led to regulatory problems . . . in the USA: over a 10-year period, only 2 out of 1000 (recent) expanded access programs according to FDA.”). FDA has also reassured companies that adverse events will “be viewed through the proper lens” and that the notion that adverse events could hold up approval is “urban lore.” Kate Rawson, *Expanded Access Data Can Support Approval Decisions, FDA Says*, PINK SHEET (Nov. 21, 2018), <https://pink.pharmaintelligence.informa.com/PS124296/Expanded-Access-Data-Can-Support-Approval-Decisions-US-FDA-Says>. Another study of programs over a 10-year period found only two instances in which FDA called a temporary halt to ongoing trials after an event involving a patient who had received early access, out of 11,000 early access arrangements. Van Norman, *supra* note 19, at 289; *see also* Amy McKee et al., *How Often Are Drugs Made Available Under the Food and Drug Administration's Expanded Access Process Approved?*, 57 J. CLINICAL PHARMACOLOGY S136 (2017) (reviewing all individual early access requests to FDA's drug center for Fiscal Year 2010 to Fiscal Year 2014 and reporting no apparent product liability cases arising out of the use).

250. Grossman, *Empowered Consumer*, *supra* note 19, at 672 (suggesting that treatment INDs are rare in part because of the risk of liability exposure without any prospect for profit).

251. Sutter, *Expanded Access Advocates Seek Reimbursement*, *supra* note 212 (“Insurers generally will not pay for the cost of investigational drugs or for ancillary services unless they represent standard of care, numerous speakers said.”); Zettler, *Implications*, *supra* note 21, at 168 (“Private health insurance, Medicare, and Medicaid have not paid for treatment access to investigational drugs in the past and probably will not pay for such access in the future. Even if

experimental medicine, unless the company does. And companies are limited in what they may charge: FDA allows a company to recover only direct costs, meaning the cost per unit to manufacture the drug (raw materials, labor, supplies and equipment that are not reusable) and the direct costs to ship and handle the drug.²⁵² But disclosing direct costs at the preapproval stage could distort the public's understanding of the true cost of bringing the medicine to market.²⁵³ The direct cost of manufacturing a particular unit of medicine—the tablets taken or the solution prepared and injected—is in many respects a meaningless number, trivial compared to the fully capitalized cost of more than a decade of premarket research and development, including any other drugs that failed in premarket trials along the way. Making the drug available at direct cost before approval can make it difficult to charge a price after approval that reflects *all* the cost of bringing the medicine to market.²⁵⁴ Increasing use of expanded access in the United States may mean addressing these financial issues.

This hypothesis finds support in the French experience. The French approach to financing early access is exactly the opposite of the U.S. approach, and some evidence suggests the French ATU program is more heavily used than the U.S. expanded access program. To begin with, French law permits drug companies to profit from ATU arrangements. Pricing is “free”—meaning that the company may profit from the sale and, indeed, the medicine is technically not subject to the price

patients are only being charged for the cost of the drugs, that cost could be unaffordable for many low-income persons.”).

252. 21 C.F.R. § 312.8(d)(1) (2020); Charging for Investigational Drugs Under an Investigational New Drug Application, 74 Fed. Reg. 40,872, 40,875 (Aug. 13, 2009). Allowing recovery of costs was intended to address industry “reluctance” to participate in expanded access. Charging for Investigational Drugs Under an Investigational New Drug Application, 74 Fed. Reg. at 40,905. If a company is providing expanded access to an intermediate-size or large patient population, it may also recover the costs of monitoring the expanded access protocol, complying with IND reporting requirements, and other administrative costs directly associated with the expanded access arrangement. 21 C.F.R. § 312.8(d)(2) (2020). A company may not charge for indirect costs, such as expenditures for physical plant and equipment used to make large quantities of the drug; research and development costs; or administrative, labor, or other costs that would be incurred anyway. Charging for Investigational Drugs Under an Investigational New Drug Application, 74 Fed. Reg. at 40,896.

253. See Bunnik, Aarts & van de Vathorst, *Little to Lose*, *supra* note 20, at 980 (suggesting that in the United States, companies preferring not to disclose direct costs may choose to provide for free or not at all).

254. Sutter, *Expanded Access Advocates Seek Reimbursement*, *supra* note 212 (quoting CEO of a third-party sponsor of large group expanded access programs, that “no company wants” to reveal its “internal cost structure, which you have to do in any cost recovery,” and “then come to market three years later and have Bernie Sanders tell everybody, ‘Hey, here’s another pharma company boosting up their prices.’”); *cf.* Lietzan, *Access Before Evidence*, *supra* note 30, at 1271–72 (noting public outrage when a drug made available inexpensively to patients for a time becomes much more expensive after the marketing authorization process is complete).

controls that would apply after approval (if it were covered by public insurance).²⁵⁵ Although companies could choose to provide the drugs for free, many avail themselves of the opportunity to charge. We know this in part because the French system ended up changing its charging rules a few years ago to control spiraling costs.²⁵⁶ Today, a company cannot deviate substantially from the price that will be set after the medicine's approval.²⁵⁷ But it may charge its *ordinary* price for the medicine, and the ability to profit could make the ATU attractive to companies, turning it into the equivalent of early market entry.²⁵⁸

Even if U.S. policymakers did not allow drug companies to profit from expanded access, they might still need to address the financial impediments that patients face.²⁵⁹ Even though investigational medicines are provided free or at cost, senior FDA officials report that patients face barriers because of costs unrelated to the medicine itself, such as laboratory work and infusion services.²⁶⁰ In contrast, nearly everyone in France is covered by statutory national health insurance, and an unapproved medicine provided to a patient under an ATU is covered by this

255. For a general overview of pharmaceutical price controls in France, see Marc A. Rodwin, *What Can the United States Learn from Pharmaceutical Spending Controls in France?*, THE COMMONWEALTH FUND (Nov. 11, 2019), <https://www.commonwealthfund.org/publications/issue-briefs/2019/nov/what-can-united-states-learn-drug-spending-controls-france>. Broadly speaking, pricing of covered products is negotiated with the French Economic Committee for Health Products (CEPS) based in part on the outcome of a health technology assessment regarding the medical benefit to be derived from the drug (as compared to previous products). See generally Martin Koehring, *Value-Based Healthcare in France: A Slow Adoption of Cost-Effectiveness Criteria*, THE ECONOMIST INTELLIGENCE UNIT (Dec. 8, 2015), <https://eiuperspectives.economist.com/healthcare/value-based-healthcare-france-slow-adoption-cost-effectiveness-criteria>.

256. See *infra* Section 0. The authors consulted with two individuals who advise companies providing medicines through ATUs in France. One reported that most of his clients provide the medicine free of charge, but the other reported the opposite, that most of her clients charge for the medicine.

257. See *infra* Section 0.

258. See, e.g., Nathan Kennell, *Insights into Utilization of French Compassionate Use Programs (ATU)*, LINKEDIN PULSE (Apr. 11, 2018), <https://www.linkedin.com/pulse/insights-utilization-french-compassionate-use-programs-nathan-kennell> [<https://perma.cc/AEF2-RY54>] (using two case studies to describe how the ATU process “presents an avenue to obtain early market access” and concluding that “effective ATU utilization may lead to earlier, more extensive patient access, which increases clinical utilization and improves the perceived value of therapy”).

259. For similar reasons, some argue that the right-to-try law is unlikely to improve access so long as payers will not reimburse for the drugs. E.g., Christine Coughlin, Nancy King, & Melissa McKinney, *Regenerative Medicine and the Right to Try*, 18 WAKE FOREST J. BUS. & INTELL. PROP. L. 590, 618 (2018) (“[R]ight to try legislation does not compel insurance providers to cover the cost of expanded access to experimental products” and “does nothing to address the reality [that] public and private payers reasonably question the cost-effectiveness of payment for unproven interventions.”); see also Bunnik, Aarts & van de Vathorst, *Little to Lose*, *supra* note 20, at 979 (arguing that very little is done in the United States to make investigational drugs available and accessible and citing, as one explanation, the fact that they are usually not reimbursed).

260. Sutter, *Expanded Access Advocates Seek Reimbursement*, *supra* note 212 (noting that patients sometimes resort to GoFundMe to raise money for expanded access).

insurance.²⁶¹ The French early access program is said to be one of the most attractive (to patients) in Europe *because* of this reimbursement.²⁶²

Many patients use the French early access scheme. The ANSM reports tens of thousands of patients receiving early access through the ATU mechanism every year. In 2017, for instance, more than 8,000 patients received medicine through cohort ATUs, and another 16,000 received medicines through named patient ATUs.²⁶³ Comparable statistics are not readily available for the United States, but the drug center at FDA receives around 1,000 requests for expanded access every year, most for single patients, and it grants over 99 percent.²⁶⁴ One report found that in a recent four-year period, only 4 percent of granted requests pertained to intermediate or large groups.²⁶⁵ FDA apparently does not keep track of the number of patients treated under these requests,²⁶⁶ so it is impossible to know whether fewer patients receive access under treatment INDs in the United States than under cohort ATUs in France. But many more patients enjoy access to experimental medicines under the nominative (single patient) ATU in France than receive expanded access on an individual patient basis in the United States.

The early access schemes of France and the United States are different, but not different enough to explain this disparity. Something else is going on. One rational explanation would be that more companies participate when they can profit and that more patients participate when insurance covers the medicine and associated care. But there could be additional contributing factors. One might be

261. Cipriano, *Conversation*, *supra* note 211. Most countries in Europe do not reimburse experimental medicines. See Bunnik, Aarts & van de Vathorst, *Little to Lose*, *supra* note 20, at 980 (noting that France and Turkey have reimbursement systems in place; that in other countries the financial burden falls on the hospital, the hospital pharmacy, or the patient; and that Dutch hospitals have policies precluding patients from paying at all which means that if the insurer will not cover the medicine the hospital will not provide it).

262. See Bunnik, Aarts & van de Vathorst, *Little to Lose*, *supra* note 20, at 980.

263. ANSM, SUMMARY ACTIVITY REPORT 2017, 1, 9, https://www.ansm.sante.fr/var/ansm_site/storage/original/application/f5c61007e0b47de16a3c07354eb6f6d6.pdf [<https://perma.cc/L4WY-7C48>]. Reports in earlier years were similar. See ANSM, 2014 ANNUAL REPORT, 1, 9, https://ansm.sante.fr/var/ansm_site/storage/original/application/ee4fa2afa64ec300a551d912ff7c0559.pdf [<https://perma.cc/5DWH-52B4>] (reporting that 12,111 patients received medicines via cohort ATUs and 12,822 patients via nominative ATUs); see also Martinalbo, *supra* note 88, at 103 (noting in 2016 that French ATU scheme had managed over 130 cohorts since 1994). The schemes do differ in scope: the French ATU scheme permits access to drugs for rare diseases in addition to drugs for serious diseases. See *supra* note 129. But because the diseases are rare, these ATUs probably do not explain the large disparity in utilization rates.

264. Jarow, *Expanded Access*, *supra* note 109, at 707; see also Grossman, *AIDS Activists*, *supra* note 59, at 739 (noting that treatment INDs remain rare).

265. U.S. Gov't Accountability Office, GAO-17-564, *Investigational New Drugs: FDA Has Taken Steps to Improve the Expanded Access Program but Should Further Clarify How Adverse Events Data Are Used* 1, 18 (Jul. 11, 2017).

266. *Id.* at 18.

that new medicine approval in France lags behind new medicine approval in the United States.²⁶⁷ Once a company is allowed to sell its new medicine in one country (the United States), perhaps it is more likely to agree to expanded access in the other (France). That said, the discrepancy between the United States and France seems to relate to access for single patients, rather than access under treatment INDs in the United States and cohort ATUs in France. If the explanation were attributable to FDA approving new medicines before the ANSM approves them, one might expect the approval lag to manifest mainly in cohort ATUs rather than nominative, single-patient arrangements. In any case, a review of nominative ATUs from 2018 shows that the ANSM provides access in many cases *before* approval in the United States.²⁶⁸ Finally, even if there are more explanations for the willingness of companies to participate in France, this brings only one party to the table. French *patients* can participate because of robust health insurance covering both the medicine and the medical services—a benefit that U.S. patients lack.

B. Addressing the Financial Structure of Expanded Access

The healthcare finance system in the United States is complex, and assessing a financial solution to the expanded access problem is beyond the scope of this Article. But a few cautionary points are worth making. The French solution has many parts that work together. A partial solution in the United States—free pricing without reimbursement, or reimbursement without free pricing, or free pricing without either price controls or insurance—may not work and could introduce new problems.

267. E.g., Nigel S.B. Rawson, *Canadian, European and United States New Drug Approval Times Now Relatively Similar*, 96 REG. TOXICOLOGY & PHARMACOLOGY 121, 121 (2018) (examining 460 drugs approved by Health Canada, FDA, or the EMA between 2002 and 2016 and finding that the median EMA approval time was 371 days, while the median FDA approval time was 304 days); Robera Joppi et al., *Food and Drug Administration vs. European Medicines Agency: Review Times and Clinical Evidence on Novel Drugs at the Time of Approval*, 86 BRITISH J. CLINICAL PHARMACOLOGY 170, 172 (2019) (finding that the median review time for the 66 drugs approved by FDA and the EMA in 2015-2017 was longer at the EMA by a median of 121.5 days).

268. While some medicines provided to individual French patients (such as brigatinib) were already available in the United States, others (such as erdafitinib and alpelisib) would not be approved by FDA until the following year. For a list of current nominative ATUs, see *Référentiel des ATU nominatives*, ANSM, [https://www.ansm.sante.fr/Activites/Autorisations-temporaires-d-utilisation-ATU/Referentiel-des-ATU-nominatives/\(offset\)/3](https://www.ansm.sante.fr/Activites/Autorisations-temporaires-d-utilisation-ATU/Referentiel-des-ATU-nominatives/(offset)/3) [<https://perma.cc/F2PV-FWKE>]. For a list of past nominative ATUs, see *Liste des spécialités autorisées dans le cadre d'ATU nominatives*, ANSM, [http://dev4-afssaps-marche2017.integra.fr/Activites/Autorisations-temporaires-d-utilisation-ATU/ATU-nominative-Liste-des-specialites-autorisees/\(offset\)/3](http://dev4-afssaps-marche2017.integra.fr/Activites/Autorisations-temporaires-d-utilisation-ATU/ATU-nominative-Liste-des-specialites-autorisees/(offset)/3) [<https://perma.cc/YT2U-JHSV>]. For a list of current cohort ATUs, see *Liste des ATU de cohorte en cours*, ANSM, [https://www.ansm.sante.fr/Activites/Autorisations-temporaires-d-utilisation-ATU/ATU-de-cohorte-en-cours/\(offset\)/5](https://www.ansm.sante.fr/Activites/Autorisations-temporaires-d-utilisation-ATU/ATU-de-cohorte-en-cours/(offset)/5) [<https://perma.cc/27DX-7QWU>].

To begin with, free pricing by itself may exacerbate disparities in access to experimental medicines.²⁶⁹ Even when companies provide their experimental medicines for free or at cost, there are concerns about allocation. The Josh Hardy story reveals one issue: companies may respond more to patients who are vocal and who use social media and political pressure in their campaigns.²⁷⁰ The other issue is ancillary costs. Even if a company provides its experimental medicine for free, the costs of the associated medical care—physician fees, the costs of services such as monitoring, the cost of travel and lodging, and opportunity costs for caregivers who accompany the patient—may limit treatment to patients with more resources. Even though companies may charge freely in France, the French ATU scheme is structured to avoid disparities; the ANSM pushes out information about medicines available through the mechanism,²⁷¹ patients receive the medicines for free, and the associated medical care is also covered by national health insurance. If U.S. policymakers permitted companies to price freely during expanded access and did not somehow mandate insurance coverage and address other financial barriers, disparities in access could become profound and would be viewed by many as morally unacceptable.

Permitting free pricing and somehow covering the cost for patients might eliminate the inequities in allocation and increase the number of patients enjoying early access. But it would require thinking about moral hazard. Classical economic theory tells us that a consumer compares the benefit he expects with the marginal

269. Darrow et al., *supra* note 139, at 284 (arguing that early access programs “can also raise concerns about equity” because insurers may not step in when the company declines to shoulder the cost, leading some to argue “that expanded access generally favors the rich or well-connected over the poor”); Schüklenk & Lowry, *supra* note 20, at 16 (citing concern, from a “justice” perspective, that cost difference might mean the burden of clinical trial participation falls “disproportionately on members of economically disadvantaged groups”). Cf. Carrieri, Peccatori & Boniolo, *supra* note 20, at 67 (arguing that the “right to try” law could reinforce preexisting financial inequalities because the wealthy are more likely to have access to experimental medicines).

270. Caplan & Moch, *Rescue Me*, *supra* note 20 (“Should an experimental product be made available to an individual patient who is more vocal, more sophisticated in the use of media, more knowledgeable about the system, more adept at electronic searches?”). That said, although sophisticated use of media and technology to pressure companies appears to be on the rise, it remains unclear whether these strategies actually work. Mackey & Schoenfeld, *supra* note 153, at 22–23 (offering “high-profile case studies” in which the patient had “a multimedia strategy in place that was well-articulated, professionally executed (including various multimedia assets), and included coordinated message propagation across multiple popular online platforms . . . in addition to personal websites” but noting that “achieving robust public engagement and media coverage did not appear to associate with better chances of accessing experimental treatment”).

271. Unlike FDA, the ANSM maintains a list of medicines that can be prescribed via a nominative ATU if certain criteria are satisfied (and in all other cases, the doctor may simply apply for a nominative ATU as previously described). See *supra* note 268.

cost to him.²⁷² In health care, this generally leads to over-consumption,²⁷³ and particularly at the end of life, this effect could be even more pronounced.²⁷⁴ Terminally ill patients and their caregivers tend to place a high value on extending life even for a few months, higher than they would if asked earlier in the patient's life.²⁷⁵ And for an insured patient in the United States, the marginal financial costs typically comprise his insurance premium and any co-payments and deductible involved. A third-party payer covers the full financial cost of the medicine and associated healthcare services, passing the cost to others (taxpayers in the case of public insurance, other policy holders in the case of private insurance).

Providing reimbursement, within the context of a national health insurance system that also covers the cost of associated health care, eliminates most disparities in access—a goal of the French legal system that generally takes priority even in the face of arguments about personal autonomy. The persistent paternalism of the French healthcare system may help reduce the insurance effect, thereby reducing moral hazard. In contrast, U.S. society emphasizes patients' rights, worships the technological imperative, and prizes fighting terminal illness over palliative care and a good death, so mandatory insurance coverage for experimental medicines could trigger high utilization rates—including the kinds of last-ditch efforts that family members, caregivers, treating doctors, and even the patients themselves may in retrospect wish they had not tried.²⁷⁶

272. See generally Russell Korobkin, Comparative Effectiveness Research as Choice Architecture: The Behavioral Law and Economics Solution to the Health Care Cost Crisis, 112 MICH. L. REV. 523, 529–31 (2014).

273. *Id.* at 529; see also Paul T. Menzel, The Value of Life at the End of Life: A Critical Assessment of Hope and Other Factors, 39 J. L. MED. & ETHICS 215, 220 (2011) ("Because of the 'insurance effect' . . . what is actually spent is not a good indication of value."); see also Sidney A. Shapiro & Joseph P. Tomain, REGULATORY LAW AND POLICY: CASES AND MATERIALS 52 ("Expense accounts, insurance, and medical benefits have the effect of encouraging consumers to spend more than they would if the expenses were paid directly (internalized) by the consumer The economic difficulty with a moral hazard is that costs can be inflated over what they otherwise would be if someone else were not paying."). There is a large body of empirical literature exploring the impact of health insurance on spending, which is beyond the scope of this Article. See Liran Einav & Amy Finkelstein, Moral Hazard in Health Insurance: What We Know and How We Know It, 16 J. EUR. ECON. ASS'N 957 (2018) (describing the literature).

274. Menzel, *supra* note 273, at 221 ("Insured patients, and often their providers as well, have an incentive to use every bit of care that has even the slimmest, pie-in-the sky prospect of benefit, regardless of its cost. People see themselves as having paid their insurance 'dues' already, and their future premiums will not increase by more than micro-pennies because of *their one current use of marginal care.*").

275. *Id.* at 217 (explaining the apparently high value of life extension, including the fact that six months of additional life is perceived as higher value by a person with a shorter remaining lifespan, both because the six additional months represent a greater proportion of his remaining life and because the gain from the extension is more temporally proximate).

276. For a compelling personal account of experimental treatments that, in retrospect from a family member's perspective, were the wrong choice, see Malinowski, *supra* note 21.

Moral hazard, though, also leads directly to the problem of cost. New medicines can be expensive while companies recover their investment in research and development and while their competitors are legally prohibited from making copies. Free pricing for experimental medicines, combined with mandatory insurance, could impose significant costs on the U.S. healthcare system. The French learned this the hard way. A review of all medicines available through ATU that received marketing authorization between January 1, 2005, and June 30, 2010, found that a 12% premium on average was paid to companies while a medicine was on this status.²⁷⁷ They now manage the fiscal impact of early access by requiring the company to reimburse the government in some cases—including when the amount paid by the government exceeds a certain threshold and when the price imposed after approval is lower than the free price during early access.²⁷⁸ Responses from industry have not been positive. Many companies have criticized the scheme, citing its administrative complexity and the business uncertainties in free pricing that will be second-guessed later.²⁷⁹ In the United States, price controls for medicines remain a controversial issue.

Finally, even if companies were allowed to charge normal prices, some might not participate in expanded access. Companies decline to participate for various reasons. Liability protection for companies and doctors within the expanded access framework is important. In addition, some companies will want to focus on enrolling patients in ongoing trials in order to complete the research needed for approval. Others might always decline to provide access, as a matter of policy, thinking that this the best way to avoid a complicated public relations challenge.²⁸⁰

277. Albane Degraissat-Théas et al., *Temporary Authorization for Use: Does the French Patient Access Programme for Unlicensed Medicines Impact Market Access After Formal Licensing?*, 31 PHARMACOECONOMICS 335, 335 (2013); Eveline Van Keymeulen & Laëtitia Bénard, *New Requirements for Temporary Authorisations for Use in France*, ALLEN & OVERY LIFE SCIENCES HUB (June 6, 2017), <https://www.aolifescienceshub.com/new-requirements-temporary-authorisations-use-france> [<https://perma.cc/AL2W-KVC9>].

278. Loi 2016-1827 du 23 décembre 2016 de financement de la sécurité sociale pour 2017, J.O., Dec. 24, 2016, no. 1. See generally *Autorisations temporaires d'utilisation (ATU)*, MINISTÈRE DES SOLIDARITÉS ET DE LA SANTÉ, <https://solidarites-sante.gouv.fr/soins-et-maladies/medicaments/professionnels-de-sante/autorisation-de-mise-sur-le-marche/article/autorisations-temporaires-d-utilisation-atu> [<https://perma.cc/DVF6-RL5T>].

279. E.g., LES ENTREPRISES DU MÉDICAMENT, *supra* note 125 (noting that medicines available through the ATU scheme are reaching only ten percent of the eligible population and arguing that the changes wrought by later financing laws—meaning the complex reimbursement requirements—have made the ATU scheme “very complicated, even ineffective”).

280. Whether public relations considerations lead to providing or declining access will vary. Providing access may be necessary to avoid a public relations nightmare triggered by a sophisticated and media-savvy patient with a compelling story, but providing access only to patients with the knowledge and resources to launch a media campaign may raise ethical issues that trigger a different kind of public scrutiny. Some companies have addressed these issues with external boards that rule on access requests or with lotteries for expanded access. See Bunnik, Aarts & van de Vathorst, *Little to Lose*, *supra* note 20 (noting that Johnson & Johnson has established an external board to review

C. Barriers to Provider and Patient Participation in Expanded Access

Senior FDA officials have reported that many doctors are unwilling to participate in expanded access because—even if the medicine is provided for free or at cost—their services are not covered by insurance.²⁸¹ With little financial upside, doctors may be deterred by the prospect of liability for injuries that may result.²⁸² The right-to-try law tries to address this risk, relieving them from “liability in a cause of action” arising out of an “alleged act or omission with respect to an eligible investigational drug provided to an eligible patient” unless there was reckless or willful misconduct, gross negligence, or an intentional tort.²⁸³ Although this provides some coverage, it may simply shift the focus of litigation to whether the doctor was reckless or grossly negligent. The drafters also overlooked the relationship between this uncodified liability provision and the codified provision governing patient eligibility in the first instance. If the patient’s informed consent was not provided, the patient was not an “eligible patient” in the first place. This appears to leave open the possibility of both a private tort suit arising out of defective informed consent and proceedings brought by the state’s licensing board. More robust liability protection may be needed to entice doctors to participate in expanded access.²⁸⁴

Finally, more targeted legislation might help address inequities caused by knowledge deficits in the United States. Perhaps eligible patients do not ask for early access because they are receiving treatment from physicians unaware of the option.²⁸⁵ Skepticism in minority communities about medical research—the legacy of significant historical failures in human subject protection—may further contribute to the knowledge deficit and reduce the number who seek access.²⁸⁶ In a system that provides early access to those who think to request it—but that does

requests based on “equality, need, and efficacy”). Still others may be concerned about the public relations challenge in the event of an unforeseen adverse event, particularly if the patient has garnered sympathetic media attention.

281. Sutter, *Expanded Access Advocates Seek Reimbursement*, *supra* note 212.

282. Zettler, *Implications*, *supra* note 21, at 170; *see also* Van Norman, *supra* note 19, at 289 (noting that physicians may be reluctant to recommend an experimental medicine on the grounds that they lack enough information make benefit-risk calls).

283. Pub. L. No. 115-176, § 2(b), 132 Stat. 1372 (2018) (not codified).

284. *See* Meghan K. Talbott, *The Implications of Expanding Access to Unapproved Drugs*, 35 J. L. MED. & ETHICS 316, 317–18 (2007) (discussing theories of physician liability such as common law fraud, intentional misrepresentation, battery, and lack of informed consent).

285. *Cf.* Bunnik, Aarts & van de Vathorst, *Changing Landscape*, *supra* note 20, at 10 (suggesting that low uptake is partially the result of knowledge deficits).

286. Allen L. Gifford et al., *Participation in Research and Access to Experimental Treatments by HIV-Infected Patients*, 346 NEW ENG. J. MED. 1373, 1379 (2002) (“[F]ewer than half as many black patients as white patients attempt to obtain experimental HIV medications, suggesting that there is less awareness and a more widespread negative attitude about research in minority communities.”).

not otherwise push out information about the availability of medicines before approval—patients with less education, less access to information, and fewer (or less sophisticated) healthcare providers are less likely to receive early access. The success of relentless social media campaigns and influential public figures in securing a patient expanded access also favors patients with greater knowledge and resources. In contrast, in part because of the long tradition of regulating to avoid disparities and inequities, the French regulator pushes out information about medicines available through the early access mechanism. In France, knowledge deficits may be less of an issue.

CONCLUSION

The right-to-try laws were never really about increasing patient access to new medicines. They were about championing individual rights and patient autonomy in matters of medical care, at least at the end of life, and reducing the role of the federal government in such matters. There is room for debate about the merits of a federal gatekeeper in this exceptional situation, though not (in the view of the authors) for serious debate about the merits of our common medicine approval framework. And because the right-to-try law represents a rejection of the basic assumptions of this framework—the need for high-quality evidence to support commercial market entry and prescribing decisions, and the importance of a single scientific regulator assessing the quality of that evidence—it is indefensible on that ground alone. Moreover, as a way of meaningfully expanding access to unapproved medicines, or improving the equity of access among groups with varying socioeconomic statuses and levels of sophistication in medical matters, it is equally indefensible. Patient groups were slow to realize that the fight for right-to-try was not really a fight in their interests, and the proponents of this law must shoulder some of the blame.

There are clear impediments to a fully functional expanded access scheme, and U.S. policymakers might look to the apparent success of the French ATU scheme—reported to be one of the most attractive in Europe, from the patient perspective—for at least some answers. Robust empirical investigation of the French scheme would be helpful. But there is good reason to think that expanded access will not be equitably available in this country so long as patients face significant financial hurdles and healthcare providers need reimbursement for the services they provide. Consistent and proactive dissemination of information about available expanded access programs from a trusted party—as in France—might mitigate some of the knowledge deficit. Allowing the companies to charge freely for their drugs might tip the balance for some companies, but doing so may create many follow-on problems, and the full French solution—nationalized health insurance and, more importantly, price controls—is not politically viable in the

United States for now. The best short-term solution may be to facilitate financial support and reimbursement under traditional expanded access programs while studying the full French solution in more detail.

Transformative Models to Promote Prescription Drug Innovation and Access: A Landscape Analysis

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Abstract:

The patent-based pharmaceutical innovation system in the US does not incentivize the development of drugs with the greatest impact on patient or public health. It has also led to drug prices that patients and health care systems cannot afford. Three alternate approaches to promoting pharmaceutical innovation have been proposed to address these shortcomings. Delinkage models involve payments for drug innovation based on public health value rather than on a per-use basis. Public manufacturing models call upon governments and nonprofit organizations to lead drug discovery, development, and production. Public-private partnership models entail publicly-funded organizations working closely with for-profit partners on drug development and price-setting. Each model exhibits promise in promoting prescription drug innovation and access. This paper reviews these transformative models in detail, examining their key characteristics, advantages, and limitations.

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TABLE OF CONTENTS

INTRODUCTION	59
I. THE DELINKAGE MODEL	60
A. CHARACTERISTICS OF DELINKAGE MODELS	63
1. DRUG CRITERIA	64
2. DEGREE OF DELINKAGE.....	64
3. INTELLECTUAL PROPERTY	65
4. PAYMENT SCHEDULE.....	66
5. REWARD OBLIGATIONS	66
6. REWARD SIZE.....	67
7. FUNDING SOURCES	68
B. OUTCOMES FROM DELINKAGE MODELS	68
C. CONCLUSIONS AND RECOMMENDATIONS	70
II. THE PUBLIC MANUFACTURING MODEL.....	74
A. CHARACTERISTICS OF PUBLIC AND NONPROFIT MANUFACTURING MODELS	76
1. INTENDED PURPOSE	76
2. DRUG CRITERIA	77
3. MANUFACTURING CONTROL	78
4. GOVERNANCE	79
5. PURCHASING AGREEMENTS.....	79
6. INTELLECTUAL PROPERTY	80
7. FUNDING SOURCES	81
B. OUTCOMES FROM PUBLIC MANUFACTURING MODELS	81
C. CONCLUSIONS AND RECOMMENDATIONS	82
III. THE PUBLIC-PRIVATE PARTNERSHIP MODEL.....	85
A. CHARACTERISTICS OF PUBLIC-PRIVATE PARTNERSHIP MODELS.....	85
1. PARTICIPANTS.....	86
2. SCOPE.....	86

3. INTENDED PURPOSE	87
4. INTELLECTUAL PROPERTY	88
5. RELATIONSHIP WITH REGULATORY AUTHORITIES	88
6. FUNDING SOURCES	89
B. OUTCOMES FROM PUBLIC-PRIVATE PARTNERSHIP MODELS	89
C. CONCLUSIONS AND RECOMMENDATIONS	91
CONCLUSION	95

INTRODUCTION

Pharmaceutical innovation is critical for patient care and public health, as drugs can be among the most effective—and cost-effective—interventions that physicians can offer. However, drug development is also long and expensive. To attract private investment in this endeavor, the US federal government provides 20-year patents and other long-lasting statutory market exclusivities that give companies time to earn back up-front investments and make profits.¹ During this market exclusivity period, manufacturers can charge whatever they want, so US prices typically far exceed those for the same drugs sold in other high-income countries.²

This innovation model has been criticized on two grounds. First, it does not incentivize the development of drugs with the greatest impact on patient or public health,³ but rather encourages private investment in drugs that are likely to generate the greatest revenues. As a result, despite being sold at high prices, many new drugs that receive US Food and Drug Administration (FDA) approval do not offer important advances in efficacy or safety. For example, among new drugs approved in 2017 in the US, about one-third were rated by expert organizations in Germany, France, and Canada to offer no or minor additional benefits over existing treatments.⁴ Another study found that 40% of the highest-spending brand-name drugs in Medicare were reformulations of previously approved active ingredients.⁵

Second, the current pharmaceutical innovation model leads to prices of brand-name drugs that patients and health care systems cannot afford. For example, when the direct-acting antiviral sofosbuvir (Sovaldi) was approved by the FDA in 2013, it offered for the first time the possibility of a cure for chronic hepatitis C virus infection, an infectious disease affecting 3-4 million US patients.⁶ But because Gilead priced the product at \$84,000 for a standard 12-week course of therapy, payers like Medicaid were unable to offer it to all qualifying patients due to

1. See Aaron S. Kesselheim, Michael S. Sinha & Jerry Avorn, *Determinants of Market Exclusivity for Prescription Drugs in the United States*, 177 JAMA INTERNAL MED. 1658, 1659 (2017).

2. See Aaron S. Kesselheim, Jerry Avorn & Ameet Sarpatwari, *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 JAMA 858, 860 (2016).

3. See Anna Kaltenboeck et al., *Grounding Value-Based Drug Pricing in Population Health*, 107 CLINICAL PHARMACOLOGY & THERAPEUTICS 1290, 1291 (2020).

4. Richard G. Frank, Jerry Avorn & Aaron S. Kesselheim, *What Do High Drug Prices Buy Us?* HEALTH AFFAIRS BLOG (April 29, 2020), <https://www.healthaffairs.org/doi/10.1377/hblog20200424.131397/full/> [https://perma.cc/LZ2A-QUL4].

5. Emily H. Jung, Ameet Sarpatwari & Aaron S. Kesselheim, *Novelty of Active Ingredients in High-Cost Brand-Name Drugs*, J. GEN. INTERNAL MED. 1, 1 (2020).

6. See Andrew Pollack, *F.D.A. Approves Pill to Treat Hepatitis C*, N.Y. TIMES (Dec. 6, 2013), <https://www.nytimes.com/2013/12/07/business/fda-approves-pill-to-treat-hepatitis-c.html> [https://perma.cc/2BLG-YFYA].

concerns that it would exceed their drug budgets.⁷ As a result, only 2.4% of eligible Medicaid patients were treated in the first year.⁸ Although prices of direct-acting antivirals have declined in recent years due to competition, they remain high, with many patients still unable to access treatment.⁹ The sofosbuvir case was particularly controversial because the drug emerged from years of publicly-funded research and development at Emory University, followed by work at a small company founded by academic scientists, before being transferred to Gilead for the final steps in development just a year before approval.¹⁰

To promote the discovery of more innovative drugs like sofosbuvir while ensuring wider access after approval, three alternate models of drug development have been suggested: first, a “delinkage” model in which payment for drug innovation is made based on its public health value rather than on a per-use basis; second, a “public manufacturing” model, in which the government or nonprofit organizations fund the entire discovery and development process and then price drugs closer to the cost of production; and third, a “public-private partnership” model, in which a publicly-funded organization that discovers a new drug would transfer intellectual property to the private market, but remain closely involved in the drug development and price-setting process.

Key values should guide assessment of these models. The current patent-based system has some strengths, including incentives that directly benefit innovators and timely invention disclosures. An ideal model would preserve these advantages, while encouraging greater needs-driven innovation, transparency, efficiency, and affordability. With these values in mind, we review delinkage, public manufacturing, and public-private partnership models in detail, examining their advantages and limitations.

I. THE DELINKAGE MODEL

While many variations of delinkage models exist, the term delinkage is often

7. See Soumitri Barua et al., *Restrictions for Medicaid Reimbursement of Sofosbuvir for the Treatment of Hepatitis C Virus Infection in the United States*, 163 ANNALS INTERNAL MED. 215, 215 (2015).

8. Joshua M. Liao & Michael A. Fischer, *Restrictions of Hepatitis C Treatment for Substance-Using Medicaid Patients: Cost Versus Ethics*, 107 AM. J. PUB. HEALTH 893, 896 (2017).

9. See Ed Silverman, *Most State Medicaid Programs Continue to Restrict Access to Hepatitis C Medicines*, STAT (Oct. 16, 2019), <https://www.statnews.com/pharmalot/2019/10/16/medicaid-hepatitis-access-drug-prices/> [<https://perma.cc/JVX9-28RG>].

10. Merrill Goozner, *Why Sovaldi Shouldn't Cost \$84,000*, MODERN HEALTHCARE (May 3, 2014), <https://www.modernhealthcare.com/article/20140503/MAGAZINE/305039983/why-sovaldi-shouldn-t-cost-84-000> [<https://perma.cc/9NXJ-REWU>]; see also WILLIAM RICE & FRANK CLEMENTE, GILEAD SCIENCES: PRICE GOUGER, TAX DODGER 1, 14 (July 2016), <https://americansfortaxfairness.org/files/ATF-Gilead-Report-Finalv3-for-Web.pdf> [<https://perma.cc/4UCJ-NX2Q>].

used synonymously with “innovation inducement prizes” and “market entry rewards.”¹¹ Conceptually, delinkage refers to the separation of an innovator’s research and development costs from the price of its products, which is achieved by rewarding the innovator directly for the innovation rather than indirectly through market exclusivity.¹² In this manner, delinkage systems reduce or eliminate an innovator’s reliance on sales to recuperate research and development investments and earn profits.¹³

Proponents of delinkage contend that it would benefit patients by lowering prices and increasing access to drugs.¹⁴ Some delinkage proposals require innovators to forfeit their patents in exchange for the rewards, allowing immediate generic entry to drive down drug prices.¹⁵ Other proposals allow innovators to retain their patents, but contractually obligate innovators to supply their drugs close to the marginal cost of production.¹⁶

Delinkage also promotes innovation by ensuring the financial attractiveness of developing desired drugs. Rewards provide innovators with predictability, guaranteeing a return on investment upon meeting stated goals,¹⁷ which can be tailored to favor certain innovation outcomes, such as developing drugs for unmet needs.¹⁸ Even the pharmaceutical industry has acknowledged the benefits of delinking financial revenues from sales, given the mitigation of financial risk for both innovators and health care systems.¹⁹ Delinkage models could also increase the overall efficiency of the system by eliminating the need for substantial manufacturer spending on marketing efforts, which currently accounts for \$30

11. See JAMES LOVE, UNITAID, AN ECONOMIC PERSPECTIVE ON DELINKING THE COST OF R&D FROM THE PRICE OF MEDICINES 1, 14 (2016), http://www.unitaid.org/assets/Delinkage_Economic_Perspective_Feb2016.pdf [<https://perma.cc/SJ4X-PUT4>].

12. U.N. Secretary General and Co-Chairs of the High-Level Panel, *Report of the United Nations Secretary-General’s High-Level Panel on Access to Medicine: Promoting Innovation and Access to Health Technologies* (Sept. 2016) (defining delinkage), <http://www.unsgaccessmeds.org/s/UNSG-HLP-Report-FINAL-12-Sept-2016.pdf> [<https://perma.cc/Z4AK-5GDH>].

13. GREGORY W. DANIEL ET AL., DUKE MARGOLIS CENTER FOR HEALTH POLICY, VALUE-BASED STRATEGIES FOR ENCOURAGING NEW DEVELOPMENT OF ANTIMICROBIAL DRUGS 7 (2017) [hereinafter Duke Margolis Report].

14. LOVE, *supra* note 11, at 15.

15. See Kevin Outterson et al., *Delinking Investment in Antibiotic Research and Development from Sales Revenues: The Challenges of Transforming a Promising Idea into Reality*, 13 PLOS MEDICINE 1, 4 (2016).

16. See *id.* at 4–5.

17. John H. Rex & Kevin Outterson, *Antibiotic Reimbursement in a Model Delinked from Sales: A Benchmark-based Worldwide Approach*, 16(4) LANCET INFECTIOUS DISEASES 500, 504 (2016).

18. LOVE, *supra* note 11, at 24.

19. *Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance* 1, 3 (Jan. 2016), https://www.abpi.org.uk/media/1675/industry_declaration_on_combating_antimicrobial_resistance_jan2017.pdf [<https://perma.cc/6QHD-BQ96>].

billion per year.²⁰

Finally, delinkage models are particularly beneficial for specific drugs, such as antibiotics, which require post-approval restrictions on use.²¹ In the current system, revenues are dependent on sales, encouraging innovators to maximize utilization during patent-protected periods, exacerbating the threat of antimicrobial resistance.²²

Critics of delinkage models point to the financial challenges of using nonmarket exclusivity rewards to incentivize research and development. Such rewards must be sufficiently large to offset the high risk of failure innovators bear to develop successful drugs. Governments may find it difficult to determine optimal reward pricing to achieve innovation, due to under- or over-valuation of research and development costs.²³ For example, estimates of the reward needed to incentivize the development of an innovative antibiotic range from \$919 million to \$5 billion.²⁴ Furthermore, governments would have to fund not only the rewards, but also the administrative costs to implement the schemes.²⁵ The difficulty in funding such efforts is exemplified by the World Health Organization Global Observatory on research and development, established in 2013. Many of its projects, including a nano-based malaria drug delivery system, were ultimately cancelled due to underfunding.²⁶

Some innovators further argue that delinkage models are too risky and may not motivate appropriate actors. A one-time upfront payment for a promising drug may be a waste of resources if the drug is later determined to be less effective than originally predicted or to have safety issues that require it to be removed from the market. As FDA regulatory approval of new drugs has increasingly occurred based on less data and less rigorous study designs,²⁷ the risk of such an outcome has increased. Additionally, pharmaceutical innovation often happens in multiple settings in parallel. If a prize is only awarded to a limited set of winners, multiple innovators may be discouraged from participating given uncertainty of being the

20. Lisa M. Schwartz & Steven Woloshin, *Medical Marketing in the United States, 1997-2016*, 321 JAMA 80, 80 (2019).

21. David Holmes, *Report Urges Controversial 'Delinkage' to Foster New Antibiotics*, 20 NATURE MED. 320, 320 (2014).

22. CHATHAM HOUSE REPORT: TOWARDS A NEW GLOBAL BUSINESS MODEL FOR ANTIBIOTICS DELINKING REVENUES FROM SALES (Charles Clift et al. eds., 2015).

23. PHILIP STEVENS, *DELINKED FROM REALITY 5* (Nov. 2017), <https://geneva-network.com/wp-content/uploads/2017/11/Delinkage.pdf> [<https://perma.cc/S99G-CSRW>].

24. Rex & Outtersson, *supra* note 17, at 501.

25. *See* STEVENS, *supra* note 23, at 4; *but see* LOVE, *supra* note 11, at 22 (concluding that a delinkage approach to drug development would be Pareto efficient and would not result in deadweight loss).

26. STEVENS, *supra* note 23, at 11.

27. Jonathan J. Darrow, Jerry Avorn & Aaron S. Kesselheim, *FDA Approval and Regulation of Pharmaceuticals, 1983-2018*, 323 JAMA 164, 164 (2020).

first to the finish line.²⁸ However, the second or third drug to enter the market in a class may offer important utility for patients.²⁹

Opposition to delinkage also stems from its centrally-planned nature that some commentators fear will result in “rent-seeking and crony capitalism.”³⁰ According to this logic, a delinkage system that gives government officials discretion to direct drug development would be susceptible to regulatory capture by special interests as well as changing political and economic tides.³¹ To mitigate the effects of politicization, several delinkage proposals suggest entrusting the execution of reward schemes to neutral “pipeline coordinators” or well-established administrative agencies, such as the National Institutes of Health (NIH).³²

Finally, lack of international cooperation could be a barrier to successful deployment of delinkage models. The top-selling drugs in the world earn billions of dollars per year in revenue.³³ Thus, the size of payments required to stimulate innovation may require global coordination, consensus, and priority alignment, which is challenging to accomplish.³⁴ Some commentators have proposed that a core group of countries with high levels of clinical research activity could initially pilot a delinkage model,³⁵ with a newly established secretariat or global organization charged with leading the effort.³⁶

A. Characteristics of Delinkage Models

Several working groups and international organizations in the US and Europe have formulated proposed delinkage models (Table 1).³⁷ The majority seek to incentivize development of new drugs to combat antimicrobial-resistant infections. However, some delinkage models outside of antibiotics have also been conceived,

28. CHANTAL MOREL, REACT, EXPLORING RESPONSES TO THE NEED FOR NEW ANTIBIOTICS: HOW DO DIFFERENT INCENTIVES COMPARE? 6 (2011).

29. See, e.g., Jing Luo et al., *Effect of Generic Competition on Atorvastatin Prescribing and Patients’ Out-of-Pocket Spending*, 176 JAMA INTERNAL MED. 1317, 1317 (2016).

30. STEVENS, *supra* note 23, at 8.

31. See MOREL, *supra* note 28, at 7.

32. See CHRISTINE ÁRDAL ET AL., DRIVE-AB, REVITALIZING THE ANTIBIOTIC PIPELINE: STIMULATING INNOVATION WHILE DRIVING SUSTAINABLE USE AND GLOBAL ACCESS 5 (2018) [hereinafter DRIVE-AB Report]; see also Improving Access to Affordable Prescription Drugs Act, S. 771, 115th Cong. (2017) [hereinafter IAAPD Act].

33. See IQVIA INSTITUTE, MEDICINE USE AND SPENDING IN THE U.S. (May 9, 2019), <https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-use-and-spending-in-the-us-a-review-of-2018-and-outlook-to-2023> [https://perma.cc/FG5X-ZR8P].

34. See Kimberly Sciarretta et al., *Economic Incentives for Antibacterial Drug Development: Literature Review and Considerations from the Transatlantic Task Force on Antimicrobial Resistance*, 63 CLINICAL INFECTIOUS DISEASES 1470, 1473 (2016).

35. See CHATHAM HOUSE REPORT, *supra* note 22, at 31.

36. See *id.*

37. MOREL, *supra* note 28, at 7.

such as the Cancer Innovation Fund.³⁸ In this section, we review the key characteristics of identified delinkage models.

1. Drug Criteria

Organizations charged with implementing delinkage programs must first establish guidance to innovators specifying what requirements drugs must meet to qualify for rewards, including clear efficacy and safety standards. These “target profile criteria” should be specific enough to provide innovators with predictability and should be fixed for several years to account for lengthy research and development times. However, they should also be flexible enough to incorporate unanticipated discoveries in the innovation process and periodically updated to reflect changing unmet needs.³⁹

For example, in the antibiotic context, groups such as Knowledge Ecology International, Chatham House, and DRIVE-AB recommend that target product profile design should be guided by assessing unmet public health needs for antibiotic innovation.⁴⁰ Chatham House recommends that delinkage program administrators conduct comprehensive global threat assessments to identify incentive targets, similar to the antimicrobial resistance threat assessment conducted by the Centers for Disease Control and Prevention (CDC) in 2013.⁴¹ The CDC’s assessment used various criteria, including incidence and prevalence, clinical impact attributable to infection, economic impact, transmissibility, preventability through public health measures, and availability of effective treatment.⁴² Alternatively, DRIVE-AB suggests prioritizing antibiotic development based on existing lists, such as the World Health Organization’s list of priority pathogens.⁴³ Target product profiles developed from these lists would ideally define specifications for safety and efficacy requirements, indications, dosing, treatment duration, and route of administration, which current proposals generally fail to do.

2. Degree of Delinkage

Delinkage models can be fully or partially delinked. In a fully delinked system, innovator profits are derived solely from reward payments, not sales.⁴⁴ The

38. Cancer Innovation Fund (2017), [https://imedproject.org/proposals-database/cif/\[https://perma.cc/4KZ5-PP42\]](https://imedproject.org/proposals-database/cif/[https://perma.cc/4KZ5-PP42]) (last visited Aug. 17, 2019).

39. DRIVE-AB Report, *supra* note 32, at 10.

40. *See id.*; CHATHAM HOUSE REPORT, *supra* note 22, at 12.

41. CHATHAM HOUSE REPORT, *supra* note 22, at 12.

42. *See id.*

43. DRIVE-AB Report, *supra* note 32, at 24.

44. *See* MATTHEW RENWICK, DAVID FINDLAY & SILAS HOLAND, AN APPROACH TO DESIGNING

drug is supplied at a price that reflects the marginal cost of production. By contrast, a partially delinked system awards innovators with smaller reward payments, and allows them to continue receiving revenue from sales, subject to negotiated price or quantity conditions.⁴⁵

The majority of delinkage proposals that we identified, including those by the Review on Antimicrobial Resistance, the Transatlantic Task Force on Antimicrobial Resistance, and the Norway Pilot Study, use partially rather than fully delinked models.⁴⁶ Some commentators argue that partial delinkage is simpler to implement within existing reimbursement systems, minimizing disruptive market effects. Additionally, by retaining revenues from sales, innovators remain engaged in the lifecycle of their product. Partial delinkage may also be more feasible and sustainable for governments to implement, given the likely limited size of reward payments they could offer.⁴⁷ The Boston Consulting Group recommends a slight variation of the partially delinked model—the “insurance mechanism”—which requires innovators to return a percentage of their profits up to the original amount of the market entry reward.⁴⁸ However, full delinkage models would more effectively accomplish the goals of containing spending and promoting more equitable access by eliminating the innovator’s involvement in pricing and ability to profit through sales.

3. Intellectual Property

In delinkage models, innovators’ drug patents can be purchased outright, licensed, or retained.⁴⁹ In a full patent buyout, the government purchases the innovators’ drug patents and then supplies the drug at prices close to marginal cost (or alternatively, licenses the intellectual property competitively to generic manufacturers). By contrast, in a partial patent buyout, innovators license their drug patents to the government in exchange for reward payments. The government is then able to establish market prices for those drugs. Finally, under marginal cost procurement contracts, innovators retain their intellectual property but supply the drug at contractually arranged prices.

MARKET ENTRY REWARDS FOR STIMULATING ANTIBIOTIC DEVELOPMENT, DRIVE-AB (2017).

45. *See id.*

46. JIM O’NEILL, REVIEW ON ANTIMICROBIAL RESISTANCE, SECURING NEW DRUGS FOR FUTURE GENERATIONS: THE PIPELINE OF ANTIBIOTICS 21 (2015); Christine Årdal et al., *Pull Incentives for Antibacterial Drug Development: An Analysis by the Transatlantic Task Force on Antimicrobial Resistance*, 65(8) CLINICAL INFECTIOUS DISEASES 1378, 1381 (2017) [hereinafter TATFAR Report]; Christine Årdal et al., *Designing a Delinked Incentive for Critical Antibiotics: Lessons from Norway*, 46 J. LAW, MED. & ETHICS 43, 47 (2018) [hereinafter Norway Pilot Study].

47. Duke Margolis Report, *supra* note 13, at 8.

48. BOSTON CONSULTING GROUP, BREAKING THROUGH THE WALL: A CALL FOR CONCERTED ACTION ON ANTIBIOTICS RESEARCH AND DEVELOPMENT 40 (2017).

49. *See* Outtersen et al., *supra* note 15, at 5.

Thus, the critical component with any intellectual property scheme in a delinked system is that the rewards ultimately replace or eliminate market exclusivity. In comparing the schemes outlined above, the full patent buyout would require the government to offer substantially higher reward payments given the historical reluctance of pharmaceutical manufacturers to part with their intellectual property.⁵⁰

4. Payment Schedule

Reward payments in delinkage models can be issued in various ways. One option is to pay the innovator an upfront lump sum payment shortly following market approval. However, such payments carry high risk because evidence of clinical value may be insufficient at the time of approval, especially for drugs approved based on changes in biomarkers or other unproven surrogate endpoints rather than clinically meaningful effects.⁵¹

Another option is milestone payments, awarded to innovators upon meeting key goals during development or following market approval. Upstream payments during development are highly valuable to innovators investing in large clinical trials but pose risk to funders.⁵² Outterson et al. recommend a staged approach, in which a base reward is granted upon drug approval, with subsequent annual payments awarded based on evaluation of effectiveness data collected in the course of usual care.⁵³ The annual payments would aid the innovator in financing manufacturing and supply-chain availability. Rex et al. and the Duke Margolis Center propose a similar scheme that would award innovators with increases to each “benchmark payment” based on desirable factors, such as proof of a novel mechanism of action, addressing serious unmet needs, reducing health care costs, targeting resistant pathogens, or label expansions to other indications.⁵⁴

5. Reward Obligations

Delinkage models can also include additional obligations for manufacturers in exchange for reward payouts. Examples include guaranteed supply of drugs and open-source information sharing of clinical data.⁵⁵ To combat overuse, delinkage models for antibiotics can include conditions on marketing and promotion.⁵⁶ For example, the Improving Access to Affordable Prescription Drugs Act, proposed in

50. See MOREL, *supra* note 28, at 8.

51. See Sciarretta et al., *supra* note 34, at 1472.

52. See CHATHAM HOUSE REPORT, *supra* note 22, at 4.

53. Outterson et al., *supra* note 15, at 4.

54. Rex & Outterson, *supra* note 17, at 502; Duke Margolis Report, *supra* note 13, at 12.

55. See LOVE, *supra* note 11, at 48.

56. See Outterson et al., *supra* note 15, at 5.

Congress in 2017, would have established an Antibiotic Prize Fund offering prizes conditional on waiver of patent rights, reasonable pricing, reports of marketing activity, and data disclosures.⁵⁷

6. Reward Size

A main challenge for delinkage model implementation is determining the magnitude of payments necessary to attract interest from private investors and for-profit companies. The payments must be large enough to motivate companies to participate but feasible for governments to finance. Proposals suggest that reward size could be estimated based on standard health technology assessments, social value of the subject of the prize fund to health systems, or general global market demand.⁵⁸ The BEAM Alliance, a network of European biopharmaceutical companies, issued a statement that innovators would be more willing to participate in delinkage schemes if the reward amount “ultimately allows a fair redistribution to those who innovated and took the initial risk to bring the science through early and clinical stages.”⁵⁹

The President’s Council of Advisors on Science and Technology report, the United Kingdom’s Antimicrobial Resistance review, and the DRIVE-AB report all estimate that prizes in the range of \$1 billion (in addition to sales) would be required in the antibiotic market.⁶⁰ It was estimated that a reward of this amount could quadruple the number of novel antibiotics over the next 30 years.⁶¹

Although such prizes may be costly upfront, delinkage systems could ultimately lead to substantial savings for health care systems by reducing or eliminating premiums normally imposed by innovators on drugs. For example, an analysis of Senator Bernie Sanders’ (I-VT) proposed Medical Innovation Prize Fund, which would allocate 0.55% of US GDP to reward health outcomes in a delinked model, estimated that it would have saved \$92 billion in 2016.⁶² Additionally, increased availability and access to novel drugs could—if effective—lower total health care costs by preventing costlier downstream use of health care resources.

57. IAAPD Act, *supra* note 32, at 77.

58. See Outtersen et al., *supra* note 15, at 4.

59. BEAM ALLIANCE, KEY GUIDELINES TO IMPLEMENT EFFECTIVE MEASURES TOWARD SMES TO REVIVE THE ANTIBACTERIAL R&D FIELD 14 (2017).

60. See PRESIDENT’S COUNCIL OF ADVISORS ON SCIENCE AND TECHNOLOGY, REPORT TO THE PRESIDENT ON COMBATING ANTIBIOTIC RESISTANCE 6 (2014) [hereinafter PCAST Report]; O’Neill, *supra* note 46, at 20; DRIVE-AB Report, *supra* note 32, at 6.

61. DRIVE-AB Report, *supra* note 32, at 6.

62. *Savings*, KNOWLEDGE ECOLOGY INT’L (2018), <https://delinkage.org/savings/> [<https://perma.cc/F5YL-KATW>] (last visited Aug. 13, 2019).

7. *Funding Sources*

Given the substantial resources needed to finance a delinkage model, commentators have suggested a broad range of potential funding sources. The most commonly cited are government health care budgets and higher insurance premiums.⁶³ Several proposals recommend the creation of international funds supported by contributions from multiple countries.⁶⁴ According to one estimate, between \$4 and \$5 billion could be raised if Organization for Economic Cooperation countries each contributed 0.01% of their GDPs.⁶⁵ Taxes could be imposed on certain prescriptions (e.g., a usage fee on all antibiotics to fund a reward pool for novel antibiotic drugs).⁶⁶ Finally, a competitive financing scheme has also been proposed in which individuals and employers would be required to contribute to pooled research and development funds managed by investment intermediaries.⁶⁷

B. Outcomes from Delinkage Models

Despite numerous proposals, there has been no large-scale implementation of delinkage models for drug development (Table 2).⁶⁸ However, several smaller, targeted prize competitions have launched. For example, the Longitude Prize, established in the United Kingdom in 2014, offers a £10 million prize fund for an accurate and affordable rapid point-of-care diagnostic test that would conserve antibiotic use.⁶⁹ No one has won it. Other biomedical prize competitions include the International AIDS Vaccine Initiative Challenge (protein research), the TB Alliance Challenge (drug production), the Archon Genomics X Prize (genome sequencing), and the CASP Prize (protein structure prediction).⁷⁰

63. See CHATHAM HOUSE REPORT, *supra* note 22, at 7.

64. See *id.* at 16.

65. See Outtersen et al., *supra* note 15, at 2–3.

66. See PCAST Report, *supra* note 60, at 41.

67. Tim Hubbard & James Love, *A New Trade Framework for Global Healthcare R&D*, 2 PLoS BIOLOGY 147, 150 (2004).

68. See MOREL, *supra* note 28, at 7.

69. LONGITUDE PRIZE, <https://longitudeprize.org/> [<https://perma.cc/E5DY-G6QK>] (last visited Aug. 13, 2019).

70. See *IAVI Posts \$150,000 Challenge on InnoCentive*, INTERNATIONAL AIDS VACCINE INITIATIVE (Dec. 17, 2008), <https://www.iavi.org/news-resources/press-releases/2008/iavi-posts-150-000-challenge-on-innocentive> [<https://perma.cc/XCE8-YU2Y>]; *A Global Effort to Reduce the Costs of a TB Drug Candidate*, TB ALLIANCE (Nov. 6, 2008), <https://www.tballiance.org/news/global-effort-reduce-costs-tb-drug-candidate> [<https://perma.cc/5PLV-SGG7>]; Peter Diamandis, *Outpaced by Innovation: Canceling an XPRIZE*, HUFFPOST (Aug. 22, 2013), https://www.huffpost.com/entry/outpaced-by-innovation-ca_b_3795710 [<https://perma.cc/S7PH-TKfV>]; Robert F. Service, *Google's DeepMind Aces Protein Folding*, SCIENCE MAGAZINE (Dec. 6, 2018), <https://www.sciencemag.org/news/2018/12/google-s-deepmind-aces-protein-folding> [<https://perma.cc/48H7-JAXM>].

The closest mechanisms to large-scale drug development delinkage models that have been implemented are advanced market commitments, which involve contracting ahead of time to buy products meeting specified conditions.⁷¹ The guaranteed purchase order is the prize. In 2007, with support from five countries and the Bill and Melinda Gates Foundation, the GAVI alliance established a \$1.5 billion advanced market commitment fund to subsidize purchases of qualified pneumococcal vaccines in developing countries.⁷² However, the fund was later criticized for having minimal influence on innovation, since manufacturers had already developed the vaccines prior to program implementation.⁷³ Another advanced market commitment is guaranteed volume purchases of childhood vaccines that the US government offers to ensure a stable supply of products that have vital importance to public health.⁷⁴

Delinkage-like models have been implemented in other sectors, including the defense, electric utility, and academic publishing industries.⁷⁵ A McKinsey study found an increase in innovation prize competitions in recent decades, noting a shift to providing incentives for specific rather than broad categories of innovation.⁷⁶ Among them are the X Prizes, a series of philanthropically-funded contests started by Peter Diamandis in 1995. The Ansari X Prize, the first such prize, offered a \$10 million reward for the development of a spacecraft capable of carrying three people into space twice within ten days.⁷⁷ The first-place team spent more than \$20 million to develop their winning spacecraft, while total spending by all competing teams exceeded \$100 million.⁷⁸ Although the competition was successful in generating publicity for the sector, the large investment-to-prize ratio highlighted the challenge of prize tailoring. By contrast, the Ashoka's Changemakers competitions, a series of contests focused on various social issues, awards smaller

71. Kevin Outterson & Aaron S. Kesselheim, *Market-Based Licensing for HPV Vaccines in Developing Countries*, 27 HEALTH AFFAIRS 130, 132 (2008).

72. *About the Pneumococcal Vaccine*, GAVI: The Vaccine Alliance, <https://www.gavi.org/investing/innovative-financing/pneumococcal-amc/about/> [<https://perma.cc/8DHR-BWUV>] (last visited Aug. 13, 2019).

73. See, e.g., Jens Plahte, *Is the Pneumococcal Vaccine Advance Market Commitment Motivating Innovation and Increasing Manufacturing Capacity? Some Preliminary Answers*, 30 VACCINE 2462, 2462 (2012).

74. See Alan R. Hinman, Walter A. Orenstein & Lance Rodewald, *Financing Immunizations in the United States*, 38 CLINICAL INFECTIOUS DISEASES 1440, 1440 (2004).

75. See CHATHAM HOUSE REPORT, *supra* note 22, at 9.

76. Jonathan Bays, Tony Goland & Joe Newsum, *Using Prizes to Spur Innovation*, MCKINSEY & CO. (July 2009), <https://www.mckinsey.com/business-functions/strategy-and-corporate-finance/our-insights/using-prizes-to-spur-innovation> [<https://perma.cc/3GRA-SW7L>].

77. *Launching a New Space Industry*, <https://www.xprize.org/prizes/ansari> [<https://perma.cc/MWF9-TZHB>] (last visited Mar. 7, 2020).

78. William A. Masters & Benoit Delbecq, *Accelerating Innovation with Prize Rewards*, INT'L FOOD POL'Y RES. INST. 8 (Dec. 2008).

prize amounts (around \$5,000).⁷⁹ The competition has been successful in fostering collaboration among competitors in online forums, resulting in the generation of novel ideas.⁸⁰

In general, commentators note that critical characteristics of effective prize competitions are clear and measurable objectives, a credible guarantee of payment, and impartial judges.⁸¹ Typical shortcomings include a lack of incentives for improvements above a certain threshold and the failure of sponsors to evaluate the impact of prizes on innovation and development.⁸²

C. Conclusions and Recommendations

The first steps in implementing a delinkage model for drug development would be to create a prioritization scheme and a well-defined target product profile. Other important details that must be worked out include:

- Defining model elements (e.g., full or partial delinkage, lump sum or milestone payments) that can gain consensus across government and industry stakeholders.
- Determining innovation-incentive prizes or market entry rewards large enough to affect new drug development.
- Identifying a suitable authority to coordinate and implement an international delinkage model.

Some drug manufacturers have already demonstrated their opposition to delinkage concepts and studies.⁸³ In response, several reports recommend that delinkage models remain voluntary, such that manufacturers can either opt-in to receive reward payments or retain their intellectual property rights.⁸⁴ However, it is unknown whether a delinkage reward model could coexist within the current patent-based system.

Since existing delinkage model proposals have predominantly targeted antimicrobial resistance, implementing a delinkage model for antibiotic development initially would be a logical start. Other possible early targets for such

79. ASHOKA CHANGEMAKERS, <https://www.ashoka.org/en-us/program/ashoka-changemakers> [<https://perma.cc/K7BA-3XN5>] (last visited Mar. 7, 2020).

80. See Bays, Goland & Newsum, *supra* note 76.

81. See *id.*; Masters & Delbecq, *supra* note 78, at 9.

82. See Bays, Goland & Newsum, *supra* note 76; Masters & Delbecq, *supra* note 78, at 10.

83. Catherine Saez, *Draft Cancer Resolution Might Be Set For Approval At World Health Assembly*, INTELLECTUAL PROP. WATCH (May 19, 2017), <https://www.ip-watch.org/2017/05/19/draft-cancer-resolution-might-set-approval-world-health-assembly/> [<https://perma.cc/W4EK-Y76K>] (reporting that drug companies were able to block a feasibility study of delinkage in a cancer prevention resolution).

84. Steven Shavell & Tanguy van Ypersele, *Rewards Versus Intellectual Property Rights*, 44 J. LAW & ECON. 525, 525 (2001).

models are tropical diseases, which are highly prevalent in low-income countries and thus do not attract a lot of investment from international for-profit manufacturers. After collecting data and evaluating the outcomes from these models, delinkage could then be expanded to other therapeutic areas of unmet need. Smaller pilot studies of delinkage models could eventually lead to an alternative system to the current patent-based model of drug development.

TABLE 1: SELECTED PROPOSED DELINKAGE MODELS

Proposal	Description
Antimicrobial Resistance Review	A partially delinked model that awards \$1 billion to cover research and development costs but continues to allow innovators to sell their drug for profit. Payment is conditional upon stewardship and global access.
BEAM Alliance Position Paper	A partially delinked “calibrated” model that awards innovators with payments to supplement value-based payments from payers. Prizes are based on flexible target product profiles and awarded for various milestones, even in the early stages of research and development.
Boston Consulting Group Report	A partially delinked model that awards \$1 billion to antibiotics meeting predefined target product profiles, paid in installments over eight years after approval. Recipients return 30% of their profits (up to \$1 billion). Payments are conditional on access, quality, and stewardship conditions.
Cancer Innovation Fund	A series research and development incentive models, including milestone prizes, end-product prizes, and open source dividends. Once a qualified product obtains approval, a panel awards prizes to entities for having shared knowledge, data, and technology to develop the product.
Chatham House Report	Rewards offered to antibiotics prioritized by global threat assessments. Financial participation begins among a core group of countries, coordinated by an international secretariat to manage pooled funding. The secretariat enters contracts, acquires full intellectual property rights, or establishes licenses with innovators.

Davos Declaration	An agreement among stakeholders in the pharmaceutical industry to support delinkage models that reduce the link between revenues and sales and mitigate financial risk for innovators and health systems.
DRIVE-AB Report	A partially delinked model that awards \$1 billion to antibiotics meeting predefined target product profiles, paid in installments over five years after approval. Payments are conditional upon product's sustainable use and equitable availability.
Duke Margolis PAVE Award	A partially delinked model that awards prizes to qualified antibiotics for the first few years following market approval. By the fifth- or sixth-year, funding is transitioned to value-based contracts with payers. Initial payments are conditional upon innovators demonstrating an increasing share of revenue is sourced from value-based contracts every year.
Improving Access to Affordable Prescription Drugs Act	A \$2 billion antibiotics prize fund that awards monetary prizes to innovators with qualified antibiotics based on criteria established by the NIH Director. Prizes are conditional upon waived patent rights, reasonable prices, marketing reports, and data disclosures.
Life Prize	An open collaborative research and development framework aimed to create an affordable, short-course treatment regimen effective against all forms of tuberculosis. Prizes are awarded to drugs in clinical trials that fulfill predefined criteria, including data and intellectual property sharing.
Medical Innovation Prize Fund	A prize fund equal to 0.55% of gross domestic product overseen by a Board of Trustees, which awards companies for certain drug approvals or interim milestones. The fund is funded by a fee on health insurers.
Norway Pilot Study	A partially delinked model that awards innovators "top-up payments" to supplement revenues from sales. Pilot study researchers determined that a partial delinkage model would be simpler to adapt to existing systems than a full delinkage model.

OECD Report	A comprehensive approach for incentivizing antibiotic development using various delinkage mechanisms, including monetary prizes, milestone prizes, and full patent buyouts for successfully developed products.
Outterson et al.	A delinked incentive framework involving marginal cost procurement contracts, partial buyout, or full buyout of an innovator's intellectual property. Payments are conditional upon rational use (e.g., no overmarketing or overselling).
PCAST Report	A fund that provides advance market commitments and milestone payments to incentivize antibiotic development. The government provides incentive payments of about \$400 million per drug.
Rex et al.	A fully delinked model that awards \$1 billion awarded to qualified antibiotics, paid in benchmark payments of \$200 million per year over 5 years. Five conditions could increase benchmark payments: novel mechanism of action, addressing unmet medical needs, reducing health care costs, targeting priority resistant pathogens, and post-approval label changes to expand indications.
TATFAR Report	A partially delinked "market-priced" model that awards innovators with small reward payments (~\$500 million) to complement revenues from unit sales. Payments are conditional upon sustainable use and access stipulations.

TABLE 2: SELECTED IMPLEMENTED DELINKAGE MODELS

Model	Description
Archon Genomics X Prize	A \$10 million prize awarded to "the first team to rapidly, accurately and economically sequence 100 whole human genomes to an unprecedented level of accuracy." The competition was later cancelled as it was "outpaced by innovation."

CASP Prize	A competition for protein structure prediction occurs every two years. In December 2018, Google subsidiary Deepmind's AI system AlphaFold won the competition.
International AIDS Vaccine Initiative Challenge	IAVI and InnoCentive offered a \$150,000 prize to the first researcher to design and create a mimic of a stable functional HIV envelope protein to aid in HIV vaccine development. Despite more than 300 responses, no submissions met the challenge requirements.
Longitude Prize	A £10 million prize fund (£8 million payout) for an accurate and affordable rapid point-of-care diagnostic test that conserves antibiotic use. The first team to be selected by the Longitude Committee by 2020 wins the prize.
TB Alliance	The TB Alliance, InnoCentive, and the Rockefeller Foundation awarded two winning teams \$20,000 each for developing a simpler and safer method of producing a tuberculosis drug candidate PA-824.

II. THE PUBLIC MANUFACTURING MODEL

Public manufacturing refers to the development and production of drugs by (or on behalf of) a government or nonprofit entity.⁸⁵ The public manufacturing model is a clear departure from the current pharmaceutical system, with a primary focus on patient and public health needs rather than profits.

The public sector is critical to pharmaceutical innovation. The US government is the largest single funder of basic and translational science in the world, with a budget of about \$39 billion in 2019.⁸⁶ In addition, numerous nonprofits support drug discovery and development.⁸⁷ But government and nonprofit investment has traditionally focused on early-stage investigations, with intellectual property often transferred to the private sector for later-stage clinical testing, and nearly always for production and dissemination of approved drug products. In leading conceptions, a public manufacturer would maintain control over drug

85. See Dan Liljenquist, Ge Bai & Gerard F. Anderson, *Addressing Generic-Drug Market Failures — The Case for Establishing a Nonprofit Manufacturer*, 378 NEW ENG. J. MED. 1857, 1858 (2018).

86. CONGRESSIONAL RESEARCH SERVICE, THE NATIONAL INSTITUTES OF HEALTH (NIH): BACKGROUND AND CONGRESSIONAL ISSUES 2 (Apr. 19, 2019), <https://crsreports.congress.gov/product/pdf/R/R41705> [<https://perma.cc/QPF4-EPL6>].

87. Rahul Nayak, Jerry Avorn & Aaron S. Kesselheim, *Public Sector Financial Support for Late Stage Discovery of New Drugs in the United States: Cohort Study*, 367 BMJ 1, 8 (2019).

development, testing, and production for widespread use, enabling the sale of medications at more affordable prices than could be expected of for-profit manufacturers. Such a model could help advance innovation in key areas of medical need that have been neglected or abandoned by the for-profit sector.⁸⁸ For example, in 2019, Amgen joined several other large pharmaceutical companies in reducing research and development investments in central nervous system drugs.⁸⁹

Public manufacturing has also been proposed in two production contexts: addressing market failures and drug shortages.⁹⁰ One example of a market at risk of failure is essential off-patent medicines supplied by small numbers of manufacturers. In such circumstances, due to the lack of competition, manufacturers have been able to increase prices, sometimes by shocking amounts. A highly publicized case of such price gouging was Turing Pharmaceuticals' over 5,000% markup of the antiparasitic drug pyrimethamine (Daraprim).⁹¹ Another example was Valeant Pharmaceuticals' price increase of penicillamine and trientine, treatments for a rare condition affecting the ability to process copper.⁹² These price hikes have made drugs prohibitively expensive for patients. Facilitating public manufacturing of such products would prevent pharmaceutical manufacturers like Turing and Valeant from cornering a market.⁹³ Overall, one-third or more of off-patent drugs may be supplied by three or fewer manufacturers and may be at risk for such market failures.⁹⁴

Generic drugs that are supplied by a limited set of manufacturers can also increase the risk of shortages. Recently, sterile intravenous medications used by hospitals—including sodium bicarbonate, injectable morphine, and sodium nitroprusside—suffered shortages in part due to natural disasters in Puerto Rico, a

88. Szymon Jaroslawski & Mondher Toumi, *Non-profit Drug Research and Development: The Case Study of Genethon*, 7 J. OF MKT. ACCESS & HEALTH POL'Y 1, 1 (2018); Ameet Sarpatwari, Dana Brown & Aaron S. Kesselheim, *Development of a National Public Pharmaceutical Research and Development Institute*, 48 J. LAW, MED. & ETHICS 225, 225 (2020).

89. Andrew Dunn, *Amgen Exits Neuroscience R&D as Pharma Pulls Back from Field*, BIOPHARMA DIVE (Oct. 30, 2019), <https://www.biopharmadive.com/news/amgen-exits-neuroscience-rd-as-pharma-pulls-back-from-field/566157/> [<https://perma.cc/EV8C-Q96U>].

90. See Reed Abelson & Katie Thomas, *Fed Up With Drug Companies, Hospitals Decide to Start Their Own*, N.Y. TIMES (January 18, 2018), <https://www.nytimes.com/2018/01/18/health/drug-prices-hospitals.html> [<https://perma.cc/86HH-SC5M>].

91. Jing Luo, Ameet Sarpatwari & Aaron S. Kesselheim, *Regulatory Solutions to the Problem of High Generic Drug Costs*, 2(4) OPEN FORUM INFECTIOUS DISEASES 1, 1 (2015).

92. See Melody Petersen, *How 4 Drug Companies Rapidly Raises Prices on Life-Saving Drugs*, L.A. TIMES (December 21, 2016), <https://www.latimes.com/business/la-fi-senate-drug-price-study-20161221-story.html>.

93. See Liljenquist, Bai & Anderson, *supra* note 85, at 1859.

94. Ravi Gupta et al., *Generic Drug Approvals Since the 1984 Hatch-Waxman Act*, 176 JAMA INTERNAL MED. 1391, 1391 (Sept. 2016); see also Ernst. R. Berndt, Rena M. Conti & Stephen J. Murphy, *The Landscape of U.S. Prescription Drug Markets, 2004-2016*, NBER Working Paper # 23640 (2017), <https://www.nber.org/papers/w23640> [<https://perma.cc/66KF-NT6E>].

major manufacturing location for such products.⁹⁵ Public manufacturing can help address this issue by providing hospitals with a more diverse supply of needed medications. By relying on manufacturers that are not profit-incentivized, the risk of unexpected price spikes would be minimized.

Although promising, the public manufacturing model, faces several challenges. Commentators have highlighted concerns over financing, particularly given the high manufacturing costs of certain therapeutics, such as biologics,⁹⁶ and the possibility of private companies undermining public manufacturers by reducing the price of their products upon the approval of competing products.⁹⁷ Additionally, public manufacturers may lack the resources and expertise to launch, produce, and distribute drugs at an efficient scale. Critics of the public manufacturing model have suggested that this may compound problems with drug access, diverting resources to building new public organizations instead of supporting established pathways.⁹⁸ Finally, at least one review raised concerns that public manufacturing could have the unintended consequence of stifling innovation,⁹⁹ arguing that if a public entity were to market a product at a low price, it could undercut the potential revenue for new products, which could result in the abandonment of investigational products targeting the same disease or therapeutic area.

A. Characteristics of Public and Nonprofit Manufacturing Models

The public manufacturing model is a relatively new concept for drugs. The Affordable Drug Manufacturing Act, proposed by Senator Elizabeth Warren (D-MA) in 2018, was one of the first proposals in the US for a government authority to manufacture generic drugs (Table 3). Other nonprofit companies in the US and Europe have launched in recent years, devoted to transforming parts of the prescription drug market (Table 4).

1. Intended Purpose

Existing public manufacturers can be divided into two groups: those dedicated to innovative drug development and those to affordable generic supply. Genethon, the Institute for OneWorld Health, and the Institute for Pediatric Innovation are

95. Alison Kodjak, *Hospitals Prepare To Launch Their Own Drug Company To Fight High Prices And Shortages*, NPR (Sept. 6, 2018), <https://www.opb.org/news/article/npr-hospitals-prepare-to-launch-their-own-drug-company-to-fight-high-prices-and-shortages/> [https://perma.cc/6XKZ-YVE7].

96. Jaroslawski & Toumi, *supra* note 88, at 3.

97. Liljenquist, Bai & Anderson, *supra* note 85, at 1857.

98. Szymon Jaroslawski et al., *Non-Profit Drug Research and Development at a Crossroads*, 35 PHARMACEUTICAL RES. 1, 3 (2018).

99. Jaroslawski & Toumi, *supra* note 88, at 3.

examples of nonprofit companies aimed at drug development in areas that have been neglected by the private sector. These nonprofits conduct similar activities as their private counterparts—including building in-house research teams, designing clinical trial protocols, managing research timelines, and guiding products through regulatory review—but have a public-oriented mission to provide their products close to marginal cost.¹⁰⁰

Other public manufacturers are dedicated to producing low-cost generic versions of drugs with expired patents. The most prominent example is Civica Rx, which launched in September 2018 as a nonprofit devoted to bringing stability to the hospital supply chain by manufacturing common generic drugs.¹⁰¹

2. Drug Criteria

Public manufacturers must decide which products to prioritize. Some nonprofits have a dedicated disease area upon formation, such as Genethon's focus on rare conditions or the Institute for OneWorld Health's focus on tropical diseases.¹⁰²

The nonprofit Civica Rx allows its hospital and health care system partners to prioritize which medications it manufactures. Its focus has been on stabilizing the pharmaceutical supply chain by supplying common hospital-administered generic drugs that have undergone price hikes or have drug shortages.¹⁰³ In October 2019, the nonprofit delivered its first manufactured drug, an injectable formulation of the antibiotic vancomycin, to a hospital facility in Utah.¹⁰⁴ Since then, Civica Rx has entered several partnerships with suppliers and health systems, including with Hikma Pharmaceuticals to provide 14 hospital drugs used in emergency care, surgery, pain, and hypertension;¹⁰⁵ with Thermo Fisher to develop nine drugs used

100. Victoria G. Hale, Katherine Woo & Helene Levens Lipton, *Oxymoron No More: The Potential of Nonprofit Drug Companies to Deliver on the Promise of Medicines for the Developing World*, 24(4) HEALTH AFF. 1057, 1059 (2005).

101. CIVICA RX, <https://civicarx.org/> [https://perma.cc/28PD-8EV7].

102. See GENETHON, <https://www.genethon.fr/en/> [https://perma.cc/YW6T-RWVL]; INSTITUTE FOR ONEWORLD HEALTH, <http://skoll.org/organization/institute-for-one-world-health/> [https://perma.cc/X4XR-8FVM].

103. Eric Palmer, *Hospital-backed Civica Rx Nabs Amgen Veteran as CEO and Targets 14 Drugs to Knock Off*, FIERCEPHARMA (Sept. 6, 2018), <https://www.fiercepharma.com/manufacturing/hospital-supported-civica-rx-to-produce-14-drugs-are-chronic-shortage> [https://perma.cc/YR93-4HM8].

104. Samantha Liss, *After Much Fanfare, Civica Rx Delivers Its 1st Drugs*, HEALTHCARE DIVE (Oct. 2, 2019), <https://www.healthcaredive.com/news/after-much-fanfare-civica-rx-delivers-its-1st-drugs/564189/> [https://perma.cc/C7MN-3HG7].

105. Press Release, PRNewswire, *Hikma and Civica Rx Sign Long-term Agreement to Reduce Generic Drug Shortages in the US* (July 23, 2019), <https://www.prnewswire.com/news-releases/hikma-and-civica-rx-sign-long-term-agreement-to-reduce-generic-drug-shortages-in-the-us-300889068.html> [https://perma.cc/9V6Y-BNE6] [hereinafter Hikma Press Release].

in critical or emergency care;¹⁰⁶ and with Blue Cross Blue Shield companies to create a new subsidiary devoted to lowering prices for high-cost generic drugs.¹⁰⁷

Proposals have called for government manufacturers to prioritize drugs with supply shortages or price hikes.¹⁰⁸ The Affordable Drug Manufacturing Act would establish an Office of Drug Manufacturing authorized to manufacture (or contract for the manufacture of) generic drugs under three listed conditions: that no company is manufacturing the drug; that fewer than three companies produce the drug and that the price has spiked or the drug is in shortage; or that fewer than three companies produce the drug, that the price is a barrier to patient access, and that the drug is listed as an “essential medicine” by the World Health Organization.¹⁰⁹

3. *Manufacturing Control*

Another variable in public manufacturing models is the degree of control public manufacturers exert over product development, production, and distribution. Given resource and expertise constraints, some nonprofits rely on outsourcing to contract organizations.¹¹⁰ For example, Civica Rx has stated that while its goal is to manufacture its own generic drugs, the company has initially relied on third-party manufacturers, such as Hikma Pharmaceuticals and Thermo Fisher,¹¹¹ while developing its own capabilities.¹¹²

Other nonprofit companies have chosen to sell their research programs to private developers. For example, the US Cystic Fibrosis Foundation developed a drug candidate and later sold it to a private company, which launched the product with a high annual price of \$300,000.¹¹³ Genethon also entered into exclusive licensing agreements with private biotechnology companies (e.g., AveXis, Spark Therapeutics) for several research programs.¹¹⁴ Although this model expedites

106. Jonathan Gardner, *Civica Advances Drug Supply Strategy with Thermo Fisher Deal*, BIOPHARMA DIVE (Jan. 16, 2020), <https://www.biopharmadive.com/news/civica-thermo-fisher-partner-drug-shortage-manufacturing/570617/> [https://perma.cc/4PBN-NSW9].

107. Press Release, Blue Cross Blue Shield Association, *Blue Cross and Blue Shield Companies Join Forces with Civica Rx to Lower Costs of Select High-Cost Generic Medications* (Jan. 22, 2020), <https://www.bcbs.com/press-releases/blue-cross-and-blue-shield-companies-join-forces-civica-rx-lower-costs-of-select> [https://perma.cc/3PAE-3EBG] [hereinafter Blue Cross Blue Shield Release].

108. Meredith Betz, *The New Nonprofit Pharmaceutical World: What's Up with That?*, NONPROFIT Q. (Sept. 12, 2018), <https://nonprofitquarterly.org/the-new-nonprofit-pharmaceutical-world-whats-up-with-that/> [https://perma.cc/RZ8Y-2BYA].

109. Affordable Drug Manufacturing Act, S.3775, 115th Cong. (2018) [hereinafter ADM Act].

110. Rena M. Conti, David O. Meltzer & Mark J Ratain, *Nonprofit Biomedical Companies*, 84(2) CLINICAL PHARMACOLOGY THERAPEUTICS 194, 197 (2008).

111. Hikma Press Release, *supra* note 105; Gardner, *supra* note 106.

112. Abelson & Thomas, *supra* note 90.

113. Jaroslawski et al., *supra* note 98, at 2.

114. Jaroslawski & Toumi, *supra* note 88, at 2.

clinical development, it also leads to ethical tensions. Commentators have noted that royalties returned to the nonprofit or government entity can be reinvested to support further research efforts. But while such reinvestment may be beneficial, high market prices limit patient access, which may be a core principle of the organization.¹¹⁵ This may be why Genethon has since announced its intentions to internalize its entire production chain, from discovery to manufacturing, enabling the organization to “fully recoup the public funds invested into research, and offer its products at affordable prices.”¹¹⁶ Such internalization is risky but can more reliably ensure fair market prices.

4. Governance

Public manufacturers should operate in ways that align with the core mission of promoting public health, which may require using different governance structures than private companies. Requiring philanthropic donors and major drug purchasers (e.g., hospital executives) to serve on the boards of nonprofit pharmaceutical companies would help ensure public accountability, given their financial interest in keeping drug prices low.¹¹⁷ Civica Rx’s Board of Advisors, for example, is comprised of several hospital directors, and their CEO is reportedly serving without compensation.¹¹⁸ By contrast, Harm Reduction Therapeutics, a nonprofit company devoted to developing a generic alternative to naloxone (Narcan), is led by a team comprised of former pharmaceutical executives¹¹⁹ and was primarily launched with a \$3.4 million grant from Purdue Pharma, a pharmaceutical company at the center of US growth in opioid sales.¹²⁰ This latter type of arrangement could lead to conflicts of interest, emphasizing the importance of transparency and autonomy.

5. Purchasing Agreements

One of the primary challenges facing public manufacturers is competing for market share with private companies that already have monopolies or broad market power. Private companies can use their control over distribution channels or market share to shut out competitors.¹²¹ These responses could be extreme enough

115. *See id.*

116. Jaroslawski et al., *supra* note 98, at 3.

117. Liljenquist, Bai & Anderson, *supra* note 85, at 1858.

118. Marc Harrison, *How the Not-For-Profit Civica Rx Will Disrupt the Generic Drug Industry*, STAT (March 14, 2019), <https://www.statnews.com/2019/03/14/how-civica-rx-will-disrupt-generic-drug-industry/> [https://perma.cc/2MUF-SHK5].

119. HARM REDUCTION THERAPEUTICS, <https://www.harmreductiontherapeutics.org/> [https://perma.cc/3TR5-U8NC].

120. Betz, *supra* note 110.

121. Kodjak, *supra* note 95.

to spur antitrust action¹²² but can also be addressed with long-term purchasing contracts. Civica Rx developed a model to commit hospitals and other drug purchasers to contracts for the purchase of generics at pre-determined low prices.¹²³ An initial proposal suggested that purchasers would have to commit 50% of their annual purchases to Civica Rx at an established price for at least five years.¹²⁴ In January 2020, Blue Cross Blue Shield companies provided an initial \$55 million to create a Civica Rx subsidiary dedicated to developing generic drugs currently identified as high cost, with the first drugs expected to be available by 2022.¹²⁵

6. Intellectual Property

Questions remain about how public manufacturers should handle intellectual property, both their own and those held by other companies. Should public manufacturers seeking to develop novel products pursue patents, and if so, what should they do with them? Nonprofit and state-run entities could seek patents to protect their inventions from private companies but make the patents available through patent pools subject to “copyleft”-like licenses that ensure their free use.¹²⁶ Such pools collect patent rights across multiple patent holders, making them available to third parties through nonexclusive licenses. The first patent pool in the public health space was UNITAID’s Medicines Patent Pool established in 2010, which improved access to treatments for HIV, hepatitis C, and tuberculosis in low- and middle-income countries.¹²⁷ Patent pools, however, have been criticized for resulting in anticompetitive licensing practices or collusion among patent pool members.¹²⁸ To address this, public manufacturers should work with partners to ensure patent pool policies and rules are explicitly designed to encourage licensing and prevent fraud or abuse, thus facilitating uptake of licensed drug products.¹²⁹

122. See, e.g., Gianna Melillo, *NY Attorney General, Federal Trade Commission Sue Martin Shkreli*, AM. J. MANAGED CARE (Jan. 27, 2020), <https://www.ajmc.com/newsroom/ny-attorney-general-federal-trade-commission-sue-martin-shkreli> [<https://perma.cc/DTA3-U9SU>].

123. Betz, *supra* note 110.

124. Alex Kacik, *Civica Rx Aims to Stabilize Fragile Pharmaceutical Supply Chain*, 49(3) MOD. HEALTHCARE (Jan. 19, 2019), <https://www.modernhealthcare.com/article/20190119/NEWS/190119931/civica-rx-aims-to-stabilize-fragile-pharmaceutical-supply-chain> [<https://perma.cc/48YH-WLZD>].

125. Blue Cross Blue Shield Press Release, *supra* note 107.

126. See Sarpatwari, Brown & Kesselheim, *supra* note 88, at 226.

127. MEDICINES PATENT POOL, <https://medicinespatentpool.org/> [<https://perma.cc/BJY9-P5ZG>].

128. See, e.g., WORLD INTELLECTUAL PROPERTY ORGANIZATION, *Patent Pools and Antitrust – A Comparative Analysis* (March 2014), https://www.wipo.int/export/sites/www/ip-competition/en/studies/patent_pools_report.pdf [<https://perma.cc/YM24-4WSY>].

129. See David B. Resnik, *A Biotechnology Patent Pool: An Idea Whose Time Has Come?*, 3 J. PHIL. SCI. & L. 1, 13–14 (2003).

Public manufacturers dedicated to supplying generic drugs will likely need to focus on drugs with expired patents and regulatory exclusivities to avoid costly litigation over intellectual property controlled by private manufacturers. Another intellectual property strategy for nonprofits is to leverage the investment that private sector companies have already made by recycling off-patent drugs for novel indications or accepting patent donations from pharmaceutical companies.¹³⁰

7. *Funding Sources*

In its initial stages, nonprofit manufacturing may have to rely on philanthropic and charitable donations, in addition to advanced purchases from health care organizations.¹³¹ For example, the launch of Civica Rx was made possible by three philanthropic organizations (the Laura and John Arnold Foundation [now Arnold Ventures], the Peterson Center on Healthcare, and the Gary and Mary West Foundation) and advance donations from health care institutions.¹³² A government-run operation would likely require resources from health care budgets or other funding mechanisms, such as fees imposed on payers. The continued operation and manufacturing of drugs can be sustained by revenues from sales. The goal should be for the public manufacturer to become financially self-sufficient through its products.¹³³

B. Outcomes from Public Manufacturing Models

Given the limited number of nonprofit and government drug manufacturers, the empirical literature evaluating the effectiveness of public manufacturing models is sparse. However, case studies suggest that public manufacturing can beneficially supplement the current pharmaceutical system. The Civica Rx nonprofit is the leading example, with 18 medications in production, including vancomycin, diazepam, fentanyl, ketamine, ondansetron, midazolam, and naloxone,¹³⁴ and a substantial consumer base of more than 1,200 hospitals.¹³⁵

Nonprofit development companies have also experienced success. Genethon has produced several gene therapy programs that it has since licensed to biotechnology companies. With increasing dedication to internalize its operations, its primary sponsors established a firm called YoosKesi to help obtain regulatory approval for its products and ensure its independence, thus replacing the need for

130. Hale, Woo & Lipton, *supra* note 100, at 1059.

131. Liljenquist, Bai & Anderson, *supra* note 85, at 1858.

132. Kodjak, *supra* note 95.

133. Conti, Meltzer & Ratain, *supra* note 110, at 4.

134. *See id.*

135. CIVICA RX, <https://civicarx.org/> [<https://perma.cc/28PD-8EV7>].

a licensing partner in the private sector.¹³⁶ An adjacent example in the medical device space is the Alfred Mann Foundation, a nonprofit focused on developing technologies for movement disorders, diabetes, limb loss, and pain.¹³⁷ The Foundation's incubator program has resulted in a robust portfolio of new companies commercializing these technologies.¹³⁸ These examples show that drug development can be successfully accomplished at cost levels far below what is generally offered by the pharmaceutical industry.

The Affordable Drug Manufacturing Act was the first proposed federal legislation calling for a government manufacturer of generic products.¹³⁹ Since it did not emerge from committee when it was first introduced in 2018, it was re-introduced in January 2020 by Senator Elizabeth Warren in an amended version that specifically directs the government manufacture certain key products, like naloxone, insulin, and antibiotics.¹⁴⁰ The bill is designed to be a fix rather than a replacement for the pharmaceutical industry. However, critics have expressed concerns that a government agency overseen by the Department of Health and Human Services would have neither the resources nor expertise to manufacture cost-effective generic drugs in competition with established private generic manufacturers.¹⁴¹ Other commentators suggest that efforts should be spent on other solutions to fix issues in the generics market, including more rigorous antitrust legislation or streamlined approval pathways for generics.¹⁴² But with a growing number of crises related to generic drug availability and cost, government and nonprofit manufacturing may be a prudent solution.

C. Conclusions and Recommendations

As the number of public manufacturers continues to grow, data from these experiences are needed to gauge achievements and identify areas of improvement and how well they operate in conjunction with other policy and structural changes to the broader pharmaceutical system. Key inquiries to guide future development of these models include:

- Aligning on outcome indicators (e.g., price, access) and methods of evaluation for performance-based assessments.

136. Jaroslawski & Toumi, *supra* note 88, at 2.

137. ALFRED MANN FOUNDATION, <https://aemf.org/> [<https://perma.cc/3375-DGSN>].

138. *See id.*

139. ADM Act, *supra* note 109109.

140. Affordable Drug Manufacturing Act of 2020, S.3162, 116th Cong. (2020).

141. Avik Roy, *Should the Federal Government Manufacture Generic Drugs?*, FREOPP (Dec. 19, 2018), <https://freopp.org/should-the-federal-government-manufacture-generic-drugs-99520f3821d7> [<https://perma.cc/WNK3-BB6E>].

142. Mark Terry, *Point-Counterpoint: Senator Warren's Generic Drug Proposal*, BIOSPACE (Dec. 26, 2018), <https://www.biospace.com/article/senator-warren-proposes-government-manufacture-of-generic-drugs/> [<https://perma.cc/G6BH-WLG5>].

□ Conducting qualitative surveys of payers and stakeholders in the pharmaceutical industry to better understand and predict private sector perspectives or reactions.

□ Modeling the viability of various manufacturing models (e.g., internalized processes vs. outsourcing) to ensure sustainability.

Public manufacturers will be distinctive in the current pharmaceutical market if they adhere to the mission of providing affordable and accessible drugs. This will require the appropriate governance, intellectual property, and incentive frameworks. Nonprofit and state-run entities must not turn into early-stage drug candidate developers for later investment by private sector companies. To protect against industry capture, governance of public manufacturing entities must be designed with clear objectives, transparency, and public participation in mind. The Democracy Collaborative proposal suggests creating public entities at the state or municipal level with two-tiered agency structures: one governing body and one operating body set up as a public trust.¹⁴³ This setup would provide public manufacturers insulation from political influence and create opportunities for public engagement. The proposal also recommends oversight boards comprised of different stakeholders (e.g., elected representatives, patient advocates) to ensure accountability. Public manufacturers must also maintain flexibility in their drug portfolio strategies to adapt to evolving patient and market needs. Finally, significant resources may need to be deployed for public manufacturing of increasingly complex drugs, including biologics.

TABLE 3: SELECTED PROPOSED PUBLIC MANUFACTURING MODELS

Proposal	Description
Affordable Drug Manufacturing Act 2020	Establishes an Office of Drug Manufacturing within the Department of Health and Human Services, charged with lowering prices, increasing competition, and addressing shortages in the market of prescription drugs. Authorizes the Office to manufacture or contract out the manufacture of generic drugs under certain conditions.

143. See Dana Brown, *Medicine for All: The Case for a Public Option in the Pharmaceutical Industry*, THE DEMOCRACY COLLABORATIVE (Sept. 2019), <https://thenextsystem.org/medicineforall> [<https://perma.cc/56D2-A6V4>].

Democracy Collaborative Proposal	Proposes a national public pharmaceutical research and development institute for full-cycle drug development with a commitment “to contributing to safe, adequate, and accessible supply of essential medicines in the US; to maximum transparency; and to management in the public interest.”
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TABLE 4: SELECTED IMPLEMENTED PUBLIC MANUFACTURING MODELS

Model	Description
Civica Rx	A nonprofit pharmaceutical company formed by a coalition of health care organizations that aims to manufacture hospital-administered generic drugs, specifically those in short supply. Funded by several philanthropic organizations and more than 800 US hospitals.
Genethon	A nonprofit research and development organization with mission to “design gene therapy products for rare diseases and to ensure their pre-clinical and clinical development in order to provide patients with access to these innovative treatments.” Historically, it has sought partnerships with biotechnology companies (e.g., AveXis, Bluebird Bio, Orchard Therapeutics) for clinical development and marketing of its products. Recently, it has increased focused on in-house production and distribution to maintain control over the sale of its products.
Harm Reduction Therapeutics	A nonprofit pharmaceutical company that aims to develop and manufacture a low-cost generic alternative for Narcan (naloxone). The nonprofit is primarily funded by a \$3.42 million grant by Purdue Pharma.
Institute for OneWorld Health	The first nonprofit pharmaceutical company in the US (now the drug development affiliate of PATH, a global health organization). Launched several successful drug development projects for diseases that included diarrheal disease, malaria, and visceral leishmaniasis.

III. THE PUBLIC-PRIVATE PARTNERSHIP MODEL

A public-private partnership (PPP) entails “a long-term contract between a private party and a [public entity], for providing a public asset or service, in which the private party bears significant risk and management responsibility.”¹⁴⁴ By combining the technical knowledge and management skills of private enterprise with the social accountability of public actors, PPPs are intended to serve as an efficient means of meeting societal needs.

As with all collaborations, a key challenge facing PPPs is achieving alignment between partnering parties.¹⁴⁵ Collaborators must agree on intended aims, timelines, and contractual terms, which can cause delay. For example, a survey of academic investigators found that contract negotiations were a primary barrier to collaboration with the pharmaceutical industry.¹⁴⁶

Another challenge is risk management. Information and resource asymmetries exist between organizations, which may lead to inappropriate distribution of risk among involved parties.¹⁴⁷ The suitable division of responsibilities and liabilities in a collaboration is particularly important for long-term research projects spanning multiple years or decades.

A. Characteristics of Public-Private Partnership Models

The number of biomedical PPPs has increased dramatically in recent years.¹⁴⁸ The leading US convener of such partnerships is the Biomedical Advanced Research and Development Authority (BARDA), a federal body created in 2006 to prepare society with biodefense and pandemic tools.¹⁴⁹ BARDA-organized PPPs have contributed to the development of more than 50 FDA-approved products addressing chemical, biological, radiological, and nuclear threats.¹⁵⁰ Around the

144. *Public-Private Partnerships – Reference Guide Version 1.0*, WORLD BANK INST. 1, 11 (2012).

145. Oktay Yildirim et al., *Opportunities and Challenges for Drug Development: Public-Private Partnerships, Adaptive Designs and Big Data*, 7 FRONTIERS IN PHARMACOLOGY 1, 5 (2016).

146. Marjan Amiri & Martin C. Michel, *Expectations and Satisfaction of Academic Investigators in Nonclinical Collaboration with the Pharmaceutical Industry*, 388 NAUNYN-SCHMIEDEBERG'S ARCH. PHARMACOLOGY 613, 613 (2015).

147. Jens K. Roehrich, Michael A. Lewis & Gerard George, *Are Public-Private Partnerships a Healthy Option? A Systematic Literature Review*, 113 SOC. SCI. & MED. 110, 114 (2014).

148. See *Build and Beyond: The (r)evolution of Healthcare PPPs*, PRICEWATERHOUSECOOPERS (2010), <https://www.pwc.se/sv/halso-sjukvard/assets/build-and-beyond-the-revolution-of-healthcare-ppps.pdf> [<https://perma.cc/6SVA-MMVY>].

149. BARDA STRATEGIC PLAN 2011 – 2016, BARDA (2011), <https://www.phe.gov/about/barda/Documents/barda-strategic-plan.pdf> [<https://perma.cc/75UB-7VAD>].

150. Kimberly Buckmon, *The Power of Partnership: BARDA Ushers in 50th FDA-Approved Product for Health Security*, ASPR BLOG (Oct. 10, 2019),

same time BARDA was established, various nonprofit organizations formed PPPs to spur research and development efforts for select diseases, especially those disproportionately affecting developing countries.¹⁵¹ These PPPs differ in scope, duration, and structure but all share a common goal of efficient drug development by relying on a bidirectional exchange of resources and expertise.¹⁵²

1. Participants

PPPs are formed by partnerships spanning three sectors: government, industry, and civil society.¹⁵³ PPPs often originate from the government, including the Medicines for Malaria Venture, which launched with funding from several European countries.¹⁵⁴ However, civil society organizations also play a critical role, given their awareness of unmet needs and access to patient networks. For example, the Drugs for Neglected Diseases Initiative (DNDi), originated from a working group organized by the nonprofit Médecins Sans Frontières.¹⁵⁵

2. Scope

Some PPPs are simple collaborations between one company and a specific group of researchers. Others involve strategic alliances between one company and an entire academic institution.¹⁵⁶ A few are expansive multi-stakeholder consortia involving numerous organizations spanning multiple sectors. For example, with an annual budget of more than €5 billion, the Innovative Medicines Initiative (IMI) oversees several smaller consortia that have distinct missions and fields more than 120 projects (Table 5).¹⁵⁷

<https://www.phe.gov/ASPRBlog/Lists/Posts/Post.aspx?ID=362> [https://perma.cc/W7AP-53F5].

151. Chan Harjivan & George Dougherty, *Drug Development for Government, Nonprofit, and Developing-World Markets*, 7 PHARMACEUTICAL TECH. SOURCING AND MGMT. (2011).

152. Importantly, some programs may fall under both the public manufacturing and PPP models. For example, Drugs for Neglected Diseases initiative (DNDi) is a nonprofit manufacturer (i.e., public manufacturing model) that engages in public-private partnerships (i.e., PPP model) to develop treatments.

153. Remco L. A. de Vruh & Daan J. A. Crommelin, *Reflections on the Future of Pharmaceutical Public-Private Partnerships: From Input to Impact*, 34 PHARMACEUTICAL RES. 1985, 1990 (2017).

154. DRUGS FOR NEGLECTED DISEASES INITIATIVE, <https://www.dndi.org/> [https://perma.cc/4TLF-YV8F]; MEDICINES FOR MALARIA VENTURE, <https://www.mmv.org/> [https://perma.cc/S9VW-MV4W].

155. *History*, DRUGS FOR NEGLECTED DISEASES INITIATIVE, <https://www.dndi.org/about-dndi/history/> [https://perma.cc/V6BV-CQ7R].

156. Yildirim et al., *supra* note 145, at 4.

157. Elisabetta Vaudano, *The Innovative Medicines Initiative: A Public Private Partnership Model to Foster Drug Discovery*, 6 COMPUTATIONAL AND STRUCTURAL BIOTECHNOLOGY J. (2013); Matthias Gottwald et al., *Public-Private Partnerships in Lead Discovery: Overview and Case Studies*, 34(9) ARCHIV DER PHARMAZIE 692, 695 (2016).

3. *Intended Purpose*

There are three broad categories of biomedical PPPs: access PPPs, precompetitive PPPs, and product development PPPs.¹⁵⁸ Access PPPs focus on promoting availability of drugs in developing countries, typically by overcoming obstacles in distribution systems.¹⁵⁹

Precompetitive PPPs generate foundational scientific concepts and infrastructure to advance drug development. They aim to reduce the risk of late-stage development failures, resulting in outputs such as research tools, platform technologies, shared databases, and predictive models. As their name implies, precompetitive PPPs do not directly compete with pharmaceutical companies, but rather supply insights that pharmaceutical manufacturers would take up in developing their own products.¹⁶⁰

The IMI consortia are one prominent example of precompetitive PPPs. Their research goals are proposed by pharmaceutical companies, which helps ensure that projects will have an impact on the industry.¹⁶¹ The output of these consortia can be grouped into five broad categories: validated models for drug development, approaches to predict adverse drug effects, compiled data from various sources for novel analysis, standards for drug development, and approaches for more efficient patient enrollment in clinical trials.¹⁶² Other consortia dedicated to specific disease areas, such as diabetes (SUMMIT) or severe asthma (U-BIOPRED), are limited to precompetitive efforts like biomarker identification and disease understanding.

Finally, product development PPPs identify and guide specific drug candidates through clinical trials for eventual regulatory approval and market launch.¹⁶³ Government and nonprofit institutions are motivated to participate in these PPPs because they gain the opportunity to “set the directions for innovation aimed at key public health milestones,”¹⁶⁴ while private sector innovators benefit from access to foundational research and relationships with key experts.

158. Roy Widdus, *Public-Private Partnerships: An Overview*, 99 TRANSACTIONS ROYAL SOC’Y TROPICAL MED. & HYGIENE S1, S5 (2005).

159. de Vruet & Crommelin, *supra* note 153, at 1987.

160. Gottwald et al., *supra* note 157, at 694.

161. *Id.* at 693.

162. Hugh Lavery, Magda Gunn & Michel Goldman, *Improving R&D Productivity of Pharmaceutical Companies Through Public-Private Partnership: Experiences from the Innovative Medicines Initiative*, 12 EXPERT REV. PHARMACOECONOMICS & OUTCOMES RES. 545, 546 (2012).

163. Widdus, *supra* note 158, at S5.

164. Mariana Mazzucato et al., *The People’s Prescription: Re-imagining Health Innovation to Deliver Public Value*, UCL INST. FOR INNOVATION AND PUB. PURPOSE 1, 7 (2018).

4. *Intellectual Property*

Intellectual property frameworks associated with PPPs affect downstream product marketing and access. Stevens et al. distinguished three such frameworks: partnership-focused, open collaboration, and hybrid.¹⁶⁵ In partnership-focused frameworks, rights to new knowledge and technology arising from PPPs (“foreground intellectual property”) are carefully negotiated among the various partners. Such frameworks are typically used in product development PPPs, for which intellectual property ownership of the final product is highly important. By contrast, open collaboration frameworks allow data sharing in the public domain. In the middle are hybrid frameworks, which are tailored to individual PPPs, but generally limit only some foreground intellectual property rights.

Precompetitive PPPs often employ open collaboration frameworks. For example, the Structural Genomics Consortium requires all results be placed in a public domain without restriction,¹⁶⁶ while the Alzheimer’s Disease Neuroimaging Initiative hosts its research on an open database, which has been cited by 750 publications.¹⁶⁷ Yet despite the open collaborative framework of many IMI consortia, several academic partners have criticized IMI for intellectual property policies that favor the private sector’s financial interests.¹⁶⁸ Academic partners have specifically decried ambiguous intellectual property policies that allow pharmaceutical industry partners to exploit technology developed as part of a research project, without having to obtain consent from other consortium partners.¹⁶⁹ Intellectual property frameworks and policies are therefore important to determine clearly upfront during the formation of PPPs to ensure transparency and trust among partners.

5. *Relationship with Regulatory Authorities*

Many PPPs have been set up to communicate with regulatory authorities in the early stages of drug candidate development. These PPPs can serve as knowledge platforms that allow regulatory authorities to better understand not only new disease evaluation tools, but also academic and industry stakeholder

165. Hilde Stevens et al., *Intellectual Property Policies in Early-Phase Research in Public–Private Partnerships*, 34 NATURE BIOTECHNOLOGY 504 (2016).

166. Gottwald et al., *supra* note 158, at 694.

167. Michael W. Weiner et al., *The Alzheimer’s Disease Neuroimaging Initiative: A Review of Papers Published Since Its Inception*, 9 ALZHEIMER’S & DEMENTIA e111 (2013).

168. Gunjan Sinha, *Spat Over IMI Funding and Intellectual Property*, 29 NATURE BIOTECHNOLOGY 473, 473 (2011).

169. *See id.* (quoting Michael Browne, Head of European Research and Development at University College, London: “The wording of the IP policy is ambiguous” such that academic institutions “get short shrift from both ends.”).

perspectives.¹⁷⁰ One prominent example is the Critical Path Initiative, which the FDA launched in 2004 to create new evaluation tools and standards for clinical trials. The Critical Path Initiative has since formed several consortia, including the Predictive Safety Testing Consortium (identifying safety biomarkers), Patient-Reported Outcome Consortium (evaluating patient-reported outcome instruments), and the Critical Path for Alzheimer's Disease (improving development process for treatments of neurodegenerative disorders), which have contributed to changing regulatory approaches and frameworks related to these diseases and concepts.¹⁷¹

6. Funding Sources

Funding sources for PPPs include grants, fees from participating member organizations, and donations from private foundations. Contributions are often split among partners. For example, 50% of research funding for the Netherlands' Technology Top Institute comes from the government and 25% each from public and private partners.¹⁷²

B. Outcomes from Public-Private Partnership Models

Comparative outcome assessments for PPPs are difficult to conduct as PPPs differ widely in purpose, number of participants, and financial budgets. Furthermore, appropriate outcome indicators are not well-established in the literature. A previous study revealed that only 2 out of a total of 12 suggested indicators of outcome for PPPs were considered measurable by experts.¹⁷³

A value assessment framework by de Vruh et al. suggested classifying outcome indicators for biomedical PPPs into five categories: networks and collaboration, research activity and knowledge, knowledge sharing and dissemination, human capital, and financials and operations.¹⁷⁴ This framework was applied to analyze four PPPs of varying size, location, and research focus: the Structural Genomics Consortium, the Alzheimer's Disease Neuroimaging Initiative, the Top Institute Pharma, and the IMI. The investigators concluded that the review "provide[s] clear evidence that precompetitive biomedical PPPs have

170. Michel Goldman, Carolyn Compton & Barbara B Mittleman, *Public-Private Partnerships as Driving Forces in the Quest for Innovative Medicines*, 2 CLINICAL AND TRANSLATIONAL MED. 1, 2 (2013).

171. Janet Woodcock & Raymond Woolsey, *The FDA Critical Path Initiative and Its Influence on New Drug Development*, 59 ANN. REV. OF MED. 1 (2008).

172. Peter R. Luijten et al., *Public-Private Partnerships in Translational Medicine: Concepts and Practical Examples*, 161 J. CONTROLLED RELEASE 416, 417 (2012).

173. Koen Dittrich, *How Valuable is Your Partnership? A Framework for Valuing Public-Private Research Partnerships in Biomedical Sciences*, DRUID SOCIETY MEETINGS 1, 23 (2012).

174. de Vruh & Crommelin, *supra* note 153, at 1990–91.

started to generate tangible outcomes.”¹⁷⁵ However, the study acknowledged that “multi-indicator, multi-method” approaches involving quantitative and qualitative analyses would be necessary in future evaluations of PPPs given the complex interactions between multiple stakeholders.¹⁷⁶

In 2016, the IMI appointed an expert group to conduct a socio-economic impact assessment of nine IMI consortia.¹⁷⁷ The group created an impact assessment model “to capture the complexities of actual practice but remain simple enough to be useful for empirical analysis and clarification of observed phenomena.”¹⁷⁸ This model involved three steps. First, the position of the PPP in the innovation system was identified (e.g., preclinical research, training, clinical development). Second, quantitative mediators and intermediate outcomes were characterized, including number of scientific publications, patents, licenses, databases, products, and trained personnel. Finally, socio-economic impact was assessed based on factors such as development time and costs, health benefits, new businesses, sales, and employment. The report summarized quantitative outputs for several ongoing IMI projects, highlighting the areas in which socio-economic impact had not yet been realized. The advantage of IMI’s impact assessment model is its ability to compare quantitative outputs and socio-economic factors at various stages of implementation. A similar impact assessment applied to PPPs outside of IMI consortia, including initiatives such as BARDA and the Critical Path Initiative, is needed.

Select PPPs have been successful in developing and commercializing novel treatments. For example, since 2003, DNDi has spearheaded the development of 7 new treatments targeted at various neglected diseases, including malaria, Chagas disease, leishmaniasis, and pediatric HIV.¹⁷⁹ The organization expects to develop 16 to 18 new treatments by 2023.¹⁸⁰

However, a common criticism of PPPs is they often lack safeguards to ensure reasonable pricing of the products they produce. For example, a BARDA program came under scrutiny for transferring a license to its Zika vaccine to Sanofi without affordable access conditions.¹⁸¹ BARDA subsequently partnered with Takeda

175. *See id.* at 1995.

176. *See id.* at 1992.

177. IMI SOCIO-ECONOMIC IMPACT ASSESSMENT EXPERT GROUP FINAL REPORT, INNOVATIVE MED. INITIATIVE 1 (May 2016), https://www.imi.europa.eu/sites/default/files/uploads/documents/reference-documents/SocioeconomicImpactAssessment_FINALMay2016.pdf [<https://perma.cc/R4EN-AU8F>].

178. *Id.* at 18.

179. DNDi *Achievements*, <https://www.dndi.org/achievements/> [<https://perma.cc/BAJ3-VTK2>].

180. *See id.*

181. Eric Sagonowsky, *U.S. Army Can’t Add A Pricing Safeguard to Sanofi’s Zika Vaccine License, Official Says*, FIERCEPHARMA (Apr. 25, 2017), <https://www.fiercepharma.com/vaccines/u-s-army-can-t-add-pricing-safeguard-to-sanofi-zika-license-official-says> [<https://perma.cc/GF8R->

Pharmaceutical, awarding the company an initial contract of \$19.8 million for Zika vaccine development through phase I testing and potential funding up to \$312 million for later-stage development,¹⁸² again without price guarantees. Control of drug pricing and marketing has often rested with the private partner due to the public entity's inability or unwillingness to implement or enforce an affordable price. Some public authorities have stated that exclusive licenses—absent price controls—are necessary for industry partners to invest in commercializing federally developed drugs.¹⁸³

C. Conclusions and Recommendations

Of the three PPP models discussed in this review, precompetitive PPPs are the most prevalent and most studied. As the number of PPPs continue to grow, additional research is needed to understand their successes and failures as well as steps in the drug development process in which they could play a greater role. Next steps should include:

- Identifying “bottleneck” areas of drug development or other issue areas best targeted by PPP models.
- Establishing broad consensus on output indicators to assess and track research project achievements and failures.
- Exploring various IP frameworks to implement in PPP contracts to ensure increased access to drugs upon successful development.

Early collaboration between private and public stakeholders has a positive influence in shaping the direction of drug development. PPPs are a proven method to facilitate this collaboration, having resulted in significant innovation. However, most PPPs continue to operate within the existing system that allows private pharmaceutical companies to retain patent-based monopolies, which can lead to high prices and suboptimal access. Reforms related to intellectual property rights associated with PPP models are necessary to prevent this outcome. Specifically, exclusive licenses granted to private partners should be discouraged. Any such licenses that are executed should include provisions designed to safeguard public interest, such as price controls, limits to the scope of exclusivity, or reductions to the years of exclusivity.

TABLE 5: SELECTED IMPLEMENTED PUBLIC-PRIVATE PARTNERSHIP MODELS

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182. Press Release, Takeda, *Takeda to Develop Zika Vaccine with up to \$312 Million in Funding from US Government* (Sept. 2, 2016), [https://www.takeda.com/newsroom/newsreleases/2016/Takeda-to-develop-Zika-Vaccine-with-up-to-\\$312-million/](https://www.takeda.com/newsroom/newsreleases/2016/Takeda-to-develop-Zika-Vaccine-with-up-to-$312-million/) [<https://perma.cc/6LLQ-W55K>].

183. See, e.g., Sagonowsky, *supra* note 181.

Model	Description
Alzheimer's Disease Neuroimaging Initiative (ADNI)	A collaboration between leading Alzheimer research centers, the National Institute on Aging, 13 pharmaceutical companies, and nonprofit foundations to identify, validate, and standardize disease biomarkers for use in clinical trials. Its core project is a multi-site, longitudinal clinical study tracking cognitive impairment and early Alzheimer's Disease. More than 750 publications have cited use of ADNI data.
Biomedical Advanced Research and Development Authority (BARDA)	The office within Department of Human and Health Services that procures and develops medical countermeasures against health threats to the US population. Partners with private biopharmaceutical companies to develop and stockpile vaccines and treatments for public health emergencies. Between 2007 and 2017, BARDA stockpiled 21 products and invested more than \$2.5 billion in advanced research and development of medical countermeasures.
Critical Path Initiative (CPI)	An independent organization focused on reducing the time, cost, and risk of drug development and regulatory review. Formed several PPP consortia under its umbrella, including the Predictive Safety Testing Consortium (identifying safety biomarkers), Patient-Reported Outcome Consortium (evaluating patient-reported outcome instruments), and the Critical Path for Alzheimer's Disease (improving development process for treatments of neurodegenerative disorders).
Drugs for Neglected Diseases Initiative (DNDi)	A public-private partnership established to develop drugs for disease neglected by industry, including sleeping sickness, Chagas disease, leishmaniasis, filaria, and later pediatric HIV/AIDS. The partnership relies on 50% public and 50% private contributions to fund research and development, has developed six new treatments since its inception, and expects to develop 10 to 12 additional new treatments by 2023.

eTOX	An IMI consortium of 13 pharmaceutical companies, 11 academic or nonprofit organizations, and 6 small and mid-sized enterprises dedicated to advancing predictive models of <i>in vivo</i> toxicology of novel drugs. The consortium created the largest database of preclinical safety data, with access to more than 7,000 systemic toxicity data sets corresponding to more than 1,800 compounds.
European Lead Factory (ELF)	An IMI consortium of 7 European companies, 13 public companies, and 10 small and mid-sized enterprises aimed at creating a pooled, diverse library of 500,000 compounds linked to a central screening center to identify novel targets.
Innovative Medicines Initiative (IMI)	A multi-consortia collaboration between the European pharmaceutical industry and the European Commission that implements and coordinates projects aimed at developing new tools and methods for drug development and improving data management. IMI projects have collectively identified over 460 biomarker candidates and over 20 new drug targets, in addition to developing over 50 animal models, over 100 <i>in vitro</i> models, and over 100 <i>in silico</i> models.
Innovative Medicines Initiative for Diabetes (IMIDIA)	An IMI consortium aimed at improving beta-cell function and identification of diagnostic biomarkers for treatment monitoring in diabetes. The consortium generated and commercially developed the first fully functional human beta cell line suitable for drug research, now used by pharmaceutical companies developing antidiabetic therapeutics.
Kinetics for Drug Discovery (K4DD)	An IMI consortium of 7 pharmaceutical companies, 9 public partners, and 4 small- and moderate-sized entities to enable the adoption of drug-target binding kinetics analysis in the drug discovery process and to improve prediction of binding kinetics to drug effect. Data generated by the consortium are integrated into a publicly accessible database.

Medicines for Malaria Venture (MMV)	A drug development venture devoted to discovery, development, and distribution of new antimalarial drugs. Partnering pharmaceutical companies include GlaxoSmithKline (to identify new drug leads) and Ranbaxy (to guide an antimalaria candidate through clinical trials).
NEWMEDS	An IMI consortium focused on developing new animal models that use brain recording and behavioral tests to identify innovative and effective drugs for schizophrenia. The consortium evaluated the impact of copy number variations conferring risk of schizophrenia by phenotyping more than 1,300 subjects carrying certain mutations.
SAFE-T	An IMI consortium creating sensitive and specific tests to diagnose and monitor drug-induced injury to the kidney, liver, and vascular systems. The consortium evaluated 153 potential translatable biomarker candidates for monitoring drug-induced injury.
Structural Genomics Consortium (SGC)	An IMI consortium of nonprofit researchers in collaboration with industry partners, focused on advancing structural biology. The consortium is committed to placing all data and research information into the public domain without restrictions and has published more than 2,000 novel protein structures and 40 chemical probes.
SUMMIT	An IMI consortium aimed at developing new biomarkers, imaging techniques, and animal models to advance drug development in diabetes. The consortium generated the largest GWAS data collection of over 26,000 cases of Type 1 and 2 diabetic nephropathy in addition to cardiovascular disease.
Top Institute Pharma (TI Pharma)	A public-private partnership aimed at building pharmaceutical research and development networks in five disease areas (autoimmune diseases, cardiovascular disease, cancer, infectious disease, and brain diseases). The partnership has resulted in 470 trained PhD and postdoctoral fellows, 750 publications, 41 lead compounds, 18 novel formulations, 11 biomarkers, 33 preclinical

	models, 28 clinical models, 11 research databases, and 87 research tools.
U-BIOPRED	An IMI consortium aimed at using information and samples from adults and children with severe asthma to understand more about the disease to aid in drug development. The consortium recruited a large clinical cohort of severe asthma patients: 1,025 adult and pediatric subjects were assessed at 14 clinical centers across Europe.

CONCLUSION

While lucrative to manufacturers, the current pharmaceutical innovation system does not incentivize the development of drugs of greatest patient or public health need and has led to pricing that patients and health care systems cannot afford. Delinkage, public manufacturing, and PPPs have been proposed as alternative models to address these shortcomings. Each model exhibits promise and can be meaningfully advanced in the short-term in several ways. For example, economic modeling of prize sizes necessary to induce manufacturers and of the budgetary impact of such prizes could convince government payers to fund delinkage pilots in discrete areas of market failure. Critical appraisal of the outcomes of existing public manufacturing models could inform their optimization and possible expansion. Finally, changes to intellectual property frameworks governing current product development PPPs could increase patient access to therapies emerging from such schemes. Timely investment in the resources necessary to perform such steps would likely reap large dividends.

Democracy and Health: Situating Health Rights within a Republic of Reasons

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Abstract:

Patterns of population health are keen reflections of structural inequities in societies, yet they are rarely subject to the requirements of democratic justification that other systemic inequalities provoke. Nor are health systems generally subject to societal scrutiny regarding fidelity to normative commitments of dignity and equality. Increased recognition of social determinants of health has challenged the narrow biomedical view of health as a stochastic phenomenon. More recently the sweeping devastation of the COVID-19 pandemic has laid bare structural injustices across many democracies, which contributed to widely disparate rates of infection and mortality. However, a lack of clarity remains regarding the conceptual linkages between the right to health and the institutional arrangements required for diverse people to live flourishing lives in a plural democracy. Here we attempt to contribute to a deeper understanding of the right to health by examining the implications of three related claims: (1) the content of a right to health (public health preconditions and care) reflects the arrangement of social institutions and the negotiation of difference in a plural democracy; (2) health systems are democratic institutions that should be organized around showing diverse persons equal moral consideration; and (3) democratic accountability can enhance health protections across borders. We argue that understanding the connections between health and democracy has profound implications for health system financing, priority-setting, and the organization and delivery of health goods and services, as well as oversight. Further, underscoring the connections between health and democracy inexorably calls upon us to enlarge our conception of the way legal determinants of health function and health rights are theorized.

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TABLE OF CONTENTS

INTRODUCTION	98
I. CONCEPTUALIZING HEALTH IN TERMS OF MORAL AND LEGAL RIGHTS WITHIN A DEMOCRACY.....	102
A. GROUNDING THE MORAL RIGHT TO HEALTH.....	102
B. DEFINITION AND SCOPE OF A LEGAL RIGHT TO HEALTH IN INTERNATIONAL LAW.....	104
C. TRANSFORMATIVE IMPLICATIONS OF NAVIGATING DEMOCRATIC DIFFERENCE THROUGH HEALTH.....	106
1. DISABILITY	107
2. WOMEN’S SEXUAL AND REPRODUCTIVE HEALTH	110
3. TRANS PEOPLE’S RIGHTS IN HEALTH	112
II. THE IMPLICATIONS OF ORGANIZING HEALTH SYSTEMS AROUND HEALTH RIGHTS	114
A. FAIRNESS IN FINANCING	117
B. FAIR AND DEMOCRATIC PRIORITY-SETTING	121
C. HEALTH SERVICE ORGANIZATION AND DELIVERY	126
D. INFORMATION TO BE ACTIVE CITIZENS REGARDING HEALTH	128
E. OVERSIGHT: REGULATION AND REMEDIES.....	131
III. HEALTH AND DEMOCRACY IN A GLOBALIZED WORLD.....	136
A. MIGRANTS.....	136
B. TRANSNATIONAL DRIVERS OF HEALTH, AND EXTRATERRITORIAL OBLIGATIONS (ETOS)	138
CONCLUSION	144

INTRODUCTION

The global COVID-19 pandemic caused by the novel coronavirus SARS-CoV-2 has focused the world's attention on the central importance of population health and health systems to the economic and social well-being of societies, and to the globalized interconnected world. It has also highlighted the challenges to the democratic rule of law through widely varying actions, and justifications for such actions, adopted by governments in response. For example, South Korea has adopted a detailed system of contact tracing that includes the publishing of personal information about infected persons' movements and medical care.¹ In countless countries, governments imposed near-total lockdowns, with police enforcement and criminal penalties for those who venture outside for non-permissible reasons.² And faced with evidence of rising gender-based violence due to such lockdowns, national and sub-national governments haven taken different measures, including, in Bogotá, Colombia, authorizing men and women to leave their homes to seek essentials on alternating days, with trans persons authorized to leave home on the days that accord with their gender identity.³ The essence of democracy—and human rights—is that a government's authority depends upon it making decisions that diverse members of the public perceive as justified and accept as legitimate.⁴ The crisis has thus brought to the fore long-standing questions about when and how governments can impose limitations on well-enshrined democratic rights and rule of law principles, in relation, for example, to declarations of states of exception and emergency, restrictions on freedoms of movement and association, and intrusions into privacy through surveillance of data or movements.⁵

1. Max. S. Kim, *Seoul's Radical Experiment in Digital Contact Tracing*, NEW YORKER (April 17, 2020), <https://www.newyorker.com/news/news-desk/seouls-radical-experiment-in-digital-contact-tracing> [https://perma.cc/DP7V-KCNQ].

2. Juliana Kaplan, Lauren Frias & Morgan McFall-Johnsen, *A Third of the Global Population Is on Coronavirus Lockdown — Here's Our Constantly Updated List of Countries and Restrictions*, BUS. INSIDER (April 17, 2020), <https://www.businessinsider.in/international/news/a-third-of-the-global-population-is-on-coronavirus-lockdown-x2014-hereaposs-our-constantly-updated-list-of-countries-and-restrictions/slideshow/75208623.cms> [https://perma.cc/8NUG-HWH7].

3. Julie Turkewitz, *To Beat the Virus, Colombia Tries Separating Men and Women*, N.Y. TIMES (April 15, 2020), <https://www.nytimes.com/2020/04/15/world/americas/virus-colombia-bogota-men-women.html> [https://perma.cc/K46R-EHQ8]. Bogotá's mayor, Claudia López, has expressly stated that transgender people can follow the gender with which they identify. *Id.*

4. G.A. Res. 217 (III) A, Universal Declaration of Human Rights, art. 21 (Dec. 10, 1948) [hereinafter UDHR].

5. See, e.g., *Governments Should Respect Rights in COVID-19 Surveillance*, HUM. RTS. WATCH (April 2, 2020), <https://www.hrw.org/news/2020/04/02/governments-should-respect-rights-covid-19-surveillance> [https://perma.cc/QD4M-WSZK]; *Human Rights Dimensions of COVID-19 Response*, HUM. RTS. WATCH (Mar. 19, 2020), <https://www.hrw.org/news/2020/03/19/human-rights-dimensions-covid-19-response> [https://perma.cc/NM2S-YP2C]; Francesco Martone, *Italy*,

Insisting upon adequate justification for limitations and derogation from civil rights established under constitutional and international legal frameworks is critical to our understandings of democratic orders. However, we focus here on situating the right to health itself—in normal times as well as crisis—in relation to a robust conception of democracy. The right to health under international law is neither a right to be healthy nor a right to health care only. Under international law, the right to health includes public health preconditions (water and sanitation) and health care that is available, accessible, acceptable, and of “adequate” quality.⁶ Our argument is three-fold: (1) equitable public health measures and health care are essential to constructing and sustaining substantive democracy in the twenty-first century; (2) the health system itself is a social institution that both reflects and refracts social norms—akin to a justice system—and therefore should be organized and function so as to ensure equal concern and respect for everyone in a democracy; and (3) in a highly interconnected world, the accountability of democratic governments must encompass people and impacts that cross borders.

On one level, the notion that population health and democracy are intimately connected seems self-evident. For instance, in the United States, the lead contamination of the water supply in the overwhelmingly Black community of Flint, Michigan, vividly reflects the exclusionary nature of American society on the basis of race and class.⁷ Indeed, at least since Rudolf Virchow’s work in the nineteenth century underscored the social origins of disease and the need to address epidemics through not merely medical but political means, there has been an awareness of health states and health systems as part of the fabric of a democratic polity.⁸ The great movements for universal health *care* in the twentieth century, including the creation of the National Health Service in the United Kingdom,⁹ were democratic struggles for inclusion in society—of organized labor, indigenous and

Democracy and COVID-19, TRANSNATIONAL INSTITUTE (April 14, 2020), <https://www.tni.org/en/article/italy-democracy-and-covid-19> [https://perma.cc/75PB-625F] (describing how COVID-19 is impacting democratic governance in Italy, from constraining political debate on pandemic-related decisions to the lack of oversight by an independent human rights institution).

6. International Covenant on Economic, Social and Cultural Rights art. 12, *opened for signature* Dec. 16, 1966, 993 U.N.T.S. 3 [hereinafter ICESCR]; Comm. on Econ., Soc. & Cultural Rights, *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12 of the Covenant on Economic, Social and Cultural Rights)*, ¶ 12(a)–(d), U.N. Doc. E/C.12/2000/4 (2000) [hereinafter *General Comment No. 14*].

7. Abby Goodnough, Monica Davey & Mitch Smith, *When the Water Turned Brown*, N.Y. TIMES (Jan. 23, 2016), <https://www.nytimes.com/2016/01/24/us/when-the-water-turned-brown.html> [https://perma.cc/44U3-9FUN].

8. RUDOLF VIRCHOW, *DISEASE, LIFE, AND MAN* (1958).

9. Christopher Newdick, *Can Judges Ration with Compassion? A Priority Setting Matrix*, 20 HEALTH & HUM. RTS. J. 107, 111 (2018).

landless persons, and the destitute.¹⁰ The narrative of health constructed by the steady rise of medicalization, beginning in the nineteenth century and accelerating in the latter half of the twentieth, and by then biomedicalization in the twenty-first century, is best thought of as a historically contingent shift constituted by economic and technological transformations, rather than some unchallengeable truth.¹¹

Nonetheless, today, health is generally conceptualized in highly technical, individualistic terms in Western societies, and in turn, the functioning of health systems is largely exiled from democratic deliberation to insulated islands of professional expertise, whether economic calculations of costs and benefits or clinical medicine. As a result, health and health systems are more complex to theorize in terms of democracy than civil rights, or even other social rights such as education,¹² notwithstanding that more than half of the countries in the world have recognized the right to health in domestic constitutional law, through incorporation of international law, or both.¹³

Moreover, scholarship and advocacy around the international right to health or “human rights-based approaches to health” often focus on programming regarding a specific area of health, such as reproductive, maternal, and child health;¹⁴ while critically important, this does not engage with necessary discussions of priorities and trade-offs in a democracy. Likewise, the growing international human rights literature on “global health governance” has tended to focus on how globalization has “upended national human rights implementation, shifting the protection and promotion of human rights from national governments to global institutions.”¹⁵ In turn, many scholars have proposed a bureaucratic, top-down version of “human rights implementation,”¹⁶ which takes a formal and

10. See generally Vicente Navarro, *Production and the Welfare State: The Political Context of Reforms*, 21 INT’L J. HEALTH SERV. 585 (1991).

11. See generally BIOMEDICALIZATION: TECHNOSCIENCE, HEALTH, AND ILLNESS IN THE U.S. (Adele E. Clarke et al. eds., 2010); Viviane Quirke & Jean-Paul Gaudillière, *The Era of Biomedicine: Science, Medicine, and Public Health in Britain and France After the Second World War*, 52 MED. HIST. 441 (2008).

12. See Comm. on Econ., Soc. & Cultural Rights, *General Comment No. 13: The Right to Education (Article 13 of the Covenant)*, U.N. Doc. E/C.12/1999/10 (1999).

13. See *A Constitutional Right to Health Care: Many Countries Have It, but Not the U.S.*, SCIENCE DAILY (July 19, 2013), <https://www.sciencedaily.com/releases/2013/07/130719104927.htm> [<https://perma.cc/EC66-H627>].

14. Flavia Bustreo & Curtis Doebbler, *Universal Health Coverage: Are We Losing Our Way on Women’s and Children’s Health?* 21 J. HEALTH & HUM. RTS. 229 (2019).

15. Benjamin Mason Meier & Lawrence O. Gostin, *Introduction to HUMAN RIGHTS IN GLOBAL HEALTH: RIGHTS-BASED GOVERNANCE FOR A GLOBALIZING WORLD*, at xxiii (Benjamin Mason Meier & Lawrence O. Gostin eds., 2018); cf. JENNIFER PRAH RUGER, *GLOBAL HEALTH JUSTICE AND GOVERNANCE* (2018).

16. For a broader critique of international human rights law as antidemocratic, see generally John O. McGinnis & Ilya Somin, *Democracy and International Human Rights Law*, 84 NOTRE DAME L. REV. 1739 (2009).

positivistic approach to international human rights law, and fails to illuminate the connections between the right to health and democratic contestation.

In suggesting an alternative socio-legal narrative, the Article proceeds as follows. First, in Part I, beginning with the idea that the central challenge in a plural democracy is the negotiation of difference among subjects of equal dignity,¹⁷ we conceptualize health as a moral and legal right, and argue that this conceptualization challenges conventional thinking in biomedicine and public health.¹⁸ Drawing on examples relating to disability rights, women's sexual and reproductive health rights, and trans people's rights in health, we note the ways in which understanding health as a democratic right deepens our understanding of heterogeneity in a plural democracy.

In Part II, we examine the implications of treating health as a right for the primary institution responsible for preventive and curative health care: the health system. The way health systems are currently conceived in much of the world obscures how health is largely a product of social structures and relations, not just individual behaviors or biological pathogens. There is no reason for health systems not to be analyzed and interrogated in the same ways as other core social institutions—such as justice and educational systems—which mediate between different interests in society, and reinforce (or fail to do so) normative commitments such as dignity and equality. For example, just as the U.S. criminal justice system reinforces racial injustice, the gaping disparities in maternal mortality ratios between white and African American women (approximately one-to-four)¹⁹ in the United States can be understood not just as lapses in quality of care but as the health system inscribing racial subordination on the bodies of women of color. We examine what it means to treat health systems as fundamental to shaping democratic norms, in terms of financing, priority-setting, the organization and delivery of services, information, and oversight.

In Part III, we address the cosmopolitan implications for health rights of today's globalized world where neither people nor determinants of health are contained within borders. Rather than shift the locus of attention in standard-setting and policymaking to global bureaucracies, we suggest that nascent initiatives relating to extraterritorial obligations (ETOs) of states can be used to extend social contracts and strengthen regulations that have implications for global equity in health and beyond. We conclude by asserting that making explicit the links between health and deliberative democracy has the potential to re-focus

17. Seyla Benhabib, *Toward a Deliberative Model of Democratic Legitimacy*, in *DEMOCRACY AND DIFFERENCE: CONTESTING THE BOUNDARIES OF THE POLITICAL* 68 (Seyla Benhabib ed., 1996).

18. NANCY KRIEGER, *EPIDEMIOLOGY AND THE PEOPLE'S HEALTH: THEORY AND CONTEXT* 126 (2011).

19. Mary Beth Flanders-Stepans, *Alarming Racial Differences in Maternal Mortality*, 9 J. PERINATAL EDUC. 50 (2000).

struggles for health and social equality in ways that should not only inform efforts to reform health systems, but also reshape our understanding of health rights more broadly.²⁰

I. CONCEPTUALIZING HEALTH IN TERMS OF MORAL AND LEGAL RIGHTS WITHIN A DEMOCRACY

A. Grounding the Moral Right to Health

John Rawls argued that justice requires the arrangement of major political and social institutions in such a way as to maximize the equality of primary goods because this is essential to enabling terms of fair cooperation and equality of diversely situated people.²¹ Primary social goods include civil liberties and political rights, income and wealth, and the social bases of self-respect, which are self-evidently affected by the legal and institutional frameworks in a society.

In his initial work, Rawls considered health not as a social good, but rather as a “natural” good, more akin to intelligence.²² However, an abundance of empirical evidence has emerged in recent decades that demonstrates that the distributions of health and ill-health are deeply influenced by “social determinants”—the “conditions in which people are born, grow, live, work, and age”²³—which are invariably shaped by the arrangements of institutions in a society. Further, the health system itself, responsible for preventive measures, such as vaccinations, as well as curative treatment, is itself a social determinant of health. In extending Rawls’ theory of justice to health, Norman Daniels has noted the extent to which patterns of health and ill-health are shaped by structural and institutional factors.²⁴ Daniels in turn argues that health should be subject to the demands of justice because it is essential to enabling people to preserve a normal range of opportunities in life.

Similarly, Amartya Sen has argued that we can claim a moral right to health because (1) health is essential for people to have the capability to exercise the functionings they value in life, and (2) health is subject to a considerable degree of social influence.²⁵ Further, in both cases, these opportunities and capabilities are

20. For a detailed discussion of construction of these linkages, *see generally* ALICIA E. YAMIN, *WHEN MISFORTUNE BECOMES INJUSTICE: EVOLVING HUMAN RIGHTS STRUGGLES FOR HEALTH AND SOCIAL EQUALITY* (2020) [hereinafter *MISFORTUNE*].

21. *See generally* JOHN RAWLS, *A Theory of Justice* 58–59 (1971).

22. *Id.* at 60–142.

23. WHO COMM’N ON SOC. DETERMINANTS OF HEALTH, *CLOSING THE GAP IN A GENERATION: HEALTH EQUITY THROUGH ACTION ON THE SOCIAL DETERMINANTS OF HEALTH* 26 (2008).

24. *See* NORMAN DANIELS, *Three Questions of Justice*, in *JUST HEALTH: MEETING HEALTH NEEDS FAIRLY* 11 (2007).

25. *See generally* Amartya Sen, *Elements of a Theory of Human Rights*, 32 *PHIL. & PUB. AFF.* 315 (2004).

not exercised in a vacuum; health enables people to participate as full and equal members of their polities. Both theories depend on the understanding that: (1) health has special moral value that sets it apart from an ordinary commodity (which could be allocated purely by the market); and (2) health is not merely a “natural” gift, nor a stochastic individual biological state, but rather is deeply influenced by the social and institutional arrangements in society.

Further, both theories are consistent with broader theories of distributive justice that call for deliberative processes to specify how to meet the health needs of diverse groups of people fairly when all health needs invariably cannot be met in rich or poor societies alike. Indeed, health may be the quintessential illustration of the most pressing challenge to plural democracy, which is the legitimate negotiation of difference. As Seyla Benhabib argues, democracy is better thought of not as a rigid form of government but rather “a model for organizing the collective and public exercise of power in the major institutions of society on the basis of the principle that decisions affecting the well-being of a collectivity can be viewed as the outcome of a procedure of free and reasoned deliberation among individuals considered as moral and political equals.”²⁶

It is important to underscore that this view of health as inextricably connected to dignity, justice, and the arrangement of institutions in a democracy, which underpins understanding health as both a moral and legal right, contrasts dramatically with how health is construed in biomedical research, clinical practice, and public health programming. When a physician evaluates one’s health using laboratory testing, health is defined as being within the “normal” range for a complete blood count, a liver function test, or a metabolic panel—i.e., the absence of disease or infirmity, or more broadly, the absence of pathology. This “negative” definition of health within biomedicine is simultaneously (1) abstracted from social context (and therefore permits standardization in research and classification of disease); and (2) susceptible to determination only through a specialized scientific expertise.²⁷ Further, as Nancy Krieger, a leading social epidemiologist, has noted, the biomedical model focuses on determinants of disease amenable to intervention through medical care in individual patients; it “considers social determinants of disease to be at best secondary (if not irrelevant), and views populations simply as the sum of individuals and population patterns of disease as simply reflective of individual cases.”²⁸ Conventional public health, in turn, operates through an inexorably utilitarian calculus that aggregates individual conditions to arrive at population burdens of disease, and compares cost-effectiveness among different interventions.

26. Benhabib, *supra* note 17, at 68.

27. *See generally* MISFORTUNE, *supra* note 20.

28. KRIEGER, *supra* note 18, at 137.

B. Definition and Scope of a Legal Right to Health in International Law

The special moral importance of health, as with all *rights*, is fundamentally connected to dignity and self-governance in the modern human rights canon.²⁹ Every country in the world, including the United States, has recognized at least some dimension of rights regarding health under international law.³⁰ Further, sometimes the domestic legal recognition of health-related rights is achieved through non-discrimination, protections of bodily integrity, or an increasingly expanded conception of the right to life in international law and in domestic jurisprudence.³¹ Moreover, international law functions not merely through domestication of ratified treaties, but also through more diffuse standard-setting and moral persuasion created when sovereign heads of nation states relinquish some of their powers to join with the commonwealth of nations in recognizing common standards of conduct.³² These common supranational standards of conduct, as well as the obligations that they entail, evolve over time in recursive relation with the particularities of specific national contexts and constitutional orders.

In 1946, the preamble to the World Health Organization (WHO) Constitution was the first mention of a right to health in international law, explicitly rejecting the idea that health is “merely the absence of disease or infirmity.”³³ The core formulation of the right to health in international human rights treaty law was set forth in Article 12(1) of the International Covenant on Economic, Social and Cultural Rights (ICESCR), which identifies the “right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”³⁴ Under this formulation, the right to health encompasses both underlying public health conditions (e.g., water and sanitation) and “*conditions which would assure to all medical service and medical attention*” and is subject to progressive achievement in accordance with resource availability.³⁵ In keeping with the notion that it enables us to preserve a range of opportunities, the right to health is not

29. See UDHR, *supra* note 4, art. 1.

30. OFFICE OF THE UN HIGH COMM’R FOR HUMAN RIGHTS & WORLD HEALTH ORG., FACT SHEET NO. 31: THE RIGHT TO HEALTH I (2008).

31. See, e.g., Convention for the Protection of Human Rights and Fundamental Freedoms art. 2, 14, *opened for signature* Nov. 11, 1950, E.T.S. 5; Ctr. for Legal Res. *ex rel* Câmpeanu v. Romania, 2014-V Eur. Ct. H.R. 1; Human Rights Comm., *General Comment No. 36 (2018) on Article 6 of the International Covenant on Civil and Political Rights, on the Right to Life*, U.N. Doc. CCPR/C/GC/36 (2018); Comm. on the Elimination of Discrimination Against Women, *Elisabeth de Blok et al. v. the Netherlands*, U.N. Doc. CEDAW/C/57/D/36/2012 (Mar. 24, 2014).

32. Robin West, *Reconsidering Legalism*, 88 MINN. L. REV. 154 (2003).

33. Constitution of the World Health Organization, *pmb.*, *opened for signature* July 22, 1946, 62 Stat. 2679, 14 U.N.T.S. 186.

34. ICESCR, *supra* note 6, art. 12.

35. *Id.* art. 12(2)(d); see generally *General Comment No. 14*, *supra* note 6.

merely a package of good and services; under international law, the right to health includes both freedoms (e.g. informed consent and freedom from coercion) and entitlements to goods, facilities and services.³⁶

Equal protection of the law is perhaps the foundational principle in a plural democracy, and non-discrimination is understood as a cross-cutting principle underlying the right to health, as well as other economic, social and cultural (ESC) rights under international law.³⁷ The Convention on the Elimination of Racial Discrimination, which the United States has ratified, raises the need to eradicate discrimination in relation to rights to “public health, medical care, social security and social services.”³⁸ The Convention on the Elimination of Discrimination Against Women (CEDAW) mandates that states “take all appropriate measures to eliminate discrimination against women in the field of health care in order to ensure, on a basis of equality of men and women, access to health care services, including those related to family planning.”³⁹ CEDAW also places a particular focus on rural women, acknowledging that categories of protected groups often mask intra-group differences.⁴⁰

The overarching importance of non-discrimination in health is two-fold. First, formal non-discrimination requires similarly situated people to be treated similarly under the law, implying that services accessible to one person should not be denied to another with the same condition based on race, gender, caste, etc.⁴¹ Second, international law goes beyond much U.S. constitutional law in that substantive non-discrimination requires treating differently situated people in ways that enable their equal effective enjoyment of rights, including the right to health.⁴² Conceptualizing health rights in terms of the distributional consequences that legal rules have upon diverse populations has been extremely important in building the normative scaffolding of the right to health under much constitutional and international law. Laws and policies that arbitrarily distinguish between groups, or alternatively formalistically fail to identify real differences between groups, can be—and have been—reformulated to afford equal effective enjoyment.

36. *General Comment No. 14, supra* note 6.

37. Non-discrimination is considered a principle in the ICESCR and is a substantive right in the International Covenant on Civil and Political Rights. *See* ICESCR, *supra* note 6, art. 2; International Covenant on Civil and Political Rights art. 2, *opened for signature* Dec. 16, 1966, T.I.A.S. No. 92-908, 999 U.N.T.S. 171.

38. International Convention on the Elimination of All Forms of Racial Discrimination art. 5(e)(IV), *opened for signature* Dec. 21, 1965, T.I.A.S. No. 94-1120, 660 U.N.T.S. 195.

39. Convention on the Elimination of All Forms of Discrimination against Women art. 12, ¶ 1, *opened for signature* Dec. 18, 1979, 1249 U.N.T.S. 13 [hereinafter CEDAW].

40. *Id.* art. 14(2)(b).

41. Comm. on Econ., Soc. & Cultural Rights, *General Comment No. 20 (2009) on Non-discrimination in Economic, Social and Cultural Rights* (art. 2, para. 2, of the International Covenant on Economic, Social and Cultural Rights), ¶¶ 8–9, U.N. Doc. E/C.12/GC/20 (2009).

42. *Id.*

For example, in a 2019 decision from the First Chamber, the Mexican Supreme Court held that a woman's right to health under the Mexican Constitution and international law was violated when she was denied a medically necessary abortion due to severe threats to her health.⁴³ The Court phrased this violation in specifically gendered terms—that the plaintiff “was prevented from having prompt and timely access to a health service that only women need with the consequent impairment of her right to the highest possible level of health and wellbeing.”⁴⁴ The Court reinforced that ensuring women's right to health necessarily requires both individual and systemic action “to avoid the historical disadvantage due to sex or gender from adversely affecting legitimate claims of justice.”⁴⁵

The integral nature of non-discrimination to a right to health calls into question the ways in which health systems foster discriminatory norms that differentiate between and hierarchize subgroups within society.⁴⁶ Indeed, what is most potentially transformative about addressing health as a right is that it forces us to re-evaluate the multiple layers of heterogeneity in our democratic institutions and broader democracies.⁴⁷ This is particularly true for those who are not white, able-bodied, cisgender men—the assumed subject upon which both medical knowledge and many laws are premised,⁴⁸ as described below in relation to disability, women's reproductive health and obstetric care, and trans persons' rights in health.

C. Transformative Implications of Navigating Democratic Difference through

43. Suprema Corte de Justicia de la Nación, Primera Sala [Supreme Court of Justice of the Nation, First House] 2019, Amparo en Revisión 1388/2015 ¶¶ 96–109, 150 (May 15, 2019) (Mex.), <https://www2.scjn.gob.mx/ConsultaTematica/PaginasPub/DetallePub.aspx?AsuntoID=190811> [<https://perma.cc/N52C-AZ3R>], translated in *Motion for Constitutional Relief Under Amparo Proceedings in Review 1388/2015*, PETRIE-FLOM CENTER FOR HEALTH LAW POLICY, BIOTECHNOLOGY AND BIOETHICS ¶¶ 51–64, 105, https://petrieflom.law.harvard.edu/assets/publications/AR_1388-2015_Tradux_FINAL.pdf [<https://perma.cc/V792-292X>] [hereinafter Amparo en Revisión 1388/2015].

44. *Id.* ¶ 137 (¶ 92 in the translation).

45. *Id.* ¶ 62 (¶ 22 in the translation).

46. See Didier Fassin, *Another Politics of Life is Possible*, 26 THEORY CULTURE & SOC'Y 44 (2009).

47. Cf. Bustreo & Doebbler, *supra* note 14.

48. Indeed, only in 1993 was the National Institutes of Health Revitalization Act passed, which mandated that National Institutes of Health-funded clinical trials include women and minorities. Since then, progress in centering these groups in medical research has been slow. See MARY HERRIGAN CONNORS CTR. FOR WOMEN'S HEALTH & GENDER BIOLOGY AT BRIGHAM & WOMEN'S HOSP., SEX-SPECIFIC MEDICAL RESEARCH: WHY WOMEN'S HEALTH CAN'T WAIT 3 (2014).

*Health**1. Disability*

The Convention on the Rights of Persons with Disabilities (CRPD) defines disability as a person's "long-term physical, mental, intellectual or sensory impairments which in interaction with various barriers may hinder their full and effective participation in society on an equal basis with others."⁴⁹ Further, Article 9 of the CRPD requires states to engage in "identification and elimination of obstacles and barriers to accessibility."⁵⁰ This definition of disability moves away from a focus on an individual's biological health state, by conceptualizing disability as the interaction between an individual, their long-term impairment, and their surroundings. Article 25 of the CRPD provides "that persons with disabilities have the right to the enjoyment of the highest attainable standard of health without discrimination on the basis of disability" and "that States Parties shall take all appropriate measures to ensure access for persons with disabilities to health services that are gender-sensitive, including health-related rehabilitation."⁵¹ This duty may include the provision of special measures to ensure effective enjoyment of health rights in practice.⁵²

The CRPD forces us to consider how the prevailing utilitarian public health paradigm of "species-typical functioning" evident in public health metrics such as Disability-Adjusted Life Years (DALYs) are predicated on devaluing the lives of disabled persons.⁵³ Under a DALY framework, health interventions for disabled people are calculated as having less impact on alleviating overall disease burden, based on the initial assumption that a disabled person is less functioning than an

49. Convention on the Rights of Persons with Disabilities art. 1, *opened for signature* Mar. 30, 2007, 2515 U.N.T.S. 3 [hereinafter CRPD].

50. *Id.* art. 9.

51. *Id.* art. 25.

52. In *Eldridge v. British Columbia (AG)*, Canada's Supreme Court held that the province had violated two patients' right to freedom from discrimination on the basis of disability under the Canadian Charter of Rights and Freedoms when they were treated during childbirth despite the communication barrier between themselves and the medical professionals, leading to them receiving "medical services that are inferior to those received by the hearing population." The Court wrote, "Given the central place of good health in the quality of life of all persons in our society, the provision of substandard medical services to the deaf necessarily diminishes the overall quality of their lives." *Eldridge v. British Columbia (AG)*, [1997] 3 S.C.R. 624 ¶ 94. In that case, which was decided before the CRPD entered into force, the Court created an entitlement for deaf patients to have access to a sign language interpreter during hospital care that enables them to communicate with healthcare providers and thus meaningfully participate in decisions relating to their health care.

53. Michael Ashley Stein, Janet E. Lord & Dorothy Weiss Tolchin, *Equal Access to Health Care Under UN Disability Rights Convention*, in *MEDICINE AND SOCIAL JUSTICE: ESSAYS ON THE DISTRIBUTION OF HEALTH CARE* 246–247 (Rosamond Rhodes, Margaret Battin, & Anita Silvers eds., 2012).

able-bodied/minded person, and therefore cannot be restored to full functionality even if they receive a health intervention for other conditions that the disabled person may be experiencing. Using this model to calculate the cost-effectiveness of introducing different health interventions leads to the unjust outcome that a disabled or chronically ill person who is already “disadvantaged in general . . . receives less medical attention for other ailments.” This model also implies that this disabled person may very well not merit other efforts to diminish the impacts of impairments (e.g., changing sidewalks and bathrooms to allow for wheelchairs or providing equal access to learning materials for visually and hearing impaired persons).⁵⁴ As Sudhir Anand and Kara Hanson have written, “[a] more appropriate measure of burden of disease must take account of the way in which individual and social resources can compensate for the level of disability experienced.”⁵⁵

The CRPD challenges us to focus on the complex interplay between a person with impairments of some kind and her environment in determining her ability to participate fully in her society.⁵⁶ To be clear: this does not mean that highly costly health-related interventions for persons with disabilities always take priority over more cost-effective measures that would impact a broader segment of society. However, a right to health does imply the need to accord diverse groups of people equal moral consideration through a deliberative process, giving due regard to the values of those most impacted as well as the broader democratic polity, rather than automatically opting for the “biggest bang for the buck.”

Moreover, the CRPD’s transformative implications also highlight the ways in which we understand informed consent and dignity in health systems. Article 3(4) mandates “[r]espect for difference and acceptance of persons with disabilities as part of human diversity and humanity,”⁵⁷ which makes clear that the goal of the CRPD is not to equalize individualized health states, but to challenge liberal democracies to adapt to different forms of otherness in order to ensure persons with disabilities can participate fully and equally in their societies regardless of their health state. That is, their “defects” need not be fixed in order for them to participate on an equal basis in their communities and societies.

Indeed, Article 12 of the CRPD on legal capacity, as interpreted in General Comment 1 of the CRPD Committee, suggests a new model of “supported decision-making” as opposed to “substitute decision-making” for people with mental disabilities.⁵⁸ As the CRPD Committee elaborates, a regime of supported

54. Amartya Sen, *Why Health Equity?* 11 J. HEALTH ECON. 659, 662 (2002).

55. Sudhir Anand & Kara Hanson, *Disability-Adjusted Life Years: A Critical Review*, 16 J. HEALTH ECON. 685, 694 (1997).

56. Sophie Mitra, *The Human Development Model of Disability, Health, and Wellbeing*, in DISABILITY, HEALTH AND HUMAN DEVELOPMENT 9 (2018).

57. CRPD art. 3(4).

58. CRPD, *supra* note 49, *See generally* Comm. on the Rights of Persons with Disabilities, *General Comment No. 1 (2014) on Article 12: Equal Recognition Before the Law*, U.N. Doc.

decision-making “comprises various support options which give primacy to a person’s will and preferences and respect human rights norms” and avoids overregulation of the lives of persons with disabilities.⁵⁹ In many existing legal regimes, once a medical expert deems a person to be incapable of making their own decisions, a legal guardian is appointed who is able to overrule the incapacitated person’s will and preferences with what is “perceived as being in his or her objective best interests.”⁶⁰

The supported decision-making framework of consent thus presents a fundamental challenge to the specialized knowledge of psychiatrists and other clinicians.⁶¹ The CRPD Committee notes: “Mental capacity is not, as is commonly presented, an objective, scientific and naturally occurring phenomenon. Mental capacity is contingent on social and political contexts, as are the disciplines, professions and practices which play a dominant role in assessing mental capacity.”⁶² Given that assessments of mental capacity are generally performed according to psychiatric “methods” that are inaccessible to laypersons (and carers who are not trained in scientifically accepted models of mental healthcare), supported decision-making and the broader disability rights paradigm behind the CRPD imply a tectonic shift in the ways in which a health system legitimately exercises power over human beings. Involuntary treatment of persons with psycho-social disabilities would require a different process of justification beyond the proverbial “second opinion” if supported decision-making were effectuated in practice. Further, the “effectiveness” of supported decision-making cannot be evaluated in short-term health outcomes alone, but also by whether persons with psycho-social disabilities are able to exercise agency without having to be re-hospitalized, incarcerated, or otherwise subjected to state confinement and control during a certain period.⁶³

CRPD/C/GC/1 (2014). [hereinafter *CRPD General Comment No. 1*].

59. *CRPD General Comment No. 1*, *supra* note 58, ¶ 29.

60. *Id.*

61. See P. Gooding, *Supported Decision-Making: A Rights-Based Disability Concept and Its Implications for Mental Health Law*, 20 *PSYCHIATRY PSYCHOL. & L.* 431 (2013); cf. M. Scholten & J. Gather, *Adverse Consequences of Article 12 of the UN Convention on the Rights of Persons with Disabilities for Persons with Mental Disabilities and an Alternative Way Forward*, 44 *J. MED. ETHICS* 226 (2018).

62. *CRPD General Comment No. 1*, *supra* note 58, ¶¶ 14-15.

63. For example, one indicator could be the rate and demographics of people who are involuntarily committed. See Jeffrey Swanson et al., *Racial Disparities in Involuntary Outpatient Commitment: Are They Real?* 28 *HEALTH AFF.* 816, 816 (2009) (“Overall, African Americans are more likely than whites to be involuntarily committed for outpatient psychiatric care in New York.”); see also Florian Hotzy et al., *Cross-Cultural Notions of Risk and Liberty: A Comparison of Involuntary Psychiatric Hospitalization and Outpatient Treatment in New York, United States and Zurich, Switzerland*, 9 *FRONTIERS PSYCHIATRY* 1 (2018) (discussing how New York and Zurich have different cultures with regard to involuntary hospitalization and concluding that New York’s culture focuses more on the “danger” of untreated mentally ill persons).

2. Women's Sexual and Reproductive Health

All persons who can become pregnant need to be able to make active choices in regard to their sexual and reproductive choices and health, not just to passively receive reproductive health care services. As a result of their socially constructed roles in reproduction, women's control over their reproductive choices and processes is a fundamental part of being able to participate as equal members of society. As recognized in the Committee on Economic, Social and Cultural Rights' (CESCR) General Comment 22, "[t]he right of women to sexual and reproductive health is indispensable to their autonomy and their right to make meaningful decisions about their lives and health."⁶⁴ Women require equal access to health facilities, goods, and services, and as recognized by the CEDAW Committee and CESCR, equal enjoyment of the right to health sometimes entails access to "additional" services, such as essential obstetric care.⁶⁵

Deciding the number and spacing of children is a fundamental part of women's self-governance;⁶⁶ laws and policies that curtail that agency in the name of demographic imperatives enshrine political discourses that women are less than fully equal subjects of rights. This principle of women's inherent dignity to make sexual and reproductive health choices undergirds the decisions by many national and supranational courts that have found that involuntary sterilization violates not only women's right to health, but also dignity and bodily integrity.⁶⁷ Involuntary sterilization is often systematically conducted on women from marginalized groups—such as women with disabilities or HIV, or certain ethnicities or social groups—yet they are frequently cloaked in medical justifications and health systems that structure medical judgments as unchallengeable.⁶⁸ While the health effects resulting from these injustices may be the same, health rights advocates and courts fail to highlight issues of democratic inequality and exclusion when they frame these issues narrowly as violations of individual bodily integrity, disconnected from the effects on the agency of women within a plural social

64. See Comm. on Econ., Soc. & Cultural Rights, *General Comment No. 22 (2016) on the Right to Sexual and Reproductive Health (Article 12 of the International Covenant on Economic, Social and Cultural Rights)*, ¶ 25, U.N. Doc. E/C.12/GC/22 (2016).

65. *Id.*; *General Comment No. 14*, *supra* note 6; Rep. of the Comm. on the Elimination of Discrimination Against Women, 20th and 21st Sessions, at 3, U.N. Doc. A/54/38/Rev.1 (1999).

66. And persons of all genders who gestate.

67. See, e.g., *Government of the Republic of Namibia v. LM and Others* (SA 49/2012), 2014 NASC 19 (Nov. 3, 2014) (Namib.); *I.V. v. Bolivia*, Preliminary Objections, Merits, Reparations, and Costs, Judgement, Inter-Am. Ct. H.R. (ser. C) No. 329 (Nov. 30, 2016), *request for interpretation of judgement denied*, Inter-Am. Ct. H.R. (ser. C) No. 336 (May 25, 2017); *V.C. v. Slovakia*, 2011-V Eur. Ct. H.R. 381.

68. Alicia Ely Yamin & Corey Prachniak-Rincón, *Compounded Injustice and Cautionary Notes for "Progress" in the Sustainable Development Era: Considering the Case of Sterilization of Women Living with HIV*, 41. HARV. J.L. & GENDER 396 (2018).

context. For example, in *Government of the Republic of Namibia v. LM and Others*, the Supreme Court of Namibia condemned the attitude of medical paternalism that led to the involuntary sterilization in the case, but failed to appreciate that this abuse is disproportionately rendered upon women who are marginalized in Namibian society by their HIV status.⁶⁹ “Intersectional discrimination,” as coined originally by Kimberlé Crenshaw, requires us to recognize how different and overlapping forms of difference inhibit women’s exercise of their health rights—and all democratic rights—in complex ways that require us to (1) pay attention to the lived experiences of diverse women; and (2) understand the contextually contingent ways in which the health system reinforces patterns of exclusion of particular groups that exist in the overall society.⁷⁰

Sexual and reproductive health and rights scholars and activists in Latin America have further challenged the prevalent ways that health systems, by being structured around the biomedical paradigm, constrain the agency of women (and other pregnant persons). Activists have argued that women are not only entitled to protection against lack of informed consent and obvious “disrespect and abuse” in receiving reproductive healthcare.⁷¹ Rather, they call for a recognition of “obstetric violence,” a concept now codified in legislation in a number of countries in Latin America,⁷² which constitutes an epistemic change that draws into question medical practices from episiotomies to unnecessary caesarean sections.⁷³ Rachelle Chadwick has identified how the concept of obstetric violence gains its “disruptive and radical edge” from its willingness to name forms of violence that have historically been “hidden and unacknowledged,” such as emotional and structural violence.⁷⁴ The struggles against obstetric violence are not about health states per se, such as reducing maternal mortality and morbidity. Obstetric violence

69. *Government of the Republic of Namibia*, ¶¶ 104-106.

70. Yamin & Prachniak-Rincón, *supra* note 68, at 410 (citing Kimberlé Crenshaw, *Mapping the Margins: Intersectionality, Identity Politics, and Violence against Women of Color*, 43 STAN. L. REV. 1241 (1991) (introducing the theory of intersectionality of race, gender, and other forms of discrimination)).

71. *Prevention and Elimination of Disrespect and Abuse During Childbirth*, WORLD HEALTH ORG. (2019), https://www.who.int/reproductivehealth/topics/maternal_perinatal/statement-childbirth-data/en [<https://perma.cc/DL97-BCEE>].

72. C.R. Williams, C. Jerez, K. Klein, M. Correa, J.J. Belizán & G. Cormick, *Obstetric Violence: a Latin American Legal Response to Mistreatment During Childbirth*, 125 BJOG: INT’L J. OF OBSTETRICS & GYNAECOLOGY 1208 (2018). For example, Argentina’s Comprehensive Law for the Sanction, Prevention, and Eradication of Violence against Women defines reproductive processes broadly, as including as pregnancy, labor work, childbirth, and post-partum periods. Law No. 26485, Apr. 14, 2009, BOLETÍN OFICIAL [B.O.] [OFFICIAL GAZETTE] no. 31632, at 1, 3 (citing Law No. 25929, Sept. 21, 2004, B.O. no. 30489, at 1, 1).

73. Carlos Herrera Vacafior, *Obstetric Violence: A New Framework for Identifying Challenges to Maternal Healthcare in Argentina*, 24 REPRODUCTIVE HEALTH MATTERS, May 2016, at 65.

74. Rachelle Chadwick, *Ambiguous Subjects: Obstetric Violence, Assemblage and South African Birth Narratives*, 27 FEMINISM & PSYCHOL. 489, 492 (2017).

encapsulates the more subtle—yet still damaging—regulation of women as embodied social beings in a democracy. By pathologizing women’s natural reproductive processes, pregnancy is treated as a “disease” and women’s bodies are reduced to objects on which “expert” medical interventions are deployed.

In *Killing the Black Body*, Dorothy Roberts has described the historical and present use of obstetric violence to police Black women’s reproduction in the United States. While Black women’s bodies were literally the mechanisms to reproduce white property under slavery, obstetric violence against Black women has more recently also been funneled through progressive medical advances such as oral and vaccine contraceptives.⁷⁵ For example, although birth control in the twentieth century was being disproportionately pushed onto Black women with the intention of reducing their birthrate based on racist and even eugenic narratives, services such as affordable and quality prenatal care were not similarly made widely available to Black women.⁷⁶ As Roberts argues, such obstetric violence is not only harmful because it leads to different reproductive outcomes for Black women, but also because these narratives serve the ideological function of making “racial inequality appear to be the product of nature rather than power.”⁷⁷ Obstetric violence “thus acts as a mode of discipline that is inextricably intertwined with multiple axes of social marginalization.”⁷⁸ In contrast, when diverse women’s lived experiences of their sexuality and bodies are taken into account through the naming of obstetric violence and the demand for redress, the univocal authority of the medical establishment to act upon the Black female body is challenged, and the ways in which racial inequality is constructed become visible. The end result is a challenge to the way in which the power to categorize people, construct difference, and establish social hierarchies is exercised through health systems and refracted throughout society.

3. *Trans People’s Rights in Health*

Yet another example of how conceiving of the right to health as having the goal of enabling people to live with dignity in a plural society—as opposed to attaining a specific individual health state—is acutely illustrated in situations faced by trans and gender-nonconforming people. In the biomedical paradigm, these persons have generally been treated as having disorders, such as “gender dysphoria.”⁷⁹ Yet in a ground-breaking case, *National Legal Services Authority v.*

75. DOROTHY ROBERTS, *KILLING THE BLACK BODY: RACE, REPRODUCTION, AND THE MEANING OF LIBERTY* 113–57 (1997).

76. *Id.*

77. *Id.* at 111.

78. Chadwick, *supra* note 74, at 493.

79. Jules Morgan, *Trans* Health: “Diversity, not Pathology,”* 2 LANCET 124 (2015); Zowie Davy & Michael Toze, *What is Gender Dysphoria? A Critical Systematic Narrative Review*, 3

Union of India, the Supreme Court of India recognized that there are divergences between dignity and medically-accepted health statuses.⁸⁰ The Court held that legal recognition of trans identity as a third category of gender identity is central to upholding the human rights and dignity of trans people in India. Moreover, the Court emphasized that legal recognition of this gender identity is based on the person's own gender expression, and is not contingent on gender reassignment surgery, hormones, or other medical procedures.⁸¹ Further, it called for local governments to take steps to provide gender-sensitive medical care as well as separate bathroom facilities for trans persons.⁸² In other countries, such legal reforms have been undertaken through public deliberation and legislation. In Argentina, the 2012 Gender Identity Law allowed for people to choose the name and gender listed on their identity documents without the need for a psychological or medical evaluation, and included sex reassignment treatment in the national health program.⁸³ Similarly, in 2013, the Dutch legislature voted to pass a bill allowing trans people to change their gender on identity documents without having to undergo hormones and surgery.⁸⁴ Thus, dignity and participation in society need not be predicated on access to procedures to attain a specific biomedically-defined outcome.

Just as in disability, the right to health does not automatically mean that trans persons should obtain all treatments they seek; it requires that their concerns be treated with equal concern and respect in the decision-making process. In *AC v. Berkshire West Primary Care Trust*, a case arising in the United Kingdom, the non-statutory citizens' committee reviewing petitions for care rejected a trans woman's request to fund a breast enlargement surgery to supplement her hormone treatment.⁸⁵ The National Health Service rejected her request on the basis that cis women would not be entitled to funding for a procedure that was classified as "cosmetic" and not medically necessary.⁸⁶ This decision was upheld by the citizens' committee, and later by a court. The court decision adopts a biomedical

TRANSGENDER HEALTH 159 (2018).

80. Nat'l Legal Serv. Auth. v Union of India, (2014) 5 SCC 438 (India).

81. *Id.* ¶ 129(2).

82. *Id.* ¶ 129(6).

83. Law No. 26743, May 24, 2012, B.O. no. 32404, at 2; *Breaking Down Barriers to Healthcare Access for Transgender People in Argentina*, ORGANISATION PANAMÉRICAIN DE LA SANTE, https://www.paho.org/hq/index.php?option=com_content&view=article&id=14259:breaking-down-barriers-healthcare-access-transgender-people-argentina&Itemid=135 [https://perma.cc/76TM-DQPD].

84. Wet van 18 december 2013, Stb. 2014, no. 1; *The Netherlands: Victory for Transgender Rights*, HUM. RTS. WATCH (Dec. 19, 2013), <https://www.hrw.org/news/2013/12/19/netherlands-victory-transgender-rights> [https://perma.cc/LV7H-CGF7].

85. *AC v. Berkshire West Primary Care Trust* [2010] EWHC 1162 (Admin), *aff'd*, [2011] EWCA Civ 247.

86. *Id.* ¶¶ 13-14.

view of “gender identity disorder” and relies heavily on “expert” medical opinion, largely ignoring the strong dignity and security interests at play for trans women seeking to change their appearance to conform with their gender identity. On the other hand, a contrary ruling granting the breast enhancement surgery at government expense may have reinforced stereotyped views of how women’s bodies should appear and suggested that dignity is contingent upon conforming to a stereotyped conception of femaleness.⁸⁷ As discussed in Part II, it is precisely because arguments about substantive equality and dignity in relation to health are invariably deeply contested, in law as well as the financing of health systems, that it is essential that these arguments be subjected to public scrutiny and deliberative practices, such as through both the citizens’ committee and the court.

In short, asserting health as a legal right changes the causal factors that we consider in relation to health states, from purely biological pathogens to social contexts and the legal rules that shape those social contexts. In turn, it must change the way we evaluate programs and progress. That is, we are concerned not merely with the number of deliveries or psychiatric treatments. If human rights are to be used effectively to foster democratic institutions and practices with respect to health, we are interested in the dynamic interaction between embodied social beings and their environment, including democratic institutions and socio-political discourses. We understand intuitively that the right to food requires access to adequate nutrition, but is not violated by individual choices to fast, nor captured by disaggregated calorie or protein measures. Similarly, promoting health rights in ways that strengthen democratic practices cannot be reduced to pasting equity indicators onto standard health outcomes. Understanding the application of human rights in health in this narrow way invariably consigns it to palliative measures, which disregard the connections to broader dignity and equality concerns of differently situated people. Rather, advancing health rights requires engaging with the far more complex arguments regarding what is required in a democracy for human beings with diverse socioeconomic, racial, ethnic, gender, and other identities—and widely divergent health needs and conditions—to receive equal moral consideration both within health systems and the larger society.

II. THE IMPLICATIONS OF ORGANIZING HEALTH SYSTEMS AROUND HEALTH RIGHTS

There is overwhelming evidence that social determinants of health are

87. For scholarship discussing the politics of passing within the trans community, see, for example, Katrina Roen, “*Either/Or*” and “*Both/Neither*”: *Discursive Tensions in Transgender Politics*, 27 *SIGNS* 501 (2001); C. Riley Snorton, “*A New Hope*”: *The Psychic Life of Passing*, 24 *HYPATIA* 77 (2009); Sandy Stone, *The Empire Strikes Back: A Posttranssexual Manifesto*, in *THE TRANSGENDER STUDIES READER* 221 (Susan Stryker & Stephen Whittle eds., 2006).

responsible for a far larger portion of the unequal distribution of morbidity and mortality than medical care.⁸⁸ However, the health system itself is a social determinant, and acts in synergy with other social determinants. The WHO defines a health system as “all organizations, people and actions whose *primary intent* is to promote, restore or maintain health. This includes efforts to influence determinants of health as well as more direct health-improving activities.”⁸⁹ As COVID-19 has unfolded, for example, it has become increasingly clear how the patchwork structure of the United States medical care system, and lack of public health systems, reinforces marginalization and risk among the most vulnerable.⁹⁰ As Wendy Parmet has written, “health law has helped to fashion a health care system that lacks the redundancy and resiliency that will be critical in a pandemic.”⁹¹ A “crisis” approach to pandemics will never be as effective as a health and legal system that “recognizes that health care itself is a public health issue.”⁹² In the United States, health insurance is far from universal—in 2018, 8.5% of U.S. residents (27.5 million people) had no health insurance at any point that year.⁹³ The overall result in the midst of this pandemic has been that low-income people, designated as “essential workers,” continue to go to work at jobs that often involve high levels of public contact or alternatively risk economic ruin, due to how the economy writ large and the health system are structured.⁹⁴ That is,

88. See, e.g., Paul Braveman, Susan Egerter & David R. Williams, 32 *The Social Determinants of Health: Coming of Age*, 32 ANN. REV. PUB. HEALTH 381 (2011); Nancy Krieger, *Methods for the Scientific Study of Discrimination and Health: An Ecosocial Approach*, 102 AM. J. PUB. HEALTH 936 (2012); Leslie London, Chuma Himonga, Nicole Fick & Maria Stuttaford, *Social Solidarity and the Right to Health: Essential Elements for People-Centered Health Systems*, 30 HEALTH POL’Y & PLAN. 938 (2015); Michael Marmot, *Social Determinants of Health Inequalities*, 365 LANCET 1099 (2005); Michael Marmot & Jessica J. Allen, *Social Determinants of Health Equity*, 104 AM. J. PUB. HEALTH S517 (2014); David Sanders, *A Global Perspective on Health Promotion and the Social Determinants of Health*, HEALTH PROMOTION J. AUSTRAL. 165 (2006).

89. WORLD HEALTH ORG., EVERYBODY’S BUSINESS: STRENGTHENING HEALTH SYSTEMS TO IMPROVE HEALTH OUTCOMES—WHO’S FRAMEWORK FOR ACTION 2 (2007).

90. See Max Fisher & Emma Bubola, *As Coronavirus Deepens Inequality, Inequality Worsens Its Spread*, N.Y. TIMES (Mar. 15, 2020), <https://www.nytimes.com/2020/03/15/world/europe/coronavirus-inequality.html> [<https://perma.cc/K3LV-N4DW>]; Michael T. Osterholm & Mark Olshaker, *Why We Are So Ill-Prepared for a Possible Pandemic Like Coronavirus*, TIME (Feb. 4, 2020), <https://time.com/5777923/america-prepared-pandemic-coronavirus> [<https://perma.cc/H3XV-ZYM3>]; *The United States Leads in Coronavirus Cases, but Not Pandemic Response*, SCIENCE (April 1, 2020), <https://www.sciencemag.org/news/2020/04/united-states-leads-coronavirus-cases-not-pandemic-response> [<https://perma.cc/SL7U-Z78F>].

91. Wendy Parmet, *Unprepared: Why Health Law Fails to Prepare Us for a Pandemic*, 2 J. HEALTH & BIOMEDICAL L. 157, 160 (2006).

92. *Id.*

93. EDWARD R. BERCHICK, JESSICA C. BARNETT & RACHEL D. UPTON, U.S. CENSUS BUREAU, P60-267 (RV), HEALTH INSURANCE COVERAGE IN THE UNITED STATES: 2018, at 2 (2019), <https://www.census.gov/content/dam/Census/library/publications/2019/demo/p60-267.pdf> [<https://perma.cc/V4KX-5JLC>].

94. Of course, this reality is not limited to the United States. Revisiting the 2010 Marmot

rather than mitigating the social inequalities in U.S. society, the patchwork and marketized health system is amplifying the marginalization of already disadvantaged groups in this pandemic.

Yet, in “normal” times, we reflect too little on the ways in which health systems reflect on democratic commitments, including through the regulation of diverse populations’ rates of birth, death, illness, fertility, and more.⁹⁵ As noted above, the stark disparities in maternal mortality ratios between white and African American women in the United States⁹⁶ have received heightened attention in the mainstream media in recent years.⁹⁷ One response would be to treat this disparity solely as a quality of care issue to be fixed by technical checklists and protocols.⁹⁸ Another would be to underscore the truth that women of color still face the damaging health effects of the toxic interactions of racial, gender and class discrimination from the moment they are born in the United States.⁹⁹ But it is

Review on Health Equity in England in a new review in 2020, Michael Marmot and his coauthors sought to interrogate why after a century of increasing life expectancy in England, these increases had slowed dramatically, and why life expectancy in fact decreased among the most deprived populations in the country. While they could not conclusively attribute the drop to austerity, they wrote that any and all of the following factors were likely contributing:

From rising child poverty and the closure of children’s centres, to declines in education funding, an increase in precarious work and zero hours contracts, to a housing affordability crisis and a rise in homelessness, to people with insufficient money to lead a healthy life and resorting to foodbanks in large numbers, to ignored communities with poor conditions and little reason for hope. And these outcomes, on the whole, are even worse for minority ethnic population groups and people with disabilities.

MICHAEL MARMOT ET AL., *HEALTH EQUITY IN ENGLAND: THE MARMOT REVIEW 10 YEARS ON* 5 (2020). Moreover, most of the concluding recommendations in the review were not focused narrowly on the health system, but advocated for increased social spending to improve employment, housing, and environmental conditions. *Id.* at 151.

95. See LYNN P. FREEDMAN ET AL., MILLENNIUM PROJECT TASK FORCE ON CHILD & MATERNAL HEALTH, WHO’S GOT THE POWER? TRANSFORMING HEALTH SYSTEMS FOR WOMEN AND CHILDREN (2005); Gunilla Backman et al., *Health Systems and the Right to Health: an Assessment of 194 Countries*, 372 LANCET 2047 (2008); Lynn Freedman, *Achieving the MDGs: Health Systems as Core Social Institutions*, 48 DEVELOPMENT 19 (2005) [hereinafter Freedman, *Achieving the MDGs*]; Paul Hunt, *The Human Right to the Highest Attainable Standard of Health: New Opportunities and Challenges*, 100 TRANSACTIONS ROYAL SOC’Y TROPICAL MED. & HYGIENE 603 (2006).

96. Flanders-Stepans, *supra* note 19.

97. Allyson Chiu, *Beyoncé, Serena Williams Open up About Potentially Fatal Childbirths, a Problem Especially for Black Mothers*, WASH. POST (Aug. 7, 2018), <https://www.washingtonpost.com/news/morning-mix/wp/2018/08/07/beyonce-serena-williams-open-up-about-potentially-fatal-childbirths-a-problem-especially-for-black-mothers> [<https://perma.cc/96D7-DGBJ>].

98. ATUL GAWANDE, *THE CHECKLIST MANIFESTO: HOW TO GET THINGS RIGHT* (2009); cf. Kelly Grant, *Surgical Checklists Have Little Effect on Patient Outcomes, Study Finds*, GLOBE & MAIL (March 12, 2014), <https://www.theglobeandmail.com/news/national/surgical-checklists-have-little-effect-on-patient-outcomes-study-finds/article17473716> [<https://perma.cc/B989-6FNQJ>].

99. See generally Arline T. Geronimus et al., *Do US Black Women Experience Stress-Related Accelerated Biological Aging?* 21 HUM. NATURE 19 (2010); Arline T. Geronimus et al., *Race-*

equally true, as Elizabeth Dawes Gay of Black Mamas Matter writes, that:

Racial discrimination within the health-care setting is a modern problem built on the legacy of slavery, reproductive oppression, and control of medicine and black bodies Today racial discrimination in clinical care presents in a variety of ways. Research has shown that implicit racial bias may cause doctors to spend less time with black patients and that black people receive less-effective care. Doctors are also more likely to underestimate the pain of their black patients. And anecdotes of disrespect and mistreatment abound.¹⁰⁰

As has been underscored in the COVID-19 pandemic, the U.S. health system reinforces societal racism not just in the treatment individual Black patients may receive by practitioners at the micro-level, but through macro-level issues (e.g. financing) and meso-level issues (e.g. inadequacy of primary care). As these issues disproportionately affect people of color, the design and functioning of the health system treats racial difference in ways that undermine the equal concern and respect that is owed to diverse members of a democracy.

Yet, in human rights scholarship and practice there has been little examination of the role of the health system—whether in the United States or elsewhere—in upholding or violating fundamental normative commitments in the same ways as, for example, the justice system. As Lynn Freedman writes, “Human rights activists have long understood the political arms of the state—prisons, judicial systems and police forces—to have the power to exclude, abuse and silence. But rarely are . . . the social institutions on which [health rights] depend approached with the same understanding.”¹⁰¹

Here we aim to contribute to that understanding of the requirements for health systems to be organized around respecting, protecting and fulfilling the right to health within a democracy. Specifically, we consider implications for: (1) financing, (2) priority-setting, (3) information, and (4) judicial as well as other oversight of health systems.

A. Fairness in Financing

The right to health is subject to progressive achievement in accordance with

Ethnicity, Poverty, Urban Stressors, and Telomere Length in a Detroit Community-Based Sample, 56 J. HEALTH & SOC. BEHAV. 199 (2015).

100. Elizabeth Dawes Gay, *Serena Williams Could Insist that Doctors Listen to Her. Most Black Women Can't*, NATION (Jan. 18, 2018), <https://www.thenation.com/article/serena-williams-could-insist-that-doctors-listen-to-her-most-black-women-cant> [<https://perma.cc/4F6M-NPXL>].

101. Freedman, *Achieving the MDGs*, *supra* note 95, at 20.

maximum available resources, as are all social rights under international law.¹⁰² Under constitutional frameworks that recognize the right to health, it is also subject to constraints of resource availability. In reality, all rights require resources, including those conventionally thought of in the liberal state as “negative shields” against the incursion of the government. For example, consider the freedom from arbitrary detention, which requires appropriately allocated funding for justice institutions as well as regulatory oversight. Moreover, civil rights vary with resource availability across contexts; think of due process in Canada versus Cameroon. However, civil and political rights are generally funded through general taxation which both reflects their status as fundamental pillars of democracy and makes them less susceptible to marketization and outsourcing to non-governmental provision.

Health goods and services, by contrast, are generally funded through combinations of general taxation, payroll taxes, and social and private insurance schemes, as well as by direct out-of-pocket payments. For health systems to function in ways that reaffirm democratic values of inclusion, solidarity, and equality, they require fair financing, including sufficient pooled resources to cover social and legal citizens.¹⁰³ Just as it should be unacceptable in any democracy in the twenty-first century to allocate basic education by a price mechanism, so too is it undemocratic for essential health goods and services to be treated as mere commodities with no special moral value nor inextricable connection to dignity.

Nonetheless, neoliberal policies that privilege market solutions encourage health systems to do exactly this across much of the world today. In David Sanders and Mickey Chopra’s case study of South Africa, they wrote, “The dominant global and national policy environment that prioritizes the market and the private sector discourages state spending on ‘unproductive’ social investment,” such as health. This policy environment “accounts largely for the continuing health and [well-being] inequities” in the country—and many other middle-income countries as well.¹⁰⁴ As Ronald Dworkin aptly noted, a laissez-faire political economy “does not show equal concern for everyone. Anyone impoverished through that system is entitled to ask: ‘There are other, more regulatory and redistributive, sets of laws that would put me in a better position. How can [the] government claim that this system shows equal concern for me?’”¹⁰⁵

The extreme of an approach that treats health—and health care—as a

102. ICESCR, *supra* note 6, art. 2.

103. ALICIA ELY YAMIN, POWER, SUFFERING, AND THE STRUGGLE FOR DIGNITY: HUMAN RIGHTS FRAMEWORKS FOR HEALTH AND WHY THEY MATTER 99-127 (2016).

104. David Sanders & Mickey Chopra, *Key Challenges to Achieving Health for All in an Inequitable Society: The Case of South Africa*, 96 AM. J. PUB. HEALTH 73 (2006). For another case study example, see Fran Baum et al., *Comprehensive Primary Health Care Under Neo-Liberalism in Australia*, 168 SOC. SCI. & MED. 43 (2016).

105. RONALD DWORKIN, JUSTICE FOR HEDGEHOGS 3 (2011).

commodity without sufficient oversight has led to egregious health and other human rights violations in Kenya, where the High Court recently found that the right to life and dignity of two women had been violated when they were detained by a hospital immediately after giving birth for being unable to pay medical fees.¹⁰⁶ But the inequities of market allocation of health care are not limited to poor or middle-income countries. For instance, in the United States, ostensibly “non-profit” hospitals have brought hundreds of thousands of lawsuits to garnish the wages of uninsured, low-income patients for unpaid medical bills.¹⁰⁷ Vicente Navarro argues that “the enormous power of corporate interests in both the media and the political process” has been a key contributing factor to the United States being the only developed country without guaranteed health care regardless of ability to pay.¹⁰⁸ Indeed, even in the lead-up to the Affordable Care Act in 2008, lobbying by key healthcare industry players—such as pharmaceutical and insurance companies—constrained political debate on this option,¹⁰⁹ notwithstanding the high levels of popular support for single-payer healthcare at the time.¹¹⁰ In 2018, U.S. health spending absorbed 17.7% of GDP,¹¹¹ and is expected to reach 19.9% of GDP by 2025.¹¹² It is more per capita than comparable countries like Canada and Sweden.¹¹³ Moreover, as discussed above, this system involves starkly disparate access and outcomes along racial and income lines. Yet, as of this writing, significant reform in the financing of the largely private, market-

106. *M.A.O. v. Attorney General*, [2015] eKLR (H.C.K. Sept. 17, 2015), <http://kenyalaw.org/caselaw/cases/view/131104> [<https://perma.cc/4YVU-XG9V>].

107. Maya Miller & Beena Raghavendran, *Thousands of Poor Patients Face Lawsuits from Nonprofit Hospitals that Trap Them in Debt*, PROPUBLICA (Sept. 13, 2019), <https://www.propublica.org/article/thousands-of-poor-patients-face-lawsuits-from-nonprofit-hospitals-that-trap-them-in-debt> [<https://perma.cc/V67F-TASP>].

108. Vincent Navarro, *Policy Without Politics: The Limits of Social Engineering*, 93 AM. J. PUB. HEALTH 64 (2003).

109. See *Examining the Single-Payer Health Care Option: Hearing Before Subcomm. on Health, Emp’t, Labor & Pensions of the H. Comm. on Educ. & Labor*, 111th Cong. (2009); *High Health Care Costs: A State Perspective: Hearing Before the S. Comm. on Fin.*, 110th Cong. (2008).

110. *American Public Opinion: Today vs. 30 Years Ago*, CBS NEWS (Feb. 1, 2009), www.cbsnews.com/htdocs/pdf/SunMo_poll_0209.pdf [<https://perma.cc/4YVB-YAKW>] (finding in a 2009 public opinion poll that 49% of those surveyed would prefer government-provided health insurance over private insurance for “all problems”).

111. U.S. CENTERS FOR MEDICARE & MEDICAID SERVICES, NATIONAL HEALTH EXPENDITURE DATA (2019).

112. Press Release, U.S. Centers for Medicare & Medicaid Services, 2016-2025 Projections of National Health Expenditure Data Released (Feb. 15, 2017), <https://www.cms.gov/newsroom/press-releases/2016-2025-projections-national-health-expenditures-data-released> [<https://perma.cc/KUU4-K24N>].

113. Niall McCarthy, *How U.S. Healthcare Spending Per Capita Compares with Other Countries*, FORBES (Aug. 8, 2019), <https://www.forbes.com/sites/niallmccarthy/2019/08/08/how-us-healthcare-spending-per-capita-compares-with-other-countries-infographic> [<https://perma.cc/EX8V-VKYJ>].

based healthcare system seems a remote possibility.

Fairness in financing relates to universal coverage across different sub-populations in a democracy; it also relates to the way coverage is financed across multiple levels of administration in federalist systems of government. For example, since Canada shifted the financing for its healthcare system to the equivalent of “block grants” to the provinces, inequities between provinces in access to and quality of care have expanded, as well as dissatisfaction among populations within provinces.¹¹⁴ In November 2019, the Supreme Court of the province of British Columbia heard closing arguments of a years-long case in which private medical clinics challenged a provincial law that disallows charging patients for necessary medical care.¹¹⁵ If plaintiffs prevail, wealthier patients will be able to pay for faster access to essential services, which has the potential to lure healthcare professionals into private clinics, worsen wait times in the public system and set off a landslide of privatization.¹¹⁶

It should be noted that this is not the first time that a plaintiff has—successfully—challenged a prohibition on private health care provision in a Canadian province. In *Chaoulli v Quebec (AG)*,¹¹⁷ the Supreme Court of Canada struck down Quebec’s law banning private insurance and held that the Quebec Charter of Rights and Freedoms allows for private insurance when the province fails to “provide public health care of a reasonable standard within a reasonable time”, which was directed at the extensive wait times for certain procedures in Quebec’s public healthcare system.¹¹⁸ The Court held that the ban on private insurance was not justified by the government’s desire to protect the public healthcare system, and listed examples of other countries, such as Germany, Sweden, and the United Kingdom, where it claimed that the availability of private insurance had not eroded the universal healthcare system.¹¹⁹

Despite the *Chaoulli* decision, Quebec’s public healthcare system has thus far remained intact without devolving into a two-tiered system, and if we are concerned with decision-making about health and the health system as part of democracy, it is instructive to understand why. Quebec’s provincial legislature produced a moderate response to the ruling, Bill 33, which cabined the impact of

114. TOBA BRYANT, AN INTRODUCTION TO HEALTH POLICY 151-152 (2009); see also Christel A. Woodward & Catharine A. Charles, *The Changing Faces of Health Care in Canada*, in HEALTH CARE REFORM AROUND THE WORLD 78, 81 (Andrew C. Twaddle ed., 2002).

115. Kelly Grant, *Universal Health Care on Trial: What You Need to Know About a Historic Charter Challenge in B.C.*, GLOBE & MAIL (Nov. 12, 2019), <https://www.theglobeandmail.com/canada/article-universal-health-care-on-trial-what-you-need-to-know-about-a-historic/> [https://perma.cc/727S-VSXU].

116. *Id.*

117. *Chaoulli v. Quebec (AG)* [2005] 1 S.C.R. 791 (Can.).

118. *Id.* ¶ 105, 162.

119. *Id.* ¶¶ 142-146.

Chaoulli by allowing private insurance to cover only specified “specialized medical treatments” that had the longest wait times in the public system, such as hip replacements and cataract surgeries.¹²⁰ However, the provincial government did not allow private insurance for other forms of care available in the public system.¹²¹ Thus, the court decision triggered a democratic dialogue about the relationship between publicly-funded interventions, and the effects on people’s dignity and equality under the Quebec Charter, which resulted in a nuanced solution that allowed for reasonable realization of various dignity and equality interests. In short, organizing a health system around a right to health does not dictate a specific modality of administering health care or precise level of health financing; however, if we understand health to be part of the texture of democracy, financing the health system must reflect equal concern and respect for diverse groups and members of society.

B. Fair and Democratic Priority-Setting

The criteria for considering that an electoral process or due process of law meets constitutional standards in a democracy have been well-established. In health systems, these rules and processes must be related to and justified in terms of dignity and consent, as described in Part I. They also relate to priority-setting processes among competing interests to define entitlements that should be available on a basis of non-discrimination. Just as a right to health is not a right to be healthy, a right to health cannot mean all treatments for everyone. To be clear, as described above, the legitimacy of any given health budget and system financing structure must be adequately justified. Decisions regarding a wide array of issues, from pharmaceutical regulation to reliance on specialist care as opposed to general practitioners, have enormous budgetary consequences, which call for democratic scrutiny. However, failure to acknowledge the need for rationing in much human rights advocacy is actually anti-democratic and unjust; it is akin to accepting that those with power, money, privilege and other sources of status will be the ones who get access to health entitlements. As Norman Daniels argues, because health needs are potentially bottomless, the question for democratic health systems is always, “how can we meet health needs fairly when we cannot meet them all?”¹²² That is, there will always be new pathogens, such as COVID-19, as well as new treatments and biotechnologies, together with demographic changes that alter population health needs and priorities.

120. See generally An Act to Amend the Act Respecting Health Services and Social Services and Other Legislative Provisions, S.Q. 2006, c. 43.

121. Yu-Sung Soh, *Shooting from the Hip: The Health of Universal Health Care Following Chaoulli v. Quebec*, THECOURT.CA (Mar. 8, 2007), <http://www.thecourt.ca/shooting-from-the-hip-the-health-of-universal-health-care-following-chaoulli> [<https://perma.cc/Q6X7-3NYB>].

122. NORMAN DANIELS, JUST HEALTH: MEETING HEALTH NEEDS FAIRLY 103 (2007).

It is fallacious to act as though progressive achievement of the right to health under international law follows some kind of linear path that can be dictated in the abstract. Indeed, as Daniels notes, unlike in a trial or an election, where the “rules of the game” are widely agreed upon, in health:

[t]here will be reasonable disagreements about how resources can most effectively be used and about what kinds of partial improvements—for example, in access to care—should be emphasized. Decisions about these issues will create winners and losers. Consequently, it is important to establish that all are being treated fairly and that the outcome of the negotiation is perceived as legitimate.¹²³

In extending Rawlsian principles of procedural justice as the result of a fair and legitimate process, Daniels argues that accountability for reasonableness in priority-setting requires four conditions: (1) publicity/transparency (which precludes implicit priority-setting based on wait lists and price); (2) decisions made upon relevant reasons (as opposed to ideology, rent-seeking, etc.); (3) revisability in light of new information; and (4) regulation and enforcement of the first three conditions.¹²⁴ Here it is important to underscore that procedural fairness can coexist with protected rights. For example, the denial of a life-saving procedure required by women, such as therapeutic abortion, cannot be excluded based upon religious or ideological reasons (“comprehensive moral doctrines” in political philosophy) even if such denials are accepted by a majority of electors.¹²⁵

Consider the most extreme example of rationing ventilators, ICU beds, or dialysis machines during the COVID-19 pandemic. As argued above, not acknowledging the need for rationing is morally and democratically unacceptable. However, the general rule of maximizing the health benefit of a treatment—which accepts that all people have equal dignity—must be done in ways that treat diverse people with equal concern and respect. A democratic health system cannot permit discrimination in information, testing and treatment for COVID-19 on the basis of gender, religion, sexual orientation, disability, race, ethnicity, or—importantly—income or socioeconomic status. Equal concern is also violated if a COVID-19 patient gets care by displacing others with similarly grave or more serious conditions who could benefit more. Moreover, rationing should not be done behind closed doors by “experts.” Taking openly about rationing with people who are affected, including persons who may have pre-existing conditions or certain

123. *Id.* at 319.

124. *Id.* at 103–39.

125. See generally Seyla Benhabib, *The Embattled Public Sphere: Hannah Arendt, Jürgen Habermas and Beyond*, 44 *THEORIA* 1 (1997).

disabilities, may produce important revisions of policy based on these considerations, such as giving extra priority to the worst off.¹²⁶ Indeed, in Massachusetts there was backlash when the public (including disproportionately affected minority populations and persons with disabilities) was not consulted. Revised crisis guidelines were then issued, which at least ensured that priority for critical equipment would only take into account immediate survival probabilities, and not long-term quality or disability-adjusted life measures that could lead to invidious discrimination against persons with certain disabilities.¹²⁷

In crisis situations and “normal” times alike, if we take seriously the connections between health and democracy, the criteria by which health entitlements are defined and ranked cannot be decided exclusively by technocrats behind closed doors.¹²⁸ Of course, health professionals (epidemiologists, clinicians and health economists, among others) play a critical role in compiling evidence regarding clinical- and cost-effectiveness; appraising the strength of that evidence; and ensuring health benefit packages are “data driven and evidence-based.”¹²⁹ Governments are ultimately responsible for ensuring the legitimacy of the decisions and process. Nonetheless, it is increasingly acknowledged that values and norms are inescapably embedded in every level and aspect of health systems, just as they are in other fundamental social institutions—such as education and justice systems. In a democracy, it would be unacceptable for curricula to be defined or trial outcomes decided without transparency and public input in one way or another. For priority-setting processes to be democratically legitimate as well as scientifically sound, meaningful consultation with those who will have to live by the priorities that are set is essential, as demonstrated even in the most extreme example of crisis triage guidelines during the COVID-19 pandemic.

Indeed, the WHO’s multi-disciplinary Technical Advisory Group on

126. See Alicia Ely Yamin & Ole F. Norheim, *3 Human Rights Imperatives for Rationing Care in the Time of Coronavirus*, BILL OF HEALTH (March 27, 2020), <https://blog.petrieflom.law.harvard.edu/2020/03/27/rationing-health-care-coronavirus-human-rights> [https://perma.cc/5F4E-UE9R]. See also Ole F. Norheim, *Ethical Priority Setting for Universal Health Coverage: Challenges in Deciding upon Fair Distribution of Health Services*, 14 BMC MED., May 11, 2016; Govind Persad, *Why Disability Law Permits Evidence-Based Triage in a Pandemic*, 130 YALE L.J.F. 26 (2020), https://www.yalelawjournal.org/pdf/PersadForumEssay_qk77t52y.pdf [https://perma.cc/X2RR-73Z8].

127. See Martha Bebinger, *After Uproar, Mass. Revises Guidelines on Who Gets an ICU Bed or Ventilator Amid COVID-19 Surge*, WBUR (April 22, 2020), <https://www.wbur.org/commonhealth/2020/04/20/mass-guidelines-ventilator-covid-coronavirus> [https://perma.cc/W83C-UUCF].

128. For further discussion of democratically legitimate priority-setting, see, for example, WHO CONSULTATIVE GROUP ON EQUITY & UNIVERSAL HEALTH COVERAGE, MAKING FAIR CHOICES ON THE PATH TO UNIVERSAL HEALTH COVERAGE (2014); and Maarten P.M. Jansen, Rob Baltussen & Kristine Bævre, *Stakeholder Participation for Legitimate Priority Setting: A Checklist*, 7 INT’L J. HEALTH POL’Y MGMT. 973 (2018).

129. WORLD HEALTH ORG., PRINCIPLES OF HEALTH BENEFIT PACKAGE DESIGN (2020).

Principles of Health Benefit Package Design argues that “[a] sound principle is that *all affected parties, all stakeholders and their interests*, should be represented in the process and able to make their voices heard on conditions of rough background equality.”¹³⁰ This opportunity for broad and equitable stakeholder input does not only apply to the design and selection of package benefits themselves, but also to the necessarily preceding discussion of what norms and values will shape the criteria that guide the inclusion and exclusion of certain benefits. Indeed, the Advisory Group expressly identifies that “social values play an important role in the selection of benefits” and a “legitimate, fair decision-making process will begin with a transparent and inclusive identification of the criteria in the local setting, with all appropriate stakeholders included in the criteria selection process.”¹³¹

Concrete examples of processes that increase participatory decision-making include exercises in deliberative polling, which Jane Mansbridge argues has knock-on benefits to democratic engagement in electoral and consultative processes.¹³² Further, the National Health Service in Britain makes use of a non-statutory Priorities Committee that “includes NHS clinicians and managers as well as a lay chair, legal advisor, and [lay] ethical advisor, and reviews treatments that local stakeholders submit for consideration.”¹³³ Health systems can also draw inspiration from structured citizen participation on public issues that are similarly complex. For example, in Toronto, Canada two panels comprised of randomly selected citizens meet every two months over a two-year period to “provide informed inputs on planning or transportation issues.”¹³⁴ Finally, democratic engagement with priority-setting in health should not be limited to “official” channels. As the society-wide debates on the issue of abortion in Argentina and Ireland have made clear, social movements play an important role in creating spaces in which social values can be clarified and health policies can be shaped.¹³⁵ This activism can have profound results, as in Ireland’s successful referendum to

130. *Id.* at 4. See also ALL. FOR HEALTH POLICY & SYS. RESEARCH, STRENGTHENING HEALTH SYSTEMS: THE ROLE AND PROMISE OF POLICY AND HEALTH SYSTEMS RESEARCH (2004); Jilil Safaai, *Deliberative Democracy in Health Care: Current Challenges and Future Prospects*, 7 J. HEALTHCARE LEADERSHIP 123 (2015).

131. PRINCIPLES OF HEALTH BENEFIT PACKAGE DESIGN, *supra* note 129, at 4.

132. Jane Mansbridge, *Deliberative Polling as the Gold Standard*, 19 GOOD SOC’Y 55 (2010).

133. MISFORTUNE, *supra* note 20 (quoting Christopher Newdick, *Can Judges Ration with Compassion?—A Priority Setting Matrix*, 20 HEALTH & HUM. RTS. J., June 2018, at 107, 111).

134. See Claudia Chwalisz, *A New Wave of Deliberative Democracy*, CARNEGIE EUROPE (Nov. 26, 2019), https://carnegieendowment.org/files/10-17-19_Chwalisz_Deliberative.pdf [https://perma.cc/8ASU-Y9GW].

135. See *Argentina Abortion: Crowds Gather to Back Pro-Choice Bill*, BBC (May 29, 2019), <https://www.bbc.com/news/world-latin-america-48444884> [https://perma.cc/8Y52-RRUA]; *Timeline: Ireland and Abortion*, BBC (May 26, 2018), <https://www.bbc.com/news/world-europe-43962738> [https://perma.cc/CM8P-RNS4].

repeal the Constitutional subsection prohibiting most abortions and replacing it with a provision that allowed the legislature to start regulating legal abortion.¹³⁶

Some courts have acknowledged the importance of user participation in a constitutionally legitimate process for designing health benefit packages. Responding to systematic regulatory failure in the health system in the famous T-760/08 decision, the Colombian Constitutional Court ordered the government to comply with its legislated responsibility to conduct a yearly “systematic review” of the obligatory health benefits scheme “with regard to: (1) changes in demographic structure, (2) the national epidemiological profile, (3) appropriate technology available in the country, and (4) the financial conditions of the system.”¹³⁷ The Court held the government accountable by setting standards and deadlines for compliance, but left most decisions about priority-setting and resource allocation to the government—albeit with mandated meaningful opportunities for public participation by the scientific community and affected groups.¹³⁸

As discussed further in Section II.E. below, this “dialogical approach” to judicial oversight is consistent with democratic experimentalism, understanding the limits of the Court’s democratic legitimacy in dictating the content of a right to health. As Mark Tushnet has described, “[a] democratic experimentalist court begins with a constitutional principle stated at a reasonably high level of abstraction” and “offer[s] an incomplete specification of the principle’s meaning in a particular context” before asking “legislators and executive officials to develop and begin to implement plans that have a reasonable prospect of fulfilling the incompletely specified constitutional requirement.”¹³⁹ Once legislative and executive actors have acted, or at least attempted, to meet constitutional demands, courts engage with the results of that experiment and assess whether the constitutional minimum has been met, and if not, what else is required.¹⁴⁰ This iterative process, a form of weak judicial review, “places into question the assumption that judicial review must involve coercive orders” and can be used

136. See Ivana Bacik, *Ireland Has Changed Utterly: the Cruel Eighth Amendment is History*, GUARDIAN (May 26, 2018), <https://www.theguardian.com/commentisfree/2018/may/26/ireland-has-changed-utterly-the-cruel-eighth-amendment-is-history> [<https://perma.cc/S4KL-PBL8>]; *History of Abortion in Ireland*, IRISH FAMILY PLANNING ASS’N, <https://www.ifpa.ie/advocacy/abortion-in-ireland-legal-timeline> [<https://perma.cc/2WTU-6SR3>].

137. *English Summary, Judgment T-760/08*, ESCR-NET, https://www.escr-net.org/sites/default/files/English_summary_T-760.pdf [<https://perma.cc/9AN8-BF5Q>] (quoting Corte Constitucional [C.C.] [Constitutional Court], julio 31, 2008, Sentencia T-760/08 § 6.1.1.1.1, <https://www.corteconstitucional.gov.co/relatoria/2008/t-760-08.htm> [<https://perma.cc/5WR4-NLMD>] [hereinafter T-760/08]).

138. *Id.* (quoting T-760/08, §§ 3.3.9, 4.1.3, 4.4.2, 6.1.3, 6.1.2.2).

139. Mark Tushnet, *New Forms of Judicial Review and the Persistence of Rights – And Democracy-Based Worries*, 38 WAKE FOREST L. REV. 813, 822-23 (2003).

140. *Id.*

effectively to enforce social and economic rights through courts in a way that is still democratically legitimate.¹⁴¹ Indeed, in practice, the T-760/08 decision fostered a process of structured participation in decision-making in relation to Colombia's health system, which was crucial to a reawakened political debate and the country's adoption of a Statutory Framework Law on Health based explicitly on the right to health in 2015.¹⁴² As discussed below, this form of judicial oversight offers particular promise in the realm of health, where the rules set out by any decision have multifaceted impacts on different stakeholders.

C. Health Service Organization and Delivery

Just as with the organization of electoral and judicial systems, the organization and delivery of services is equally important to the democratic function of a health system. Indeed, they function in synergy. Consider again the example of rationing ventilators, ICU beds, or dialysis machines during the global COVID-19 pandemic.¹⁴³ Rationing of patients' access to intensive care at the micro-level is deeply affected by prior decisions and policies regarding health system capacity and function, including allocations of scarce health resources among sub-national areas.

Further, containing transmission rates is inextricably related to testing, contact tracing, and isolation, which depends upon public health and systems that have invested in primary care capacities. Likewise, systems that invest in strengthening primary care capacities are critical for ensuring availability and accessibility of a wide swath of interventions in "normal" times, which cannot be met by systems that focus on specialty and tertiary care.

Under the formulation of the right to health set out by CESCR, the organization of a health system must ensure that health care services are not only available and accessible, but also acceptable and of adequate quality.¹⁴⁴ The organization of a health system affects all of these inter-related elements. For example, accessibility has been interpreted as having several dimensions, including non-discrimination, affordability, accessibility of information concerning health issues, and physical accessibility.¹⁴⁵ Physical accessibility can be further broken down into safe geographic accessibility, especially for

141. MARK TUSHNET, *WEAK COURTS, STRONG RIGHTS* 228, 249 (2008).

142. *Id.* at 16. *See also* L. 1751, febrero 16, 2015, DIARIO OFICIAL [D.O.] (Colom.); OFFICE OF THE UN HIGH COMM'R FOR HUMAN RIGHTS, *GUIDE FOR THE JUDICIARY ON APPLYING A HUMAN RIGHTS-BASED APPROACH TO HEALTH* 11-12 (2010).

143. *See* James Hamblin, *The Curve is not Flat Enough*, ATLANTIC (Mar. 28, 2020), <https://www.theatlantic.com/health/archive/2020/03/coronavirus-forcing-american-hospitals-ration-care/609004> [<https://perma.cc/QFV7-WW2R>].

144. *General Comment No. 14*, *supra* note 6, ¶ 12.

145. *Id.* ¶ 12(b).

marginalized populations, as well as physical accessibility of buildings for disabled persons.¹⁴⁶ One local initiative that has worked to foster accessibility in health care is the establishment of Mohalla Clinics in Delhi, which were an integral part of the Aam Aadmi Party's vision for local democracy. In response to constituents' public demands, they designed the Mohalla Clinics to increase underserved urban populations' access to basic health services, without having to travel long distances or pay fees.¹⁴⁷ The results have been stunning: on average, these clinics increased their patients' average number of healthcare visits per year to 5.6; the average across India is just 1 per year.¹⁴⁸

In addition to accounting for the rights of diverse patients, the organization of a democratic healthcare system should account for the rights of workers as well. Workers are not cogs in a technical apparatus designed to achieve specific outcomes. Rather, in the same way that due process and equal justice suffer when overworked public defenders cannot provide quality representation to indigent defendants,¹⁴⁹ the healthcare system functions less democratically—and less effectively—when healthcare workers are set up to fail by long hours, low pay, a lack of adequate facilities, and other poor working conditions.¹⁵⁰ We have witnessed this acutely during the COVID-19 crisis, as overworked health workers have faced inadequate safety protections in a number of countries.

In some instances, “human rights-based approaches” to health have not paid

146. *Id.*

147. Chandrakant Lahariya, *Mohalla Clinics of Delhi, India: Could These Become Platform to Strengthen Primary Healthcare?* 6 J. FAMILY MED. & PRIMARY CARE 1 (2017); Subir Roy, *Mohalla Clinics, A Viable Primary-Care Model*, HINDU BUSINESSLINE (Nov. 28, 2019), <https://www.thehindubusinessline.com/opinion/columns/mohalla-clinics-a-viable-primary-care-model/article30099666.ece> [<https://perma.cc/YL9J-UY9E>]; Sadhika Tiwari, *How the Aam Aadmi Party's Mohalla Clinics Changed Public Healthcare in Delhi*, SCROLL.IN (Feb. 7, 2020), <https://scroll.in/article/952440/how-the-aam-aadmi-party-s-mohalla-clinics-changed-public-healthcare-in-delhi> [<https://perma.cc/439B-2HFZ>].

148. Tiwari, *supra* note 147.

149. *See, e.g.*, Matt Ford, *A 'Constitutional Crisis' in Missouri*, ATLANTIC (Mar. 14, 2017), <https://www.theatlantic.com/politics/archive/2017/03/missouri-public-defender-crisis/519444> [<https://perma.cc/4SCF-FJ4P>]; Oliver Laughland, *The Human Toll of America's Public Defender Crisis*, GUARDIAN (Sept. 7, 2016), <https://www.theguardian.com/us-news/2016/sep/07/public-defender-us-criminal-justice-system> [<https://perma.cc/59MH-L7NB>]; Pamela Melzger, *Equal Justice Depends on Properly Funding Public Defenders*, HILL (May 22, 2019), <https://thehill.com/opinion/criminal-justice/444588-equal-justice-depends-on-properly-funding-public-defenders> [<https://perma.cc/DJT3-2P7R>].

150. *See, e.g.*, Ryan Cronk & Jamie Bartram, *Environmental Conditions in Health Care Facilities in Low- and Middle-Income Countries: Coverage and Inequities*, 221 INTL. J. HYGIENE & ENVTL. HEALTH 409 (2018); Jack Needleman et al. *Nurse-Staffing Levels and the Quality of Care in Hospitals*, 22 NEW ENGL. J. MED. 1715 (2002); Roni Jacobson, *Widespread Understaffing of Nurses Increases Risk to Patients*, SCI. AM. (July 14, 2015), <https://www.scientificamerican.com/article/widespread-understaffing-of-nurses-increases-risk-to-patients> [<https://perma.cc/38JJ-U7ET>].

sufficient attention to the rights of health workers, or to systemic issues. For example, maternal death reviews—which have been touted as a “human rights-based approach” to accountability for maternal deaths¹⁵¹—more likely than not scapegoat health workers with little control over the circumstances of a woman’s death, while systemic issues, such as supply chain problems, are left unaddressed. Punitive treatment of health workers invariably affects the treatment of patients as well. Indeed, it is simply impossible to create and sustain democratic health systems without recognizing health workers’ rights to safe and respectful work environments and adequate compensation. In a positive development, in December 2019, Uruguay became the first country in the world to ratify ILO Convention 190 on Violence and Harassment,¹⁵² which recognizes that in addition to impacting women’s health in myriad ways, sexual harassment also “affects the quality of public and private services.”¹⁵³ A potential effect of the current pandemic could be to raise much needed consciousness of how the health rights of patients are inter-dependent on the rights of healthcare providers and other nonclinical workers in healthcare settings.

D. Information to be Active Citizens Regarding Health

Conceiving of health in terms of rights, and health systems as democratic institutions, immediately makes apparent that people are not just passive patients or targets of health policies and programming; they should be treated as informed and active participants in both personal and policy decisions with respect to health and their health systems. As noted in Section II.C., the availability and accessibility of information is listed as an inter-related element of the right to health in CESCR General Comment 14, including “the right to seek, receive and impart information and ideas concerning health issues.”¹⁵⁴ In Article 14(2)(b), CEDAW mandates that states must ensure that even women in rural areas “have access to adequate health

151. Paul Hunt, *Rep. of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Health*, Paul Hunt, *Addendum 2: Mission to India*, U.N. Doc. A/HRC/14/20/Add.2 ¶¶ 71-74 (Apr. 15, 2010); Office of the UN High Comm’r for Human Rights, *Technical Guidance on the Application of a Human Rights-Based Approach to the Implementation of Policies and Programmes to Reduce Preventable Maternal Morbidity and Mortality*, U.N. Doc. A/HRC/21/22 ¶ 75(c) (July 2, 2012).

152. *Uruguay is the First Country in the World to Ratify ILO Convention 190*, PUB. SERV. INT’L (Dec. 18, 2019), <https://publicservices.international/resources/news/uruguay-is-the-first-country-in-the-world-to-ratify-ilo-convention-190?id=10498&lang=en> [https://perma.cc/9UV9-5DSP]. Following the second ratification by Fiji on June 25, 2020, the convention will enter into force in 2021. *ILO Violence and Harassment Convention Will Enter into Force in June 2021*, INT’L LABOR ORG. (June 25, 2020), https://www.ilo.org/global/about-the-ilo/newsroom/news/WCMS_749148/lang--en/index.htm [https://perma.cc/Y4PP-QLUT].

153. Convention Concerning the Elimination of Violence and Harassment in the World of Work, *adopted by the International Labor Organization* June 21, 2019, 58 I.L.M. 1170 pmb1.

154. *General Comment No. 14*, *supra* note 6, ¶ 12(b).

care facilities, including information, counselling and services in family planning.”¹⁵⁵ Elaborating on this duty to ensure that health information is accessible, in General Recommendation 34 on the Rights of Rural Women, the CEDAW Committee specifies that states parties should ensure:

[t]hat health-care information is widely disseminated in local languages and dialects through various media, including in writing, through illustrations and orally, and that it includes information on, inter alia: hygiene; preventing communicable, non-communicable and sexually transmitted diseases; healthy lifestyles and nutrition; family planning and the benefits of delayed childbearing; health during pregnancy; breastfeeding and its impact on child and maternal health; and the need to eliminate violence against women, including sexual and domestic violence and harmful practices.¹⁵⁶

Ensuring the right to health requires broad accessibility and availability of information, in terms of both form and content.

Courts have consistently played a role in ensuring protection against insufficient and misleading information about health. For example, the European Court of Human Rights has recognized the importance of having sufficiently clear—medical and legal—information to effectively challenge a healthcare decision. In *Tysiac v. Poland*, Ms. Tysiac was denied a legal abortion by her doctor, despite evidence that pregnancy could cause irreparable damage to her vision.¹⁵⁷ The Court found that Poland had violated Ms. Tysiac’s right to privacy under article 8 of the European Convention on Human Rights by providing no clear legal mechanism by which she could challenge her doctor’s denial of a medically necessary abortion, and no requirement for doctors to provide accessible, documented reasons upon which the challenge could be based.¹⁵⁸ The Court emphasized that a proper framework needs to “ensure clarity of the pregnant woman’s legal position” with regard to the abortion she is seeking.¹⁵⁹ In a later case, the European Committee on Social Rights recognized that the requirement of accessible and accurate information does not only apply in the context of individual health decisions, but also more broadly, in its holding that sexual health education including discriminatory and incorrect information about LGBTQI

155. CEDAW, *supra* note 39.

156. Comm. on the Elimination of Discrimination Against Women, *General Recommendation No. 34 (2016) on the Rights of Rural Women* ¶ 39(f), U.N. Doc. CEDAW/C/GC/34 (2016).

157. *See generally* *Tysiac v. Poland*, 2007-I Eur. Ct. H.R. 219.

158. *Id.* ¶¶ 114-135.

159. *Id.* ¶ 116.

sexual health violates the right to health under the European Social Charter.¹⁶⁰ If health and health systems are democratic social institutions, the right to information must then be understood not in a narrow instrumental way but broadly, as fundamental to the legitimate authority of a democratic government.

For health to be treated as a matter of democracy, people need to be enabled to participate meaningfully not just in decisions that affect their own health, and in priority-setting, as discussed above. In a pandemic and in normal times, diversely situated people also need to be able to see how government policies are rationally related to, and justifiable in terms of, protecting public health. Such policies also include the regulation of private actors. For example, a United States Court of Appeals decision found that Philip Morris USA, a cigarette manufacturer, engaged for decades “in a scheme to defraud smokers and potential smokers” by denying various adverse health effects of smoking and second-hand smoke.¹⁶¹ While this case was not framed in terms of the right to health, many of the remedies were fashioned to provide consumers with health information they should have had all along, including providing corrective statements, disclosing marketing data, and publishing all previously withheld health research on the company website.¹⁶²

Similarly, the use of algorithms to govern our lives has been increasingly questioned as highly undemocratic.¹⁶³ Nowhere is this more evident than in the potential effects on population health, where algorithms are now deployed to make distributive decisions within domestic welfare systems and public health interventions. If the value of democracy lies in establishing a “republic of reasons,”¹⁶⁴ it requires more than the black box assessments that algorithms offer. Rather, it requires some mechanism for providing those affected by algorithm-informed choices with a meaningful opportunity to shape the normative framing of the issue, values, and assumptions that are inherently built into the algorithm. For example, in terms of framing, Philip Alston has written about how the digitization of welfare, while presented as a benign and efficient update to existing systems, broadly facilitates “a move towards a detached bureaucratic process” that puts the onus on the citizen to meet technical eligibility requirements.¹⁶⁵ This

160. *Interights v Croatia*, Complaint No. 45/2007, ¶¶ 60–61 (Eur. Comm. Soc. Rights Apr. 9, 2009), <http://hudoc.esc.coe.int/eng/?i=cc-45-2007-dmerits-en> [<https://perma.cc/2BNL-Q3KZ>].

161. *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 852 (D.D.C. 2006), *aff’d on this issue*, 566 F.3d 1095 (D.C. Cir. 2009).

162. *Id.*

163. See, e.g., Ben Green, *The Responsible City: Avoiding Technology’s Undemocratic Social Contracts*, in *THE SMART ENOUGH CITY* (2019), available at <https://smartenoughcity.mitpress.mit.edu/pub/yyv9j2i/release/1>; Henry A. Giroux, *Totalitarian Paranoia in the Post-Orwellian Surveillance State*, 29 *CULTURAL STUD.* 108 (2015); David Lyon, *State and Surveillance*, *CTR. FOR INT’L GOVERNANCE INNOVATION*, <https://www.cigionline.org/articles/state-and-surveillance> [<https://perma.cc/FZF8-ZZ7W>].

164. CASS R. SUNSTEIN, *DESIGNING DEMOCRACY: WHAT CONSTITUTIONS DO* 239 (2001).

165. Philip Alston, *What the “Digital Welfare State” Really Means for Human Rights*, *OPEN*

conceptualization of individuals as “applicants” rather than “rights-holders” flips the presumption that undergirds the exercise of human rights, as “[i]nstead of the State being accountable to the citizen for ensuring an adequate standard of living for all, the burden of accountability is now on the citizen to demonstrate that he or she is somehow deserving.”¹⁶⁶

Moreover, algorithmic assessments of who is deserving of assistance can reinforce existing biases and power imbalances. Algorithms may not inherently be biased, but often end up that way due to the unexamined assumptions of the people and organizations that design and implement them. The exploding use of algorithms in health is particularly dangerous because it invisibly *institutionalizes* these biases and cloaks them in a veneer of scientific legitimacy. One well-publicized example involved a widely used risk-prediction tool in the United States,¹⁶⁷ which was used to identify at-risk patients who need additional healthcare intervention.¹⁶⁸ The tool used cost of care as a proxy for the patient’s need, despite the fact that “unequal access to care means that we spend less money caring for Black patients than for White patients.”¹⁶⁹ The result of this imbalance was that the algorithm failed to identify nearly 30% of cases where extra intervention was warranted for Black patients—therefore not only failing these individual patients, but reinforcing a cycle in which Black patients systemically receive less care.¹⁷⁰ In short, a democratic health system’s determination regarding the contours of health entitlements should not only be able to justify the decisions, but also the reasons for those decisions.

E. Oversight: Regulation and Remedies

As suggested throughout this Article, if we understand health systems to embed normative values, then in order to meet democratic standards, health system standards and procedures require not just technical oversight but also regulatory and judicial oversight, to ensure they are consistent with normative commitments set out in legal frameworks. In all of the cases mentioned above, whether financing a sexual reassignment surgery or allowing private providers to offer certain non-essential health services, courts can play important roles in subjecting decisions in

GLOB. RIGHTS (Jan. 8, 2020), <https://www.openglobalrights.org/digital-welfare-state-and-what-it-means-for-human-rights> [<https://perma.cc/NH87-CCGE>].

166. *Id.*

167. This tool was applied to approximately 200 million patients annually. See Ziad Obermeyer, Brian Powers, Christine Vogeli & Sendhil Mullainathan, *Dissecting Racial Bias in an Algorithm Used to Manage the Health of Populations*, 366 SCI. 447, 448 (2019).

168. *Id.*

169. *Id.*

170. See *id.*; see also Milena A. Gianfrancesco, Suzanne Tamang, Jinoos Yazdany & Gabriela Schmajuk, *Potential Biases in Machine Learning Algorithms Using Electronic Health Record Data*, 178 JAMA INTERNAL MED. 1544 (2018).

health to scrutiny in line with constitutional or international human rights commitments.

In addition to protecting democratically justified decisions, courts can spur public learning regarding constitutional and human rights commitments by taking normative arguments seriously and making visible concerns of often marginalized groups.¹⁷¹ According to Keith Syrett, courts' decisions have the ability to strengthen the public legitimacy of necessary rationing in the health system.¹⁷²

The provision of reasons for decisions therefore enables judges to offer an explanation to (and thus to educate) both the losing side and the wider public in terms which meet the conditions of reciprocity: that is, those which “fair-minded people” seeking social co-operation can recognise as valid and germane in the light of principles and ideals which they endorse as rational, even if they may disagree on the conclusion reached in the instant case. In this manner, the practice of judicial reason-giving may contribute to legitimacy either through acceptance of the validity of the reasons offered or, more indirectly, through its impact as a stimulus for a further process of public deliberation which can provide the conditions through which such legitimacy may be secured.¹⁷³

Thus, court intervention into health systems need not be seen as a threat to those systems—rather, courts can play an “instrumental” or “facilitative” role, by “channeling and guiding decision-making processes” and “diagnosing and addressing institutional and/or systemic problems and weaknesses.”¹⁷⁴ For example, as in the case in Kenya discussed above in which women were detained postpartum at the hospital because they could not pay their medical bills, a court holding that their human rights were violated provides a signal to the legislature that healthcare cannot be left entirely to market forces. Rather, it must be organized in a more principled way to meet human rights requirements. Indeed, as the right to health is inherently complex—due both to the “spiderweb-like effects” of health decisions, as Lon Fuller described,¹⁷⁵ and to the uncertainty regarding what the

171. Roberto Gargarella, *Dialogic Justice in the Enforcement of Social Rights: Some Initial Arguments*, in LITIGATING HEALTH RIGHTS: CAN COURTS BRING MORE JUSTICE TO HEALTH? 232, 242 (Alicia Ely Yamin & Siri Gloppen eds., 2011).

172. KEITH SYRETT, LAW, LEGITIMACY AND THE RATIONING OF HEALTH CARE: A CONTEXTUAL AND COMPARATIVE PERSPECTIVE 136 (2007).

173. *Id.* at 156.

174. *Id.* at 127, 135, 157.

175. See Lon L. Fuller, *The Forms and Limits of Adjudication*, 92 HARV. L. REV. 353, 395 (1978).

right to health entails—this facilitative role is essential.

Further, if we are concerned with strengthening links between democracy and health, even individual protection writ remedies (e.g., *amparos* and *tutelas* in Latin America) should seek to catalyze and reinforce legitimate priority-setting and regulation, rather than substitute judicial judgment in *ad hoc* ways. In such mixed common and civil law jurisdictions, the accumulation of protection writ cases regarding clusters of complaints allows courts to address regulatory and compliance gaps, and to ensure the priority-setting processes conform to democratic principles.

Likewise, in structural matters, courts can supplement rather than supplant political discussion regarding health by “set[ting] the boundaries of a political decision, or provid[ing] politicians with criteria about basic constitutional demands—criteria to be taken into account by the legislators in their decisions.”¹⁷⁶ As Robin West has written, “[t]he pinnacle moment of ordinary legalism is not the trial . . . it is the legislative process” through which a shared commitment to certain legal ends is made.¹⁷⁷ Courts can thus also intervene to address structural problems that legislators systematically fail to address, such as environmental issues and the health rights of marginalized minorities.¹⁷⁸ Indeed, this is what occurred in the Mexican Supreme Court’s abortion decision—after holding that the denial of abortion services discriminatorily deprived only women of an essential health service, the court instructed Mexican sub-national states to take up an issue that had previously been ignored, and to design and implement “policies aimed at providing women with access to a full range of high-quality and affordable health care, including sexual and reproductive healthcare services.”¹⁷⁹

Courts can also play this democratically legitimate role with public health conditions beyond care, which tend to be equally polycentric and spiderweb-like. For example, in *Beatriz Silvia Mendoza y Otros c. Estado Nacional y Otros*, the Argentine Supreme Court addressed extreme the environmental pollution of the Matanza/Riachuelo River and the ensuing health impacts, and presided over a resulting mega “Clean-Up Plan” undertaken by the government defendants.¹⁸⁰ The Court set forth three goals: (1) improving the river basin inhabitants’ quality of life; (2) restoring the environment; and (3) preventing reasonably foreseeable harm, including to health. In its follow-up, the Court established highly complex reporting and compliance requirements on a variety of issues, including public

176. Gargarella, *supra* note 171, at 239.

177. Robin West, *Reconsidering Legalism*, 88 MINN. L. REV. 119, 154 (2003).

178. *Id.*

179. Amparo en Revisión 1388/2015, *supra* note 43, ¶ 104 (¶ 59 in the translation).

180. Corte Suprema de Justicia de la Nación [CSJN] [National Supreme Court of Justice], 8/7/2008, “Beatriz Silvia Mendoza y Otros c. Estado Nacional y Otros / daños y perjuicios,” Fallos de la Corte Suprema de Justicia de la Nación [Fallos] (2008-331-1622).

information, industrial pollution, landfill clean-up, sanitation, and emergency health plans. In the process, the Court engaged technical experts and emphasized the importance of strengthening citizen participation in the monitoring, but like that in T-760/08, it left the exact methods for compliance to the government's discretion. Notwithstanding the unwieldy challenge of overseeing government compliance, ten years later there were notable, if slow, improvements, including the removal of 1,500 tons of solid waste from the river, the construction of 14 health centers, the development of sewage plans, and relocation of 122 families out of high-risk zones near the river.¹⁸¹ It also led to the establishment of a new oversight mechanism, ACUMAR, and to sustained citizen engagement in a structured participation process for making decisions that affect residents' lives and well-being.¹⁸² The *Mendoza* case, as others, demonstrates that courts can play a catalytic role in spurring democratic action regarding health issues, rather than instituting top-down solutions: "if the law is to bind [the people] as free men and women, they must also be its makers."¹⁸³

Needless to say, in health, just as in other fields, complex structural remedies do not catalyze democratic deliberation automatically—they call for participatory follow-up, together with significant independent authority and a robust mandate for the court. A 2001 case from the African Commission on Human and Peoples' Rights reveals the outcome when ongoing oversight processes are absent. The case alleged severe environmental degradation and resulting health harms in the Ogoniland area of Nigeria from the activities of oil corporations.¹⁸⁴ The Commission called on Nigeria to provide "meaningful access to regulatory and decision-making bodies [for] communities likely to be affected by oil operations" but had no ability to meaningfully monitor state implementation of and compliance with the decision.¹⁸⁵ As a result of the lack of a compliance structure, as well as

181. Fabiana Frayssinet, *It Takes More than Two to Tango — or to Clean up Argentina's Riachuelo River*, IPS NEWS (Aug. 13, 2014), <http://www.ipsnews.net/2014/08/it-takes-more-than-two-to-tango-or-to-clean-up-argentinas-riachuelo-river> [https://perma.cc/5QPH-QNZH].

182. *Mendoza Beatriz Silva et al. vs. State of Argentina et al. on damages (damages resulting from environmental pollution of Matanza/Riachuelo river)*. File M. 1569. XL, ESCR-NET (Jan. 2, 2019), <https://www.escri-net.org/caselaw/2011/mendoza-beatriz-silva-et-al-vs-state-argentina-et-al-damages-damages-resulting> [https://perma.cc/T9WH-HBMT].

183. Michael Walzer, *Philosophy and Democracy* 9 POL. THEORY 379, 383 (1981).

184. Soc. & Econ. Rights Action Ctr. v. Nigeria, Comm'n No. 155/96 (Afr. Comm'n on Human & Peoples' Rights Oct. 27, 2001), <https://www.achpr.org/sessions/descions?id=134> [https://perma.cc/9FWK-BM65].

185. *Id.* Estimates by the Centre for Human Rights in Pretoria suggest that "in 2004-2005 approximately 34-35% of the ACHPR's recommendations had been implemented" and that the Commission's limited follow-up procedures stem from a lack of funding. *Follow-Up and Implementation of Decisions by Human Rights Treaty Bodies*, HUMAN RIGHTS IMPLEMENTATION CTR., UNIV. OF BRISTOL LAW SCH. 6-7 (2009), <http://www.bristol.ac.uk/media-library/sites/law/migrated/documents/semrep2009.pdf> [https://perma.cc/4466-G45N] [hereinafter *Follow-Up and Implementation*].

the refusal of corporate giant Shell to take any action in relation to its oil-producing activities in Ogoniland, severe environmental and health degradation in the area has continued.¹⁸⁶ Importantly, this lack of an effective compliance structure is not a problem unique to the African human rights system—it is present to some degree in all regional human rights systems, as well as UN treaty-monitoring bodies,¹⁸⁷ suggesting challenges for trying to use supranational bodies to catalyze systemic change.

In short, in this section we have posited that if addressing disagreements among a diverse population is *the principal* challenge of the democratic state, there is no area in which such disagreements have more immediate—indeed, often life-and-death—consequences than in health, and these disagreements are played out in health systems, as well as in the policies that affect health. Understanding the right to health as connected to the negotiation of competing claims and interests through democratically legitimate processes significantly shifts the focus of progressive achievement of the right to health. Progressive realization must entail institutionalizing processes that provide choice situations that both continually evolve in light of changing demographics, technologies, and epidemiology, and also reinforce norms of equality and solidarity. Here we have argued that taking seriously the connection between rights claims and the role of health systems as democratic social institutions has implications for how laws structure health

186. *Shell and Nigeria Have Failed on Oil Pollution Clean-Up, Amnesty Says*, GUARDIAN (Aug. 4, 2014), <https://www.theguardian.com/environment/2014/aug/04/shell-nigeria-oil-pollution-clean-up-amnesty> [https://perma.cc/2BF3-6WLA].

187. In the Inter-American system, “between 2001 and 2006, the [Inter-American] Commission reported full compliance with its decisions in only 5.3% of cases” while the Inter-American Court reported full compliance in only “11.57% of judgments.” *Follow-Up and Implementation*, *supra* note 185, at 9. In contrast, the European Court of Human Rights has a “long-standing, formal and well-documented” follow-up procedure which involves the “Committee of Ministers,” a body which meets four times per year for the sole purpose of documenting state action taken to comply with judgments. The Committee keeps state judgments on its docket and continues to seek state redress until full compliance is achieved, and publishes its findings after each meeting. However, despite this relatively effective follow-up procedure for individual cases, the existence of “repetitive cases” being brought against certain member states indicates that the European Court’s follow-up procedures are not necessarily resolving systemic problems within the offending states. *Id.* at 11–12.

Some treaty-monitoring and supranational bodies also have follow-up procedures to guide state implementation of human rights decisions, but like the regional procedures, tend to be unable to enforce full compliance. The UN Human Rights Committee that oversees compliance with the International Covenant on Civil and Political Rights (ICCPR) uses a “grading” system to determine how well a defendant state has implemented the Committee’s “Communications” (decisions) on individual complaints brought under the First Optional Protocol to the ICCPR. The committees charged with enforcing other UN treaties, including CRPD, CEDAW, ICESCR, and the Convention Against Torture, use similar, yet not identical grading systems. However, not only do the committees lack any actual enforcement power, but the actual grades given to states being monitored are not sufficiently disseminated to human rights advocates and communities. See Vincent Ploton, *The Implementation of UN Treaty Body Recommendations*, 14 SUR: INT’L J. HUM. RTS., Jul. 2017, at 219.

system financing, priority-setting processes, and health service organization and delivery, and guarantee information regarding health. It also makes apparent the need for judicial oversight to catalyze and reinforce democratic commitments to equal moral consideration in health systems.

III. HEALTH AND DEMOCRACY IN A GLOBALIZED WORLD

It might seem counterintuitive to argue that health is a matter of democracy and at the same time suggest that obligations go beyond borders and transcend the state-citizen dyad. Yet perhaps the most obvious lesson of the COVID-19 pandemic is that diseases do not respect borders, and states' obligations to protect the security of their inhabitants must adjust to that fact. Likewise, diseases do not respect taxonomies of access to entitlements based upon legal citizenship. And beyond the current pandemic, treating the right to health as fundamental to liberal democracies calls for rewriting the narrative of who is entitled to assets of democratic inclusion and reconsidering the nature of shared national-global health governance. As Jennifer Prah Ruger has argued, such a model of shared health governance "differs from the technocratic model in understanding that political legitimacy involves normative reasoning and public deliberation."¹⁸⁸ Shared health governance is "based on a genuine commitment among global health actors to achieve health justice as opposed to pursuing narrow self, group, or state interest alone,"¹⁸⁹ through the sharing of resources, accountability, and most importantly, power.¹⁹⁰ Here we consider how in a global context of massive migration and forced displacement,¹⁹¹ democracies must account for more liminal forms of citizenship in access to health entitlements and consider the claims of people beyond borders whose health is affected by the actions of a state or by actors under the state's effective control.¹⁹²

A. Migrants

Patricia Illingworth and Wendy E. Parmet have argued that neither of the two theories of citizenship typically offered by legal scholarship "provides an adequate justification for the denial of health-related rights" to migrants.¹⁹³ First, they argue

188. JENNIFER PRAH RUGER, *GLOBAL HEALTH JUSTICE AND GOVERNANCE* 366 (2018).

189. *Id.* at 145.

190. *Id.* at 167–70.

191. Adrian Edwards, *Forced Displacement at Record 68.5 Million*, UNHCR: UN REFUGEE AGENCY (June 19, 2018), <https://www.unhcr.org/news/stories/2018/6/5b222c494/forced-displacement-record-685-million.html> [<https://perma.cc/F8XP-G8B6>].

192. ETO CONSORTIUM, *MAASTRICHT PRINCIPLES ON EXTRATERRITORIAL OBLIGATIONS OF STATES IN THE AREA OF ECONOMIC, SOCIAL AND CULTURAL RIGHTS* (Sep. 28, 2011) [hereinafter *MAASTRICHT PRINCIPLES*].

193. PATRICIA ILLINGWORTH & WENDY E. PARMET, *THE HEALTH OF NEWCOMERS* 170–71

that the ascriptive, or legal, theory of citizenship—as “something that attaches to people as a result of an innate status, such as birth in a territory or membership in a distinct demographic group”—is tautology, providing no justification for why any particular status that endows citizenship should also automatically determine health rights.¹⁹⁴ The second theory of citizenship, the consent view, is more logically and morally defensible, but still inconsistent with the denial of health rights to non-legal citizens, because social citizens do “demonstrate their consent to membership in the nations to which they have immigrated” in many different ways.¹⁹⁵ These include working (often in “necessary jobs, such as caretaking for the ill, that citizens abjure”); paying taxes; and engaging in volunteer work or political activism.¹⁹⁶ Starkly divergent choices with respect to immigrants’ inclusion in U.S. democracy, as Tiffany Joseph has identified, are illustrated by the express exclusion of many non-legal citizens from the Federal Patient Protection and Affordable Care Act (ACA) versus their inclusion in Massachusetts’ 2006 health care reforms (which ironically served as a model for the ACA).¹⁹⁷ The Massachusetts healthcare system has a larger immigrant population than the national average, yet recognizes a broader category of immigrants that have consented to be part of its “civic community” than the ACA.¹⁹⁸

Importantly, immigrants’ rights to health can also be indirectly violated even if health care is available but practical barriers inhibit access to services. In *Defence for Children International (DCI) v. Belgium*,¹⁹⁹ the European Committee of Social Rights—charged with interpreting and monitoring compliance with the European Charter of Social Rights—addressed the failure of Belgium to enforce its laws providing for the reception of unaccompanied foreign minors into observation and guidance centres where they could theoretically receive support and material assistance. The committee noted “the total lack—since 2009—of reception facilities for accompanied foreign minors and the partial lack of such facilities for unaccompanied foreign minors, leading some of them to live in the street, makes it difficult for foreign minors unlawfully in the country to access the health system.”²⁰⁰ The committee connected the state’s failure to ensure that

(2017).

194. *Id.* at 170–71.

195. *Id.* at 173.

196. *Id.*

197. See Tiffany D. Joseph, *What Health Care Reform Means for Immigrants: Comparing the Affordable Care Act and Massachusetts Health Reforms*, 41 J. HEALTH POL. POL’Y & L. 101 (2016).

198. *Id.* at 104, 111.

199. *Defence for Children International (DCI) v. Belgium*, Complaint No. 69/2011 (Eur. Comm. Soc. Rights Oct. 23, 2012), <http://hudoc.esc.coe.int/eng?i=cc-69-2011-dmerits-en> [https://perma.cc/9SQE-BB4U].

200. *Id.* ¶ 116.

migrant children were not living on the street, with poor access to health care. Thus, the committee found a violation of the right of access to health care under Article 11, Section 1 of the European Social Charter, first finding that failing to apply Article 11, Section 1 to unlawfully present minors “would mean not securing their right to the preservation of human dignity and exposing the children and young persons concerned to serious threats to their lives and physical integrity.”²⁰¹ In turn, the committee held that “providing foreign minors with housing and foster homes is a minimum prerequisite for attempting to remove the causes of ill health among these minors (including epidemic, endemic or other diseases)” and that Belgium had failed to meet this obligation.²⁰²

B. Transnational Drivers of Health, and Extraterritorial Obligations (ETOs)

It is not just infectious diseases that cross borders and cause ill-health. In today’s world many determinants of health and structures of health systems lie in transnational space. The Lancet–University of Oslo Commission on Global Health Governance dubbed the “norms, policies, and practices that arise from transnational interaction” the “political determinants of health,” which “cause and maintain health inequities.”²⁰³ Transnational obligations relating to health do not relate only to the health of migrants, but can apply extraterritorially as well.²⁰⁴ Under international human rights law, there are obligations of “assistance and co-operation, especially economic and technical” to facilitate national states progressively realizing the right to health, as well as all other economic and social rights.²⁰⁵

A number of scholars have emphasized the importance of the financial aspect of these obligations. Perhaps most notably, Gorik Ooms and Rachel Hammonds have argued in a number of papers to the effect that “[w]ithout international obligations to provide assistance—without global responsibility, that is—the right to health is not a right but a privilege reserved for those who are born outside of the world’s poorest countries.”²⁰⁶ Ooms and Hammonds further suggest that rich countries could satisfy this obligation of international cooperation and assistance by apportioning no more than 0.1% of their GDP to international health assistance,

201. *Id.* ¶ 102.

202. *Id.* ¶ 117.

203. Ole P. Ottersen et al., Lancet–Univ. of Oslo Comm’n on Glob. Governance for Health, *The Political Origins of Health Inequity: Prospects for Change*, 383 LANCET 630 (2014).

204. MAASTRICHT PRINCIPLES, *supra* note 192.

205. ICESCR, *supra* note 6, art. 2, ¶ 1.

206. Gorik Ooms & Rachel Hammonds, *Taking up Daniels’ Challenge: The Case for Global Health Justice*, 12 HEALTH & HUM. RTS., June 2010, at 29, 36; *See also* 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 (2013).

to assist lower-income countries to realize the “core content” of the right to health.²⁰⁷ Obligations of assistance and cooperation are fundamental to support countries with limited resource capacities in achieving functional health capacities, as is the recognition of and support for global public goods in health, such as an eventual vaccine for COVID-19.

However, the linkage that we have been constructing in these pages between health and democracy suggests examining more closely the underlying structural requirements that make the reapportionment of finances in sustainable and needs-based ways dependent on the level of democratic solidarity between governmental units. For example, reapportioning finances is done within the United States, where the federal government routinely apportions tax revenue among states through grants, to entice certain states to fulfill federal objectives with regard to issues like education, social security, and health care.²⁰⁸ Indeed, the federal matching rate for Medicaid is higher in states with lower per capita income,²⁰⁹ indicating that richer states’ resources are being redistributed to some degree to pay for the Medicaid needs of poorer states.²¹⁰ Currently, West Virginia, Kentucky, and Mississippi have some of the highest federal funding shares for Medicaid—with the federal government paying between 75% and 80% of the cost of the program in each of these states—and are all also among the ten states that consistently have the lowest GDP per capita in the country.²¹¹ Similarly, within the European Union (EU), wealthier countries subsidize public investment in poorer countries mainly through the EU’s Cohesion Policy, which accounts for nearly one-third of the EU’s budget, or €355.1 billion between 2014–2020.²¹² As part of that policy, the EU is targeting

207. Ooms & Hammonds, *supra* note 206, at 41. Here, Ooms and Hammonds suggest that this framework for international assistance would stretch only to “core content,” and after the minimum core content is reached in lower-income countries, richer countries could then revert to prioritizing the domestic obligation to meet the highest attainable standard of health. *Id.* at 36. However, they use the formulation of “core content” in CESCR’s *General Comment No. 14*, which, as discussed above in Section II.C, includes a host of social determinants and may swallow up many other rights. See *General Comment No. 14*, *supra* note 6, ¶ 16.

208. CTR. ON BUDGET & POLICY PRIORITIES, FEDERAL AID TO STATE AND LOCAL GOVERNMENTS (April 19, 2018), <https://www.cbpp.org/sites/default/files/atoms/files/policybasics-federalaid.pdf> [<https://perma.cc/A2XD-7N9B>].

209. Robin Rudowitz, Kendal Orgera & Elizabeth Hinton, *Medicaid Financing: The Basics*, KAISER FAMILY FOUND. (Mar. 21, 2019), <http://files.kff.org/attachment/Issue-Brief-Medicaid-Financing-The-Basics> [<https://perma.cc/6GBH-MLN7>].

210. John Tierney, *Which States Are Givers and Which Are Takers?* ATLANTIC (May 5, 2014), <https://www.theatlantic.com/business/archive/2014/05/which-states-are-givers-and-which-are-takers/361668> [<https://perma.cc/Y7CE-BUA2>].

211. KAISER FAMILY FOUND., FEDERAL AND STATE SHARE OF MEDICAID SPENDING (2018), <https://www.kff.org/medicaid/state-indicator/federalstate-share-of-spending> (last visited June 26, 2020); *Per Capita Real GDP by State (Chained 2012 Dollars)*, BUREAU OF ECON. ANALYSIS, <https://www.bea.gov/data/gdp/gdp-state> (last visited June 26, 2020).

212. *The EU’s Main Investment Policy*, EUROPEAN COMMISSION, https://ec.europa.eu/regional_policy/en/funding/cohesion-fund [<https://perma.cc/SLY9-PHGZ>].

€63.4 billion over that same time period to member states with per capita GNIs less than 90% of the EU average through the Cohesion Fund, in order to reduce economic and social disparities and promote development.²¹³ Beneficiaries include Poland, Hungary, Greece, Romania, Bulgaria, and Portugal.²¹⁴

These may be radically insufficient in practice. But what is crucial to recognize is that the above examples of transfers between locations do not occur merely due to coincidentally proximate geographic boundaries; they are unions tied together by some version of a social contract. States within the United States, or to a lesser extent members of the European Union, do not tend to frame their contributions as obligations of charitable assistance; these exchanges are mutually beneficial and are in fact constitutive of the political and economic communities to which the states belong. Indeed, the current “assistance” framing of the international legal obligation of rich countries to assist poor countries in realizing the right to health (and other ESC rights) constrains development of such a social contract in at least two ways. First, wealthy nations are able to sidestep their first and primary obligation to “do no harm,” and refrain from in any way undermining poorer nations’ efforts to realize the right to health. Second, the framing of these obligations in terms of *foreign affairs* and *aid* tends to remove the substantive issues from the domestic political realm in both donor and recipient states, making governments less accountable to their constituents.²¹⁵

More broadly, a focus on “assistance” and “aid” anneal the structural inequalities in the political economy of global health and beyond. The benefits that wealthier states extract from poor states, and the resulting resource and power asymmetries, are largely obfuscated by the focus on interstate assistance from donor states to aid-dependent states. Importantly, the same commission that defined “political determinants of health” also recognized that “[p]lower asymmetry and global social norms limit the range of choice and constrain action on health inequity” and that “major drivers of ill health lie beyond the control of national governments and, in many instances, also outside of the health sector.”²¹⁶ For example, transnational corporations contribute to social and political determinants of health, and result in health inequity, when they aggressively market health-damaging products—such as in the cigarette, sugar, and alcohol industries—onto local populations.²¹⁷ Transnational corporations, such as those

213. *Cohesion Fund*, EUROPEAN COMMISSION, https://ec.europa.eu/regional_policy/en/funding/cohesion-fund [https://perma.cc/4TSY-5LFV].

214. *Id.*

215. Indeed, “aid” now actually more often comes from private donors, such as the Bill and Melinda Gates Foundation, which are not politically accountable in the same way as governments.

216. Ottersen et al., *supra* note 203, at 630–31.

217. *See generally* Philip Morris Brands Sàrl, Philip Morris Products S.A. & Abal Hermanos S.A. v. Oriental Republic of Uruguay, ICSID Case No. ARB/10/7, Award (July 8, 2016), http://icsidfiles.worldbank.org/icsid/ICSIDBLOBS/OnlineAwards/C1000/DC9012_En.pdf

within the soft drink industry, have also fostered the privatization—and sometimes the contamination—of local water supplies in developing countries, with the support of international financial institutions, including the International Monetary Fund and World Bank.²¹⁸

Perhaps less intuitively, developing nations suffer even more profoundly at the hands of transnational corporations and international financial institutions through extraction of funds that would otherwise go to domestic infrastructure, including health. Despite the typical view of foreign aid as flowing from richer to poorer countries, current estimates indicate that “for every \$1 of aid that developing countries receive, they lose \$24 in net outflows.”²¹⁹ These “outflows” occur through poorer states’ interest payments on sovereign debt, uneven trade agreements, illicit flows, and corporate tax evasion. For example, countries in the global South have paid over \$4.2 trillion in interest payments on sovereign debts since 1980.²²⁰ “Illicit flows” comprise an even larger share of the money being drained out of developing nations, by transnational corporations seeking to avoid paying domestic taxes—often the same corporations hawking their corrosive products into the domestic markets. For example, corporations engage in a practice known as “trade misinvoicing” to evade taxes, which involves reporting “false prices on their trade invoices in order to spirit money out of developing countries directly into tax havens and secrecy jurisdictions” in sums that add up to hundreds of billions each year.²²¹ Similar tactics for avoiding taxation, such as “same-invoice faking” or “transfer pricing,” drain further hundreds of billions in tax dollars that could otherwise go toward the host states’ development of local infrastructure, including health.²²²

The response to these facts then cannot be solely—or even primarily—calls for crumbs of charitable assistance that reify the colonialist global order. On the contrary, the actions of transnational corporations occur under the effective control of governments in the economic North, as do many of the policies instituted by

[<https://perma.cc/7D6D-MGWR>], *rectified*, Decision on Rectification (Sept. 26, 2016), http://icsidfiles.worldbank.org/icsid/ICSIDBLOBS/OnlineAwards/C1000/DC9013_En.pdf [<https://perma.cc/6N7P-KMKJ>]; WORLD HEALTH ORG., GLOBAL STATUS REPORT ON ALCOHOL AND HEALTH (2018); Tjidde Tempels, Marcel Verweij & Vincent Blok, *Big Food’s Ambivalence: Seeking Profit and Responsibility for Health*, 107 AM. J. PUB. HEALTH 402 (2017).

218 JONATHAN M. HARRIS & BRIAN ROACH, ENVIRONMENTAL AND NATURAL RESOURCE ECONOMICS: A CONTEMPORARY APPROACH 554–555 (4th ed. 2017).

219 Jason Hickel, *Aid in Reverse: How Poor Countries Develop Rich Countries*, GUARDIAN (Jan. 14, 2017), <https://www.theguardian.com/global-development-professionals-network/2017/jan/14/aid-in-reverse-how-poor-countries-develop-rich-countries> [<https://perma.cc/KHD3-WTMW>].

220. *Id.*

221. *Id.* See also GLOBAL FINANCIAL INTEGRITY, FINANCIAL FLOWS AND TAX HAVENS: COMBINING TO LIMIT THE LIVES OF BILLIONS OF PEOPLE 15 (2015).

222. *Id.* at 95; MISFORTUNE, *supra* note 20.

international financial institutions. The response, then, should be to reassert democratic control over decisions, which have fundamental implications for the fiscal space available for health institutions and beyond. As UN Special Rapporteur on Extreme Poverty and Human Rights, Philip Alston called out the World Bank and the International Monetary Fund, challenging longstanding pretensions that their policies and lending do not affect “political” questions.²²³ The visibly ravaging effects of decisions regarding sovereign debt burdens and austerity during the COVID-19 pandemic,²²⁴ lend urgency to the imperative of radically democratizing these decisions in the future.

The influential, although non-binding, *Maastricht Principles on the Extraterritorial Obligations of States in the Area of Economic, Social and Cultural Rights* provide that a state has extraterritorial obligations with regard to situations “over which it exercises authority or effective control” in which its “acts or omissions bring about foreseeable effects” on the enjoyment of ESC rights, “whether within or outside its territory.”²²⁵ Since the issuance of the *Maastricht Principles*, UN treaty-monitoring bodies, domestic courts, and supranational tribunals have increasingly begun to examine countries’ extraterritorial obligations (ETOs) that stem from the actions of states or non-state actors and have harmful impacts elsewhere. These situations include those in which “the State, acting separately or jointly, whether through its executive, legislative or judicial branches, is in a position to exercise decisive influence or to take measures to realize” ESC rights.²²⁶

For example, in issuing an advisory opinion on *State Obligations in Relation to the Environment in the Context of the Protection and Guarantee of the Rights to Life and to Personal Integrity*,²²⁷ the Inter-American Court on Human Rights

223. Philip Alston (Special Rapporteur on Extreme Poverty and Human Rights), *Extreme Poverty and Human Rights*, U.N. Doc. A/70/274, summary (Aug. 4, 2015) (“The Special Rapporteur concludes that the existing approach taken by the Bank to human rights is incoherent, counterproductive and unsustainable The biggest single obstacle to moving towards an appropriate approach is the anachronistic and inconsistent interpretation of the ‘political prohibition’ That inhibits its ability to take adequate account of the social and political economy aspects of its work within countries and contradicts and undermines the consistent recognition by the international community of the integral relationship between human rights and development.”).

224. Juan Pablo Bohoslavsky, *COVID-19 Economy vs Human Rights: A Misleading Dichotomy*, HEALTH & HUM. RTS. J.: VIEWPOINTS. (April 20, 2020), <https://www.hhrjournal.org/2020/04/covid-19-economy-vs-human-rights-a-misleading-dichotomy> [<https://perma.cc/B497-VN4E>] (citing Juan Pablo Bohoslavsky (Independent Expert on the Effects of Foreign Debt and Other Related International Financial Obligations of States on the Full Enjoyment of Human Rights, Particularly Economic, Social and Cultural Rights), *Private Debt and Human Rights*, U.N. Doc. A/HRC/43/45 (Jan. 3, 2020)).

225. MAASTRICHT PRINCIPLES, *supra* note 192, art. 9.

226. *Id.*

227. The Environment and Human Rights (State Obligations in Relation to the Environment in the Context of the Protection and Guarantee of the Rights to Life and to Personal Integrity:

extended states' obligations to respect the right to a healthy environment of those residing outside of a state's territory. The Court clarified that the "concept of jurisdiction under Article 1(1) of the American Convention encompasses any situation in which a State exercises authority or effective control over an individual, either within or outside its territory."²²⁸ Thus, states are responsible for extraterritorial impacts of activities occurring within their jurisdiction, and "must ensure that their territory is not used in such a way as to cause significant damage to the environment of other States or of areas beyond the limits of their territory" if such damage would violate any person's rights.²²⁹

As tectonic a shift as ETOs might seem to imply, basic legal frameworks and models for addressing ETOs domestically have been generated in the past. For example, in the United States, the amended U.S. Foreign Corrupt Practices Act of 1977 prohibits U.S.-based persons (including corporations) from bribing officials of foreign jurisdictions to obtain business benefits.²³⁰ It is possible to imagine extending this sort of prohibition to persons and corporations whose U.S.-based activities contribute to the many kinds of extraterritorial flows out of foreign countries which can be tied directly to health. Moreover, in recent years there has been bipartisan support for incorporating requirements for improved—yet still tepid—labor and environmental standards for people in other countries under trade agreements such as the United States–Mexico–Canada Agreement,²³¹ passed by the U.S. Congress in January 2020.²³² In short, social pressures can be generated to hold governments that have effective control over the drivers of ill health accountable by their citizens through democratic institutions, rather than solely invoking the responsibility of countries where impacts are felt.

While groundwork for ETOs has begun to be laid, we fully acknowledge that additional work and legal experimentalism is needed to refine the extent and

Interpretation and Scope of Articles 4(1) and 5(1) in Relation to Articles 1(1) and 2 of the American Convention on Human Rights), Advisory Opinion OC-23/17, Inter-Am. Ct. H.R. (ser. A) No. 23 (Nov. 15, 2017).

228. *Id.* ¶ 244(1).

229. *Id.* ¶ 104(f).

230. 15 U.S.C. § 78dd-1 to -3.

231. See, e.g., Nicole M. Aschoff, *The New NAFTA Is a Raw Deal for Workers*, JACOBIN (Dec. 14, 2019), <https://jacobinmag.com/2019/12/nafta-deal-usmca-united-states-mexico-canada-agreement> [<https://perma.cc/CZP2-GRL3>]; Beth Baltzan & Jeffrey Kucik, *NAFTA's Replacement Gives Labor Some Shelter from Globalization's Storms*, FOREIGN POL'Y (Jan. 16, 2020), <https://foreignpolicy.com/2020/01/16/usmca-mexico-canada-trump-workers-democrats-naftas-replacement-gives-labor-some-shelter-from-globalizations-storms> [<https://perma.cc/5DUH-L28J>]; David Bacon, *The New NAFTA Won't Protect Workers' Rights*, NATION (Nov. 8, 2019), <https://www.thenation.com/article/archive/nafta-usmca-trade-agreement> [<https://perma.cc/LS7Z-K333>].

232. United States–Mexico–Canada Agreement, Pub. L. No. 116-113 (2020).

content of ETOs under different circumstances.²³³ However, the realities of our globalized world and the transnational drivers of health demand subjecting the policy and legal decisions that impact health abroad to greater democratic scrutiny and decision-making. Without doing so, assistance in the current political economy of global health compounds and obscures the legacies of colonialism and neocolonialism that generated the existing economic and political power imbalances in the first place, and displaces accountability to citizens with aid dependent upon donors. Imposing ETOs on states would necessitate that we first reconstitute and enlarge our understanding of the social contract as being inclusive of the transboundary effects of states and transnational corporations in this globalized world.

CONCLUSION

As underscored by differential governmental responses during the COVID-19 pandemic, we have argued here that it is urgent to advance understanding of the linkage between democracy and health, which is too often considered a technical, “norm-free” subject. In doing so, we have emphasized that health, perhaps more than any other right, calls for a reconsideration of the traditionally isolated way in which human rights realization has generally been theorized. As South African Constitutional Court Justice Albie Sachs noted in his *Soobramoney v. Minister of Health* concurrence:

Health care rights by their very nature have to be considered not only in a traditional legal context structured around the ideas of human autonomy but in a new analytical framework based on the notion of human interdependence When rights by their very nature are shared and inter-dependent, striking appropriate balances between the equally valid entitlements or expectations of a multitude of claimants should not be seen as imposing limits on those rights . . . but as defining the circumstances in which the rights may most fairly and effectively be enjoyed.²³⁴

To date, health rights have too often been articulated in the abstract untethered from the institutional arrangements and democratic practices necessary to breathe life into them, as well as the political economy that invariably shapes such arrangements in practice.

That scaffolding for health rights is inadequate because, as Rawls reminds us, “[t]he kind of lives that people can and do lead is importantly affected by the moral conception publicly realized in their society. What sorts of persons we are is shaped by how we think ourselves and this in turn is influenced by the social forms

233. Human Rights Council Res. 26/9, U.N. Doc. A/HRC/RES/26/9 (July 14, 2014).

234. *Soobramoney v. Minister of Health (Kwazulu-Natal)* 1998 (1) SA 765 (CC) at para. 54 (Sachs, J., concurring).

we live under.”²³⁵ The set of rights the law recognizes as assets of citizenship and the ways health-related rights are defined play a fundamental role in understandings of governmental and private responsibility for patterns of suffering and well-being. COVID-19 struck a world shackled by decades of legal rules embedding privatization in health systems and inequalities in national and global political economies. Today, to move beyond the horrors and massive social trauma of the pandemic, we will need to rebuild our democracies in new ways, and rethinking the role of health and health systems, and the transboundary impacts on health that different structural factors have, should be an integral part of how we do so.

As we have argued here, an understanding of health systems as democratic social institutions has implications, among other things, for (1) financing and delivery of goods, facilities, and services (including public health goods and services); (2) defining the contours of a legally enforceable health entitlement through legitimate processes; (3) oversight and regulation of the preceding conditions; and (4) provision of adequate information that allows decisions affecting health (made by governments and commercial actors alike) to be subjected to democratic scrutiny. As suggested by Justice Sachs in *Soobramoney*, here we have asserted that defining the contours of health rights—the process for determining what is included in guaranteed care and how it is delivered—belies the idea of rights as protections from the state and against one another: rights to be left alone. Rather, health rights require people to come together under conditions of background equality to analyze and make decisions about collective imperatives.

Indeed, at a time when international human rights are increasingly widely perceived as disconnected from broader struggles for social justice and substantive democracy, we would do well to recall that all rights are ultimately “dependent for their normative force on the engagement and commitment of an active citizen body.”²³⁶ Nowhere is this recognition more crucial than in health, which determines so much of our ability to execute life plans and participate as diverse but equal members of our societies in one shared world.

235. John Rawls, *The Independence of Moral Theory*, 48 PROC. & ADDRESSES OF THE AM. PHIL. ASS'N 5, 20 (1974–75).

236. Benjamin R. Barber, *Foundationalism and Democracy*, in DEMOCRACY AND DIFFERENCE, *supra* note 17, at 348, 354.

Health Justice Strategies to Eradicate Lead Poisoning: An Urgent Call to Action to Safeguard Future Generations

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Abstract:

Despite over a century of evidence that lead is a neurotoxin that causes irreparable harm, today, lead continues to pervade children's environments and remains a constant threat to health and wellbeing. One in three homes across the United States housing children under the age of six has significant lead-based paint hazards that place occupants at risk of permanent neurological harm and lifelong poor health risks. Federal, state, and local governments must use a range of primary prevention strategies in order to fully eradicate the risks and protect children from lead poisoning. This Article provides a comprehensive examination of best practices for addressing lead poisoning and proposes urgent reform measures at the local and state levels. Successful interventions ultimately prioritize health justice strategies and rely on community ownership and cross-sector participation; dedicate significant resources and funding to completely eliminate lead in the environment; and prioritize primary prevention practices that identify lead-based paint hazards before children are exposed.

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TABLE OF CONTENTS

INTRODUCTION	149
I. A HEALTH JUSTICE FRAMEWORK FOR LEAD POLICY	153
A. PRIMARY PREVENTION APPROACHES MUST BE PRIORITIZED	153
B. INTERVENTION MUST FOCUS ON THE WHOLE COMMUNITY	154
C. LOW-INCOME AND TRADITIONALLY MARGINALIZED COMMUNITIES MUST BE ENGAGED AS LEADERS IN LEAD POISONING PREVENTION.....	156
D. INTERPROFESSIONAL COLLABORATION AMONG COMMUNITY MEMBERS AND DIVERSE STAKEHOLDERS IS CRITICAL TO ELIMINATING LEAD POISONING	158
E. THE HEALTH OF LOW-INCOME PEOPLE, CHILDREN, AND COMMUNITIES OF COLOR MUST BE PRIORITIZED IN ALL POLICIES	160
II. ENGAGE IN PRIMARY PREVENTION PRACTICES TO PREVENT LEAD POISONING.....	161
A. PROACTIVE LEAD HAZARD INSPECTIONS	162
1. PRE-1978 RENTAL UNIT INSPECTIONS	162
2. POINT OF SALE INSPECTIONS	169
B. COMPREHENSIVE AND ACCURATE IDENTIFICATION OF HAZARDS	170
1. UPDATE LEAD HAZARD STANDARDS TO PROTECT HEALTH	170
2. IDENTIFY ALL SOURCES OF LEAD IN THE ENVIRONMENT	172
C. USING TECHNOLOGY & DATA TO IDENTIFY AND REMOVE LEAD HAZARDS AND PREVENT FUTURE HARM	174
1. DATA COLLECTION	174
2. LEVERAGING TECHNOLOGY TO IDENTIFY COMMUNITIES AND CHILDREN AT RISK OF LEAD EXPOSURE	175
III. SECONDARY PREVENTION STRATEGIES TO IDENTIFY AND IMMEDIATELY ELIMINATE CHRONIC LEAD POISONING	177
A. UNIVERSAL SCREENING.....	177
B. STATE MEDICAID SCREENING.....	181
C. DEFINITION OF LEAD POISONING AND ACTION LEVELS	182

IV. INCREASED FUNDING AND COMPLIANCE	186
A. RAISING REVENUE	186
1. MEDICAID & CHIP	187
2. HEALTH CARE PROVIDERS, SYSTEMS, AND HOSPITALS AS INVESTORS IN LEAD POISONING PREVENTION AND COMMUNITY HEALTH	188
3. REGIONAL FINANCIAL INSTITUTIONS	192
4. PAY FOR SUCCESS	193
5. TAXES & FEES TO INCREASE LEAD POISONING PREVENTION FUNDS ...	194
6. TAX CREDITS	197
7. FEDERAL GRANT AND LOAN PROGRAMS	198
B. ACCOUNTABILITY	199
1. ROBUST ENFORCEMENT	199
I. TENANT RIGHTS AND REMEDIES	202
II. LIABILITY FOR THE LEAD PAINT INDUSTRY ASSOCIATION AND PAINT MANUFACTURERS	204
2. REMEDIES INVOLVING THE PROPERTY	206
I. RENT REDUCTION AND ESCROW	206
II. LIENS	206
3. ENFORCEMENT OF LEAD-SAFE PRACTICES	207
I. STATE ADOPTION AND ENFORCEMENT OF THE LEAD RENOVATION, REPAIR, AND PAINTING RULE	207
II. LICENSING STANDARDS FOR PROFESSIONALS	208
CONCLUSION	209

INTRODUCTION

Over the past century, tens of millions of children have been poisoned by lead. Despite early warnings of its toxic effects,¹ the heavy metal was used extensively in the American home.² Today, lead is prevalent in children's environments—from the homes in which they live to the water they drink—and it remains a constant threat to health and wellbeing. Children are most often exposed to lead hazards in the form of chipping and peeling lead-based paint, lead-contaminated dust, and lead-contaminated soil in and around pre-1978 homes.³ Over thirty-seven million homes (34.9% of all housing units) in the United States have lead-based paint that will become a lead hazard if not closely monitored and maintained,⁴ and, of these, twenty-three million homes contain active lead hazards.⁵ Nationwide, one in three homes with children under the age of six has significant lead-based paint hazards that place occupants at risk of grave harm.⁶

Despite ample evidence of the danger of lead-based paint and lead dust, executives in the paint and lead industries, including Sherwin Williams, manufactured and promoted lead-based paint for use on and in residential homes during the 20th Century.⁷ The Lead Industries Association spearheaded a successful

1. See generally A. Jefferis Turner, *On Lead Poisoning in Children*, 1 BRIT. MED. J. 895 (1909) (discussing the signs and symptoms of lead poisoning in children); see also David Rosner & Gerald Markowitz, *A 'Gift of God?': The Public Health Controversy over Leaded Gasoline during the 1920s*, 75 AM. J. PUB. HEALTH 344 (1985) (arguing that the public, scientists, and government officials were aware of the dangers posed by the introduction of lead into gasoline as early as the 1920s).

2. See generally GERALD MARKOWITZ & DAVID ROSNER, *LEAD WARS: THE POLITICS OF SCIENCE AND THE FATE OF AMERICA'S CHILDREN*.

3. Lead in soil, water, and consumer products are other common sources of exposure. See Arthur Delaney, *Lots of Cities Have the Same Lead Pipes That Poisoned Flint*, HUFFINGTON POST (Jan. 28, 2016), https://www.huffpost.com/entry/lead-pipes-everywhere_n_56a8e916e4b0f71799288f54; Michael Hawthorne, *Chicago to Test for Lead in Water on Higher-Risk Streets*, CHI. TRIB. (Aug. 2, 2016), <https://www.chicagotribune.com/investigations/ct-chicago-water-testing-20160801-story.html>. Chicago mandated leaded pipes until the mid-1980s. *Id.*; see also CTRS. FOR DISEASE CONTROL & PREVENTION, *CHILDHOOD LEAD POISONING* (2013), https://www.cdc.gov/nceh/lead/factsheets/Lead_fact_sheet.pdf; *Lead and Drinking Water from Private Wells* (2015), <https://www.cdc.gov/healthywater/drinking/private/wells/disease/lead.html>.

4. U.S. DEP'T OF HOUS. & URBAN DEV., *AMERICAN HEALTHY HOMES SURVEY: LEAD AND ARSENIC FINDINGS*, 1, 15 (2011), https://www.hud.gov/sites/documents/AHHS_REPORT.PDF. [hereinafter *AMERICAN HEALTHY HOMES SURVEY*]

5. *Id.* at ES-1 (“23.2 million homes (22%) have [lead-based paint] hazards”).

6. *Id.* (“Of 16.8 million homes with children under the age of 6, 5.7 million (3.4%) have [lead-based paint]”).

7. See GERALD MARKOWITZ & DAVID ROSNER, *supra* note 2, at 40. (“[T]he industry made it its business to promote the metal as good for society and to challenge assertions that lead in the atmosphere was dangerous.”); see also *People v. ConAgra Grocery Prods. Co.*, 17 Cal. App. 5th 51, 82 (Ct. App. 2017) (“[P]laintiff’s experts testified to even more specific conclusions: ‘Sherwin-Williams had actual knowledge about the hazards of lead as early as 1900.’”).

campaign to defeat legislative attempts to control the neurotoxin and diverted attention away from the paint and lead industries' roles in lead poisoning by blaming the problem on the parents and the cleanliness of housing.⁸ As a result of this industry opposition, the use of lead-based paint in housing was not banned nationwide until 1978, years after the United Nations' ban and despite ample evidence of its dangers.⁹

Unlike most public health issues, which can be addressed by regulating the source of harm, lead poisoning cannot be eliminated through the regulation of lead and lead-based paint alone. Rather, because "legacy lead" saturates children's environments, lead poisoning can only be prevented by eliminating sources of exposure.¹⁰ Unable to justify the costs associated with lead elimination, federal and local governments settled on reactive approaches that fall short of prevention. As a result, and despite undisputed scientific evidence of lead's toxicity and widespread knowledge about how to eliminate the hazard, current public policy follows a predominately "wait and see" approach, in which children are biologic monitors for lead hazards.¹¹

Children who live in impoverished communities have the highest prevalence of elevated blood lead levels.¹² The risk of lead poisoning falls disproportionately on minority children, with non-Hispanic Black children nearly three times as likely as White children to have highly elevated blood lead levels and the subsequent disabling conditions.¹³ In one study, lead toxicity prevalence rates among children

8. See generally David Rosner & Gerald Markowitz, *Building the World That Kills Us: The Politics of Lead, Science, and Polluted Homes, 1970 to 2000*, 42 J. URB. HIST. 323 (2016).

9. CPSC Announces Final Ban on Lead-Contaminated Paint, U.S. CONSUMER PROD. SAFETY COMMISSION (Sep. 2, 1977), <https://www.cpsc.gov/Recalls/1977/cpsc-announces-final-ban-on-lead-containing-paint>.

10. *Public Health Statement for Lead*, AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY (Aug. 2007), <https://www.atsdr.cdc.gov/phs/phs.asp?id=92&tid=22> ("However, elemental lead cannot be broken down.").

11. Comm. on Envtl. Hazards & Comm. on Accident & Poison Prevention, *Statement of Childhood Lead Poisoning*, 79 PEDIATRICS 457, 463 (1987), <https://pediatrics.aappublications.org/content/pediatrics/79/3/457.full.pdf>.

12. See Elise Gould, *Childhood Lead Poisoning: Conservative Estimates of the Social and Economic Benefits of Lead Hazard Control*, 117 ENVTL. HEALTH PERSPS. 1162, 1162–63 (2009); Jaime Raymond et al., *Lead Screening and Prevalence of Blood Lead Levels in Children Aged 1–2 Years — Child Blood Lead Surveillance System, United States, 2002–2010 and National Health and Nutrition Examination Survey, United States, 1999–2010*, 63 MORBIDITY & MORTALITY WKLY. REP. 36, 39 (2014) (indicating that 5.3% of children one to two years of age with blood lead levels ≥ 5 $\mu\text{g/dL}$ are on Medicaid while merely 2.1% of children not insured by Medicaid have blood lead levels ≥ 5 $\mu\text{g/dL}$).

13. See 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, e380 (2009) ("A higher percentage of children with BLLs . . . were non-Hispanic black (3.4% vs 1.2% for Mexican American and 1.2% for non-Hispanic white children)").

in Black and Hispanic neighborhoods topped 90% of the child population.¹⁴ The authors concluded, “lead toxicity is a source of ecological inequity by race and a pathway through which racial inequality literally gets into the body.”¹⁵

Because lead is a neurotoxin with no safe level of human exposure, the public health consequences of reactive and siloed policy interventions are severe.¹⁶ Lead poisoning causes irreversible neurological harm that affects bodily functions, growth, cognition, behavior, and development.¹⁷ Adults are at elevated risk for chronic renal failure, premature death, and hypertension and coronary heart disease, and lead exposure may be the leading risk factor for death from cardiovascular disease.¹⁸ The financial consequences of these outcomes include billions of dollars in public spending on health care, special education, juvenile justice, and other social services.¹⁹

14. Robert J. Sampson & Alix S. Winter, *The Racial Ecology of Lead Poisoning: Toxic Inequality in Chicago Neighborhoods, 1995–2013*, 13 DUBOIS REV.: SOC. SCI. RES. ON RACE 261, 279 (2016).

15. *Id.* at 279.

16. *Childhood Lead Poisoning Prevention*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/nceh/lead/default.htm> (last accessed Mar. 3, 2020).

17. Even at the lowest levels of exposure, lead poisoning can lead to reduced IQ, diminished intellectual and academic abilities, academic failure, juvenile delinquency, high blood pressure, learning disabilities, behavioral problems, developmental delay, and premature death. *See* WORLD HEALTH ORG., LEAD POISONING AND HEALTH (Aug. 23, 2019), <https://www.who.int/en/news-room/fact-sheets/detail/lead-poisoning-and-health>. Lead exposure is a risk factor for adult onset disability and disease, including neurological disorders, adult hypertension, heart disease, stroke, kidney malfunction, elevated blood pressure, osteoporosis, cognitive decline, and cardiovascular disease. *See* NAT’L TOXICOLOGY PROGRAM, U.S. DEPT. OF HEALTH & HUMAN SERVS., NTP MONOGRAPH: HEALTH EFFECTS OF LOW-LEVEL LEAD 1, 19–43 (2012), https://ntp.niehs.nih.gov/ntp/ohat/lead/final/monographhealtheffectslowlevellead_newissn_508.pdf; Gould, *supra* note 12, at 1162–64; Bruce P. Lanphear, *The Conquest of Lead Poisoning: A Pyrrhic Victory*, 115 ENVTL. HEALTH PERSPS. A484, A484 (2007) (citing Andy Menke et al., *Blood Lead Below 0.48 µmol/L (10 µg/dL) and Mortality Among US Adults*, 114 CIRCULATION 1388 (2006); Brian S. Schwartz et al., *Occupational Lead Exposure and Longitudinal Decline in Neurobehavioral Test Scores*, 16 EPIDEMIOLOGY 106 (2005); Marc G. Weisskopf et al., *Cumulative Lead Exposure and Prospective Change in Cognition Among Elderly Men: The VA Normative Aging Study*, 160 AM. J. EPIDEMIOLOGY 1184 (2004)); Bruce P. Lanphear et al., *Cognitive Deficits Associated with Blood Lead Concentrations <10 µg/dL in US Children and Adolescents*, 115 PUB. HEALTH REPS. 521, 526–28 (2000); Bruce P. Lanphear et al., *Low-Level Environmental Lead Exposure and Children’s Intellectual Function: An International Pooled Analysis*, 113 ENVTL. HEALTH PERSPS. 894, 897–98 (2005); Bruce P. Lanphear et al., *Low-Level Lead Exposure and Mortality in US Adults: A Population-Based Cohort Study*, 3 LANCET PUB. HEALTH E177 (2018); Letter from Sheela Sathyanarayana, Chair, Children’s Health Prot. Advisory Comm., to Gina McCarthy, Adm’r, Env’tl. Prot. Agency 1, 2 (Jan. 8, 2015), https://www.epa.gov/sites/production/files/2015-01/documents/naaqs_for_lead_letter.pdf (stating that at blood lead level of 0.1 µg/dL, lead poisoning was associated with a one-point IQ loss, as well as other neurological and other health and developmental harms).

18. Lanphear et al., *Low-Level Exposure and Mortality*, *supra* note 17, at E177.

19. HEALTH IMPACT PROJECT, 10 POLICIES TO PREVENT AND RESPOND TO CHILDHOOD LEAD

To prepare policymakers to address this urgent health and safety threat to children,²⁰ this Article provides a comprehensive examination of best practices for the elimination of lead poisoning in the United States and proposes urgent reform measures at the local and state levels.²¹ As discussed herein, ultimately, the success

EXPOSURE 1, 86 (AUG. 2017), http://www.pewtrusts.org/~media/assets/2017/08/hip_childhood_lead_poisoning_report.pdf; COLUMBIA LAW SCH. HEALTH JUSTICE ADVOCACY CLINIC, THE COST OF CHILDHOOD LEAD POISONING IN THE UNITED STATES OF AMERICA 1, <https://www.networkforphl.org/wp-content/uploads/2020/03/Cost-of-Childhood-Lead-Poisoning-in-US.pdf> (last accessed Mar. 7, 2020).

20. See Deborah Bennett et al., *Project TENDR: Targeting Environmental Neuro-Developmental Risks*, *The TENDR Consensus Statement*, 124 ENVTL. HEALTH PERSPS. A118, A118 (2016) (citing Bruce P. Lanphear, *The Impact of Toxins on the Developing Brain*, 36 ANN. REV. PUB. HEALTH 211 (2015); Kristen Lyall, Rebecca J. Schmidt & Irva Hertz-Picciotto, *Maternal Lifestyle and Environmental Risk Factors for Autism Spectrum Disorders*, 43 INT'L J. EPIDEMIOLOGY 443 (2014); Deborah Rice & Stan Barone Jr., *Critical Periods of Vulnerability for the Developing Nervous System: Evidence from Humans and Animal Models*, 108 ENVTL. HEALTH PERSPS. 511 (2000)); see also National Ambient Air Quality Standards for Lead, 73 Fed. Reg. 66,963, 66,972 (Nov. 12, 2008) (to be codified at 40 C.F.R. pts. 50, 51, 53, 58); ADVISORY COMM. ON CHILDHOOD LEAD POISONING PREVENTION, CTRS. FOR DISEASE CONTROL & PREVENTION, LOW LEVEL LEAD EXPOSURE HARMS CHILDREN: A RENEWED CALL FOR PRIMARY PREVENTION 1 (2012), https://www.cdc.gov/nceh/lead/acclpp/final_document_030712.pdf; AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY, U.S. DEP'T OF HEALTH AND HUMAN SERVS., TOXICOLOGICAL PROFILE FOR LEAD 1, 31 (2019), https://www.ncbi.nlm.nih.gov/books/NBK158766/pdf/Bookshelf_NBK158766.pdf ("MRLs [minimum risk levels] were not derived for lead because a clear threshold for some of the more sensitive effects in humans has not been identified."); CTRS. FOR DISEASE CONTROL & PREV., CDC RESPONSE TO ADVISORY COMMITTEE ON CHILDHOOD LEAD POISONING PREVENTION RECOMMENDATIONS IN "LOW LEVEL LEAD EXPOSURE HARMS CHILDREN: A RENEWED CALL OF PRIMARY PREVENTION 1, 5 (2012), https://www.cdc.gov/nceh/lead/acclpp/cdc_response_lead_exposure_recs.pdf ("CDC will emphasize that the best way to end childhood lead poisoning is to prevent, control or eliminate lead exposures. Since no safe blood lead level in children has been identified, a blood lead 'level of concern' cannot be used to define individuals in need of intervention."); HUD Proposes New Rule to Help Children Exposed to Lead Paint Hazards: Lower Definition of "Elevated Blood Lead Levels" in Young Children to Match CDC, U.S. DEP'T OF HOUS. & URBAN DEV. (Aug. 31, 2016), <https://archives.hud.gov/news/2016/pr16-129.cfm>; Basic Information About Lead in Drinking Water, U.S. ENVTL. PROT. AGENCY, <https://www.epa.gov/ground-water-and-drinking-water/basic-information-about-lead-drinking-water> (last accessed Nov. 24, 2017) ("EPA and the Centers for Disease Control and Prevention (CDC) agree that there is no known safe level of lead in a child's blood. Lead is harmful to health, especially for children."). The effects of lead are particularly dangerous for children because the "blood-brain" barrier is less effective in children than it is for mature adults. Theodore I. Lidsky & Jay S. Schneider, *Lead Neurotoxicity in Children: Basic Mechanisms and Clinical Correlates*, 126 Brain 5, 6 (2003).

21. For a detailed analysis and discussion of the United States' toxic legacy of lead poisoning, the social determinants of lead poisoning, the legislative history of federal lead poisoning prevention laws, lead poisoning in federally assisted housing, and the importance of fighting for the elimination of lead poisoning, see generally the companion article, Emily A. Benfer, *Contaminated Childhood: How the United States Failed to Prevent the Chronic Lead Poisoning of Low-Income Children and Communities of Color*, 41 HARV. ENVTL. L. REV. 493 (2017), and the books, MONA HANNA-ATTISHA, WHAT THE EYES DON'T SEE (2019); MARKOWITZ & ROSNER, *supra* note 2.

of these interventions is dependent upon community ownership, prioritizing primary prevention practices that identify lead-based paint hazards before children develop lead poisoning, and dedicating significant funding to eliminate lead hazards. For a detailed analysis and discussion of the United States' toxic legacy of lead poisoning, the social determinants of lead poisoning, the legislative history of federal lead poisoning prevention laws, lead poisoning in federally assisted housing, and the importance of fighting for the elimination of lead poisoning, please see the companion articles, *Duty to Protect*, *Contaminated Childhood*, and the books *Lead Wars* and *What the Eyes Don't See*.²²

I. A HEALTH JUSTICE FRAMEWORK FOR LEAD POLICY

Health justice requires that all persons have equal ability to be free from the social determinants²³ that jeopardize their health and well-being.²⁴ At the same time, it requires equal access to opportunity and the ability to fully participate in society.²⁵ Lead policy, if it is to eliminate lead poisoning, must abide by health justice principles and strategies. The best practices described throughout this article are premised on the following foundational principles: (1) primary prevention approaches must be prioritized; (2) the whole community must be the focus in high risk areas; (3) affected populations, especially low-income and traditionally marginalized communities, must be engaged as leaders in lead poisoning prevention; (4) interprofessional collaboration among community members and diverse stakeholders is critical to eliminating lead poisoning; and (5) the health of children and low-income communities of color must be prioritized in all policies.

A. Primary Prevention Approaches Must be Prioritized

According to the Centers for Disease Control and Prevention, “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” to eliminate lead poisoning.²⁶ In light of the

22. See generally Benfer, *Contaminated Childhood*, *supra* note 21; Emily Benfer et al., *Duty to Protect: Enhancing the Federal Framework to Prevent Childhood Lead Poisoning and Exposure to Environmental Harm*, 18 YALE J. OF HEALTH POL., L. & ETHICS 1 (2019); see also HANNA-ATTISHA, *WHAT THE EYES DON'T SEE*, *supra* note 21; MARKOWITZ & ROSNER, *supra* note 2.

23. The social determinants of health are defined as the conditions in which people are born, grow, work, play, and live. *Social Determinants of Health*, WORLD HEALTH ORG., http://www.who.int/social_determinants/sdh_definition/en/ (last accessed Mar. 7, 2020).

24. For an overview of the health justice approach to policymaking, see Emily A. Benfer, *Health Justice: A Framework (and Call to Action) for the Elimination of Health Inequity and Social Justice*, 65 AM. U. L. REV. 275, 278–79 (2015).

25. See *id.* at 281.

26. CTRS. FOR DISEASE CONTROL AND PREVENTION, PREVENTING LEAD POISONING IN YOUNG

irreversible nature of lead poisoning, children can no longer continue to play the role of proverbial “canary in the coalmine,” identifying lead hazards with their developing bodies. “Screening children for elevated BLLs [blood lead levels] and [addressing] their housing only when their BLL is already elevated should no longer be acceptable practice.”²⁷ Rather, policymakers must make every effort to develop and implement strategies to address the conditions that disproportionately affect low-income communities and eliminate lead hazards *before* a child is lead poisoned.²⁸ Primary prevention is the most reliable and cost-effective measure to protect children and individuals from exposure to hazards and must be prioritized. Section II, *infra*, details policy measures rooted in this principle.

B. Intervention Must Focus on the Whole Community

It is widely recognized that lead poisoning affects low-income communities of color at a disproportionate rate. It is also well-documented that this disparity is due to longstanding structural racism and systemic factors. Given the lasting segregation by race and income, and the steadily increasing rates of lead poisoning among children of color, “demographic- and place-centered policy has greater potential to reach children and communities who can benefit the most.”²⁹ In order to address the historic roots of this disparity, a whole community approach is critical.

In a 2018 editorial in *JAMA Pediatrics*, Dr. Jessica Wolpaw Reyes proposed that, instead of solely targeting homes child by child, policy should prioritize “(1) the sources of exposure that are likely to affect the most children and (2) the children who are most likely to experience elevated blood lead levels.” The first priority places emphasis on remediating public sources of lead hazards, such as playgrounds and schools, pre-1978 rental units, and lead in water. This “exposure centric” approach maximizes the impact of a single intervention. Dr. Reyes’

CHILDREN: A STATEMENT BY THE CENTERS FOR DISEASE CONTROL AND PREVENTION 1, 1 (2005), <http://www.cdc.gov/nceh/lead/publications/PrevLeadPoisoning.pdf>. In public health, primary prevention approaches aim to prevent the development of disease entirely, while secondary prevention is designed to identify a disease at its earliest stages, before symptoms appear. Tertiary prevention is directed at preventing further deterioration in those who already have symptoms of disease. See *Primary, Secondary and Tertiary Prevention*, INST. FOR WORK & HEALTH (Apr. 2015), <https://www.iwh.on.ca/what-researchers-mean-by/primary-secondary-and-tertiary-prevention>.

27. See generally ADVISORY COMM. ON CHILDHOOD LEAD POISONING PREVENTION, LOW LEVEL EXPOSURE HARMS CHILDREN, *supra* note 20, at 15, ix.

28. In contrast, secondary prevention is designed to identify a disease at its earliest stages, while tertiary prevention is directed at preventing further deterioration in those who already have symptoms of disease. See *Primary, Secondary and Tertiary Prevention*, *supra* note 26.

29. Jessica Wolpaw Reyes, *A Social Justice Framework for Lead Policy*, 172 JAMA PEDIATRICS 912, 913 (2018) (“Essentially, hypersegregation by race and income has gathered the risks and the most at-risk children together, making primary prevention at the community level an excellent policy choice.”).

second priority focuses public policy on the whole communities where children are most at risk of lead poisoning. In these communities, home-centered interventions may not be the best policy tool.³⁰ This shift in lead policy focus from an individual lead poisoned child to a community at risk could not only result in a reduction of lead poisoning rates, it could also support broader movements to address structural racism and housing and environmental injustice in low-income communities of color. Before any interventions can be implemented, states and cities must lay the groundwork for ongoing collaboration across fields and with affected communities.

Community development offers a model for community investment and outreach. The strategy includes efforts to “improve the physical, economic, and social environment by promoting affordable housing, small-business development, job creation, and social cohesion.”³¹ As an anti-poverty tool, community development emphasizes investment in “affordable housing, small-business development, job creation, and social cohesion.”³² These efforts are important on two levels to address the health issues stemming from lead poisoning. First, community development is focused on addressing poverty, a social determinant of poor health. Children living in inadequate homes and low-income communities are at increased risk of behavioral and developmental problems, infectious and chronic diseases, and injury.³³ Local home assistance programs help communities by providing grants for repairs. Without such assistance, homes deteriorate, causing hazardous conditions that harm residents and the wider community.³⁴ Second, a focus on the community empowers individuals to mobilize and counteract specific environmental and health inequities in the long run.³⁵ A community-based process of eliminating lead poisoning would focus on primary prevention in entire blocks

30. *Id.*

31. Amanda Cassidy, *Community Development and Health*, HEALTH AFFAIRS 1, 1 (Nov. 10, 2011). For a more detailed discussion on community development, see generally Alexander von Hoffman, *The Past, Present, and Future of Community Development in the United States, Investing in What Works for America's Communities*, (Joint Ctr. For Housing Stud., Harv. U., Paper No. W12-6, 2012), https://www.jchs.harvard.edu/sites/default/files/w12-6_von_hoffman.pdf.

32. See Cassidy, *supra* note 31.

33. *Housing's and Neighborhoods' Role in Shaping Children's Future*, U.S. DEP'T OF HOUS. & URBAN DEV. (2014), <https://www.huduser.gov/portal/periodicals/em/fall14/highlight1.html>.

34. JOINT CTR FOR HOUS. STUDIES, HARVARD UNIV., *THE US HOUSING STOCK: READY FOR RENEWAL, IMPROVING AMERICA'S HOUSING* 2013 1, 7 (2013), https://www.jchs.harvard.edu/sites/default/files/harvard_jchs_remodeling_report_2013_0.pdf.

35. According to the U.S. Commission on Civil Rights, “[m]eaningful public participation by affected communities in the decision-making process is one of the cornerstones of environmental justice. The input of communities of color and low-income communities is integral to decision-making, planning, monitoring, problem-solving, and implementation and evaluation of environmental policies and practices.” U.S. COMM’N ON CIVIL RIGHTS, *NOT IN MY BACKYARD: EXECUTIVE ORDER 12,898 AND TITLE VI AS TOOLS FOR ACHIEVING ENVIRONMENTAL JUSTICE* 1, 169 (2003), <https://www.usccr.gov/pubs/envjust/ej0104.pdf>.

rather than individual homes.³⁶ Community development groups could create programs to educate community members about lead poisoning risks and prevention resources and train the workforce necessary for inspection and lead hazard reduction and abatement.

For example, Neighborhood Housing Services, a national community-based organization, works in specific communities to rehabilitate dilapidated homes (including lead abatement), carry out homeowner and financial literacy trainings for community members, and create community spaces.³⁷ These efforts create stable, revitalized neighborhoods with safe, affordable homes.³⁸ Renewing and increasing focus on community development that includes lead hazard abatement is crucial in eliminating lead poisoning.

It is well-documented that greater investment in low-income communities can lead to increased housing stability, less strain on families, and lower levels of violence.³⁹ Without such assistance, conditions in older low-income neighborhoods will continue to deteriorate, causing health hazards that harm residents and the community.⁴⁰ Any community development program must emphasize healthy homes strategies that address hazards, specifically lead poisoning.⁴¹

C. Low-Income and Traditionally Marginalized Communities Must be Engaged as Leaders in Lead Poisoning Prevention

Environmental inequality demonstrates the importance of focusing interventions on disadvantaged communities of color in poor neighborhoods with higher rates of lead poisoning, rather than on individual units.⁴² Especially in these communities, the elimination of lead poisoning is not possible unless the people most impacted by lead poisoning have the opportunity and the tools to participate in the development and implementation of lead poisoning prevention strategies.⁴³

36. See generally Joseph M. Braun et al., *Effect of Residential Lead-Hazard Interventions on Childhood Blood Lead Concentrations and Neurobehavioral Outcomes: A Randomized Clinical Trial*, 172 JAMA PEDIATRICS 934 (2018).

37. See, e.g., NHS OF NEW HAVEN, <https://nhsofnewhaven.org/> (last visited Mar. 7, 2020).

38. *About NHS New Haven*, NHS OF NEW HAVEN, <https://nhsofnewhaven.org/about/> (last visited Mar. 7, 2020).

39. See Alistair Woodward & Ichiro Kawachi, *Why Reduce Health Inequalities?*, 54 J. EPIDEMIOLOGY & CMTY. HEALTH 923, 924 (2000); Benfer, *supra* note 24, at 347; and Kevin Park, *Good Home Improvers Make Good Neighbors* 1, 19 (Joint Ctr. For Housing Stud., Harv. U., Paper No. W08-2, 2008), https://www.jchs.harvard.edu/sites/default/files/w08-2_park.pdf.

40. JOINT CTR FOR HOUS. STUDIES, *THE US HOUSING STOCK: READY FOR RENEWAL*, *supra* note 34, at 7.

41. *Id.* at 10.

42. See Reyes, *A Social Justice Framework for Lead Policy*, *supra* note 29, at 912–13.

43. The Health Impact Project report followed this model, conducting listening sessions and interviews of community members and parents directly affected by toxic lead, in addition to

Lead poisoning will continue to disproportionately affect low-income communities of color if residents are not given the opportunity to reverse the historic lack of bargaining power and become agents of change.⁴⁴ Communities and individuals affected by health inequity are “best positioned to identify the major challenges to overcoming inequity and to evaluate the viability of proposed solutions.”⁴⁵ However, in the case of lead poisoning, legal, social, historical and medical complexity, coupled with general lack of information, has created barriers to community empowerment and engagement. In the community-based participatory approach, a tool developed by the public health field, affected individuals interact with policymakers while identifying issues and developing strategies that address social determinants of poor health.⁴⁶ In order to be effective, the approach must include the education of low-income communities in current legal rights and remedies, policy reform recommendations, scientific definitions of lead hazards, health effects of even low blood lead levels, and best practices for protecting children from exposure to lead hazards. Community members should be offered trainings in grassroots organizing, leadership, and other community-based participatory approaches. At a minimum, community members must be consulted during the development, implementation, and enforcement of lead poisoning prevention laws, regulations, and policies. Community members should be informed about both the policy considerations and the justification behind decision making that affects their families.

At the same time, advocates and decision-makers must be cognizant of the underlying demands on the time of low-income residents that can prevent engagement. To reach low-income communities, decision-makers should: (1) meet individually with key community leaders, (2) attend existing stakeholder meetings, and (3) develop a committee of core neighborhood leaders.⁴⁷ By providing decision-makers with a deeper understanding of the specific needs of each community, such actions can help inform decision-makers of how to best craft engagement and education spaces.

quantitative analyses, to find solutions for lead poisoning’s impact on public health and health equity. HEALTH IMPACT PROJECT, 10 POLICIES, *supra* note 19.

44. Woodward & Kawachi, *supra* note 39, at 924.

45. Benfer, *supra* note 24, at 346.

46. See generally Barbara A. Israel et al., *Community-Based Participatory Research: A Capacity-Building Approach for Policy Aimed at Eliminating Health Disparities*, 100 AM. J. PUB. HEALTH 2094 (2010) (describing efficacy of Detroit Community-Academic Urban Research Center, a CBPR partnership between neighborhood organizations, Detroit Department of Health, health systems, and academic institutions). See also Benfer, *supra* note 24 (describing application of the community-based participatory approach to community engagement beyond research).

47. Planning & Zoning Center at Michigan State University, *A Guidebook to Community Engagement: Involving Urban and Low-Income Populations in an Environmental Planning Process*, September 2014, available at https://www.canr.msu.edu/uploads/375/65818/GuidebooktoCommunityEngagement_FINAL_Sept2014_1.pdf.

These long-term engagement strategies allow affected individuals to interact with policymakers while identifying issues and mechanisms to address social determinants of poor health.⁴⁸ Without focusing on individual empowerment and participation within the community, lead poisoning prevention work will fall short of its ultimate goals. In order to eliminate lead poisoning and for the maximum benefit, residents of high-risk neighborhood must be able to participate in the creation and implementation of the interventions.⁴⁹

D. Interprofessional Collaboration Among Community Members and Diverse Stakeholders is Critical to Eliminating Lead Poisoning

Widespread collaboration and commitment are critical to eliminating lead poisoning. Numerous governmental organizations, advocacy groups, and community development agents have an interest in lead poisoning prevention.⁵⁰ Such entities might include: local health departments that investigate cases of lead poisoning; building code enforcement agencies that address structural violations in a unit; homeowner advocacy groups that assist landlords in navigating regulations; tenant and housing advocacy groups that advocate for increased tenant rights; community development groups that secure funding to rehabilitate neighborhoods; hospitals and medical providers that identify and treat lead poisoned children; community-based organizations and organizers that work within affected communities; environmental justice advocates that address causes of pollution and environmental harm to residents; healthy homes advocates that seek to improve the energy-efficiency and safety of the home; educators that

48. See Barbara A. Israel et al., *Review of Community-Based Research: Assessing Partnership Approaches to Improve Public Health*, 19 ANN. REV. PUB. HEALTH 173, 177–79 (1998) (explaining that participatory approaches can be instrumental in poverty reduction strategies and improved health outcomes by: (1) recognizing community as a unit of identity; (2) building on strengths and resources within the community; (3) facilitating a collaborative, equitable partnership that increases community ownership and control; (4) integrating knowledge and action for mutual benefit of all partners; (5) promoting a co-learning and empowering process that attends to social inequalities; (6) disseminating findings and knowledge gained to all partners); see also PUB. HEALTH LEADERSHIP SOC'Y, PRINCIPLES OF THE ETHICAL PRACTICE OF PUBLIC HEALTH 1, 2–3 (2002), https://www.apha.org/-/media/files/pdf/membergroups/ethics/ethics_brochure.ashx.

49. See S. Leonard Syme & Miranda L. Ritterman, *The Importance of Community Development for Health and Well-Being*, 3 COMMUNITY DEV. INV. REV. 1, 1 (2009) (“[N]o matter how elegantly wrought a physical solution, no matter how efficiently designed a park, no matter how safe and sanitary a building, unless the people living in those neighborhoods can in some way participate in the creation and management of these facilities, the results will not be as beneficial as we might hope. It turns out that, for maximum benefit, physical improvements must be accompanied by improvements in the social fabric of the community.”).

50. See CHANGELAB SOLUTIONS, UP TO CODE: CODE ENFORCEMENT STRATEGIES FOR HEALTHY HOUSING 1, 14 (2015), https://www.changelabsolutions.org/sites/default/files/Up-to-Code_Enforcement_Guide_FINAL-20150527.pdf (emphasizing the need for “intragovernmental communication and collaboration”) [hereinafter UP TO CODE].

respond to learning delays and behavioral problems among students exposed to lead hazards; civil rights advocates seeking to secure fair housing and address discrimination on the basis of race and other protected classes; design labs that analyze social problems and evaluate the user experience of interventions; and most important the people directly affected by lead poisoning, among others. Ultimately, lead poisoning touches every sector of the community and those who serve it.

These entities and individuals often work in the same communities in unintentional silos or without coordination.⁵¹ A growing recognition that stakeholders across disciplines have similar objectives, targets, and challenges⁵² has increased national momentum towards cross-sector collaboration.⁵³ Inclusive partnerships and resource sharing are critical to addressing lead poisoning and its roots in structural racism and poverty.⁵⁴ In order to increase and encourage collaboration, state and local jurisdictions should replace barriers to, or mandates against, cross-sector and cross-system initiatives with incentives.⁵⁵ Together, the

51. See Cassidy, *supra* note 31.

52. See *id.*

53. See 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 HARV. L. & POL'Y REV. S1, S45 (2017) ("There is growing recognition that the community development and public health fields have similar objectives, targets, and challenges, and national momentum towards cross-sector collaboration is increasing.") (citing Bethany Rogerson et al., *A Simplified Framework for Incorporating Health into Community Development Initiatives*, 33 HEALTH AFF. 1028, 1028 (2014)); Paul W. Mattessich & Ela J. Rausch, *Cross-Sector Collaboration to Improve Community Health: A View Of The Current Landscape*, 33 HEALTH AFF. 1968, 1968 (2014). For example, at the federal level, identifying, designing, and implementing health-based solutions would require multiple entities, including the Departments of Health and Human Services, Education, Agriculture, Housing, Transportation, and the Internal Revenue Service, Environmental Protection Agency (EPA). Yet, each department and agency has different deadlines, evaluation systems, and reporting requirements, complicating partnerships. The Partnership for Sustainable Communities is an example of a successful interagency program between HUD, Department of Transportation, and the EPA to coordinate resources and achieve agency mission. See U.S. ENVTL. PROT. AGENCY, CREATING EQUITABLE, HEALTHY, AND SUSTAINABLE COMMUNITIES: STRATEGIES FOR ADVANCING SMART GROWTH, ENVIRONMENTAL JUSTICE, AND EQUITABLE DEVELOPMENT 1, 46 (2013), <https://www.epa.gov/sites/production/files/2014-01/documents/equitable-development-report-508-011713b.pdf>.

54. At the second annual New England Lead Poisoning Conference, the plenary panel consisted of major players in advocating for lead prevention in Claremont, New Hampshire — the Mayor, the CEO of the hospital, the superintendent of schools, a community advocate from Southwest Community Services, the city manager, and a building inspector. All panelists spoke about their individual roles in the city's initiative, but also about the importance of relationships and working beyond siloes. New England Lead Conference, *Conference & Registration Information 3* (Nov. 1, 2017), <http://35vcuc2ted113iiuuk1smndg.wpengine.netdna-cdn.com/wp-content/uploads/2017/09/2017-New-England-Lead-Conference-Registration.pdf>.

55. Wilhelmine D. Miller, Tabashir Sadegh-Nobari & Marsha Lillie-Blanton, *Healthy Starts for All: Policy Prescriptions*, 40 AM. J. PREVENTIVE MED. S19, S30 (2011).

community development, health, government, and other sectors, can design holistic interventions to improve the health and environment of the community.⁵⁶

E. The Health of Low-Income People, Children, and Communities of Color Must be Prioritized in All Policies

State and local governments should also consider the impact of their policies consider the impact on community health, low-income individuals, children, and communities of color. Health care alone only contributes to ten to fifteen percent of overall health and longevity.⁵⁷ Social, physical, and economic environments and conditions have a far greater impact on individual health and well-being.⁵⁸ Because the social determinants of health are often affected by government decision-making, it is imperative that states take an elevated “health in all policies” approach to policy development that anticipates possible negative health consequences for low-income people, children, and communities of color. Policymakers must monitor legislation and remove laws that negatively impact low-income and minority populations. This analysis must take place before the harm occurs. “[S]tates must (1) evaluate how a law might be applied, intentionally or inadvertently, to the disadvantage of marginalized individuals; and (2) examine the potential health effects on the entire population, paying special attention to marginalized individuals.”⁵⁹ Tools, such as the Environmental Impact Assessment, Health Equity Impact Assessment, or the Child Impact Assessment, can be used to identify deleterious health effects that disproportionately impact children, low-income people, and communities of color.⁶⁰ Failure to take these precautions will result in policies that either perpetuate health inequity or create new health hazards.

56. U.S. ENVTL. PROT. AGENCY, CREATING EQUITABLE, HEALTHY, AND SUSTAINABLE COMMUNITIES, *supra* note 53, at 2.

57. J. Michael McGinnis, Pamela Williams-Russo & James R. Knickman, *The Case for More Active Policy Attention to Health Promotion*, 21 HEALTH AFFAIRS 78, 78 (2002).

58. Only 25% of individual health is determined by genetics, medical care, and health behaviors, while 75% of health is determined by social and environmental factors. NCHHSTP *Social Determinants of Health*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/nchhstp/socialdeterminants/index.html> (last accessed Mar. 8, 2020); *What Drives Health*, ROBERT WOOD JOHNSON FOUNDATION: COMMISSION TO BUILD A HEALTHIER AMERICA, <http://www.commissiononhealth.org/WhatDrivesHealth.aspx> (last accessed Mar. 8, 2020).

59. Benfer, *supra* note 24, at 341.

60. KIDSIMPACT: ADVOCATES FOR CHILDREN, kidsimpact.org (last visited Mar. 8, 2020); *HIAs and Other Resources to Advance Health-Informed Decisions: A Toolkit to Promote Healthier Communities Through Cross-Sector Collaboration*, PEW, <https://www.pewtrusts.org/en/research-and-analysis/data-visualizations/2015/hia-map?sortBy=relevance&sortOrder=asc&page=1> (last updated April 1, 2020).

II. ENGAGE IN PRIMARY PREVENTION PRACTICES TO PREVENT LEAD POISONING

Current state and local responses to lead poisoning largely fail to prevent exposure to lead hazards. While some jurisdictions employ innovative approaches designed to identify and remove lead hazards before children are exposed, they are the exception to the rule. The overwhelming majority of jurisdictions employ a “downstream” approach that does not identify lead hazards or provide a right of action until the harm has already occurred—when it is too little, too late.⁶¹ Further exacerbating the ineffectiveness of most interventions, commonplace strategies are often fragmented and lack interprofessional and interdepartmental cooperation.

The reactive public policy approach is often attributed to concerns over the cost of comprehensive lead hazard inspections and remediation or abatement, fear that remediation will result in a loss of affordable housing stock, belief that property rights of a landlord supersede tenants’ rights to live in housing that is free of health hazards, lack of investment in preventative lead remediation, lack of inspectors or remediation and abatement firms in a community, blaming parents or cultural practices for children’s exposure to lead, and silos between city and state officials tasked with safeguarding the public from lead hazards making interventions challenging to implement. As discussed herein, these concerns do not justify the failure to eliminate lead poisoning. Rather, they should be further explored and, if substantiated, addressed as part of a comprehensive lead poisoning prevention strategy.

To effectively address lead poisoning, state and local jurisdictions must replace traditional approaches with prevention-oriented strategies. There is no single “silver bullet” to eliminating lead poisoning. Rather, successful lead poisoning prevention requires employing a variety of complementary strategies that are both community-wide and individual-centric, as well as catered to the unique structure, resources, and characteristics of the area.

This section describes primary prevention strategies that would prevent lead poisoning. Namely, state and local governments must identify the presence of lead-based paint and lead hazards through regular lead hazard inspections of homes and rental units, especially in high risk areas. In addition, state and local governments must define lead hazards based on the evolving science and identify all sources of exposure in the community. Robust enforcement of any lead poisoning prevention laws and the use of technology and data in identifying high risk areas and children are critical components of any primary prevention strategy.

61. Bruce P. Lanphear, *Childhood Lead Poisoning Prevention: Too Little, Too Late*, 293 JAMA 2274, 2274–75 (2005).

A. Proactive Lead Hazard Inspections

All pre-1978 properties that have not been abated of lead should be inspected for lead hazards before being leased, during tenancy, and prior to sale. Requiring property owners to obtain a lead poisoning prevention certification prior to conveying an interest in the property would quickly identify the location of lead-based paint and lead hazards in a community, provide notices to occupants and, where remediated or abated, decrease rates of lead poisoning. Most importantly, lead hazard inspections shift the burden of identifying lead hazards from children to entities that have control over, and/or can influence the state of the property.

1. Pre-1978 Rental Unit Inspections

Several states and cities mandate proactive rental inspections (“PRI”) to address habitability violations and lead hazards.⁶² Under PRI programs, local officials inspect rental housing on a periodic basis and/or at tenant turnover to ensure that the home is safe for occupancy. The efficacy of PRI is well-documented. For example, in Sacramento, California, officials implemented a PRI system for substandard housing conditions, after which “dangerous housing and building cases dropped by twenty-two percent.”⁶³ In Los Angeles, California, officials established a “Systemic Code Enforcement Program” in 1998, resulting in inspections of ninety percent of multifamily dwellings, the subsequent correction of more than 1.5 million habitability violations, and the reinvestment of \$1.3 billion into the city’s housing supply.⁶⁴

The PRI approach has had a similar effect on lead poisoning rates. Rhode Island’s certificate system, which requires landlords to inspect and obtain lead-safe or lead-free certificates for rental properties,⁶⁵ “significantly reduced [the lead burden] after [lead hazard mitigation certificates] were obtained, demonstrating that [pre-rental lead hazard inspections] could have a protective effect for

62. See, e.g., SAN DIEGO, CAL., MUNICIPAL CODE § 54.1009 (2019); D.C. CODE § 8-231.04 (2012); MD. CODE ANN., ENV’T. § 6-815 (West 2019); 150 MASS. CODE REGS. 460.100 (2017); DETROIT, MICH., CODE OF ORDINANCES §§ 9-1-82(d), 9-1-83 (2017); GRAND RAPIDS, MICH., CITY CODE §§ 304.2.1, 10003 (2018); ROCHESTER, N.Y., MUNICIPAL CODE § 90-55 (2019); TOLEDO, OHIO, MUNICIPAL CODE § 1760.04(14) (2018); PHILA, PA., MUNICIPAL CODE § 6-803(3)(b) (2016); R.I. LEAD MITIGATION REGULATIONS RULE 6D (2005); BURLINGTON, VT., CODE OF ORDINANCES § 18-112(a)(2) (2019); ST. LOUIS, WASH., ORDINANCE § 69202 (2012).

63. Benfer & Gold, *supra* note 53, at S28.

64. *Id.* at S28–S29.

65. Richard Salit, *Study: Compliance with R.I.’s Lead-Paint Law Low, but Children’s Exposure Reduced*, PROVIDENCE J. (July 7, 2014), <http://www.providencejournal.com/breaking-news/content/20140707-study-compliance-with-r.i.s-lead-paint-law-low-but-childrens-exposure-reduced>.

children.”⁶⁶ In 2006, the city of Rochester, New York incorporated pre-rental lead hazard inspections into the city’s certificate of occupancy requirement for rental properties.⁶⁷ The prevalence of elevated blood lead levels among tested children dropped from 8.3%, just two years before the inspections were implemented, to 4.4% two years after implementation.⁶⁸ Similarly, the number of lead poisoning cases dropped 98% in Maryland after PRI laws were enacted in 1994.⁶⁹ The Maryland PRI law requires owners to present a lead-safe certificate from an accredited inspector at initial registration and tenant turnover.⁷⁰ At the core of Maryland’s success is enforcement. In enforcing these requirements, Maryland’s Department of the Environment files between five hundred and eight hundred violation notices annually, and the attorney general’s office is responsible for enforcing actions against noncompliant owners.⁷¹ Many PRI programs give tenants the right to request a lead hazard inspection in pre-1978 units with, or regularly visited by, a pregnant woman or child under the age of six, and may also request a clearance report prior to occupying the unit and at any time during tenancy.⁷² These laws protect high-risk populations and give tenants more control over conditions in their home.

The City of Philadelphia too has established a strong PRI program that ties compliance with lead inspections and lead safety certification to rental licensure.⁷³ When landlords apply for a new or annual renewal of a rental license, they must identify each housing unit in their buildings built before 1978 and certify that the

66. Michelle L. Rogers et al., *Primary Prevention of Lead Poisoning: Protecting Children from Unsafe Housing*, 104 AM. J. PUB. HEALTH e119, e122 (2014).

67. Katrina S. Korfmacher, Maria Ayoob & Rebecca Morley, *Rochester’s Lead Law: Evaluation of a Local Environmental Health Policy Innovation*, 120 ENVTL. HEALTH PERSPS. 309, 310 (2012); see generally KATRINA SMITH KORFMACHER, BRIDGING SILOS: COLLABORATING FOR ENVIRONMENTAL HEALTH AND JUSTICE IN URBAN COMMUNITIES (2019); *Lead Paint — Get Prepared*, City of Rochester, NY, <http://www.cityofrochester.gov/article.aspx?id=8589936091>.

68. Byron S. Kennedy, et al., *Decline in Elevated Blood Lead Levels Among Children* 46 AM. J. PREV. MED. 259 (2014); Korfmacher, Ayoob & Morley, *supra* note 67, at 312.

69. Jay Apperson, *Lead Poisoning Cases Drop in Baltimore and in Maryland*, Department of the Environment Moves to Reduce Potential Exposure in More Homes, MARYLAND.GOV (Sept. 3, 2015), <http://news.maryland.gov/mde/2015/09/03/lead-poisoning-cases-drop-in-baltimore-and-in-maryland-department-of-the-environment-moves-to-reduce-potential-exposures-in-more-homes/>.

70. The Green & Healthy Homes Initiative has commented on the efficacy of Maryland’s model. See GREEN & HEALTHY HOMES INITIATIVE, STRATEGIC PLAN TO END CHILDHOOD LEAD POISONING: A BLUEPRINT FOR ACTION 1, 15 (2016), <https://www.greenandhealthyhomes.org/wp-content/uploads/strategic-plan.pdf>.

71. HEALTH IMPACT PROJECT, 10 POLICIES, *supra* note 19, at 42.

72. See, e.g., D.C. CODE § 8-231.04(c) (2020); see also Katrina S. Korfmacher & Michael L. Hanley, *Are Local Laws the Key to Ending Childhood Lead Poisoning?*, 38 J. HEALTH POL., POL’Y & L. 757, 776 (2013).

73. Department of Public Health, City of Philadelphia, *A Landlord’s Guide to the Philadelphia Lead Disclosure and Certification Law 1*, 7 (Nov. 2018) https://www.phila.gov/media/20181109120607/LandlordGuidance_2018.pdf.

lead inspection requirements have been met. The law allows the city to increase compliance by linking the Health Department's database with the License and Inspections database. Rental licenses are automatically denied for property owners who are out of compliance, reducing enforcement costs and building predictability into the system.⁷⁴

Currently, thirteen cities, five states, and the District of Columbia are the only jurisdictions that require any form of proactive lead hazard inspection in the private rental market. (See Table 1.) The types of inspection vary across jurisdictions and can include visual assessment, risk assessment, clearance testing, lead paint XRF testing, and dust wipe testing. It is well documented that visual assessments alone are incapable of identifying lead hazards that result in lead poisoning and are not the preferred method of inspection.⁷⁵ Dust wipes are a "point in time" inspection that only identify the presence of lead in dust, and not the source of the lead hazard. Cleaning prior to a dust wipe examination can alter the accuracy of the test. Lead-based paint inspections utilize sampling or x-ray fluorescence testing to measure the concentration of lead in paint on a surface-by-surface basis, enabling the owner to manage all lead-based paint, since the exact locations have been identified. Risk assessments are on-site investigations to determine the existence, nature, severity, and location of lead-based paint hazards and are accompanied by a report explaining the results and options for reducing lead-based paint hazards.⁷⁶ Where feasible, jurisdictions should require a combination risk assessment and lead-based paint inspection in rental housing, as well as lead water, lead plumbing and service line identification, which is rarely included in these inspections.

The timing of the inspections varies as well. Some jurisdictions mandate inspections at the time of tenant turnover, while others require inspections after a set period of time (e.g., twelve months, two years, three years, five years, or six years). A presumption of lead-based paint in pre-1978 units exists in San Diego, California; Washington, D.C.; Detroit, Michigan; Rochester, New York; Syracuse, New York, and in the state of Vermont.⁷⁷ Enforcement mechanisms also vary;

74. City Council of Philadelphia, *Philadelphia City Council Passes Landmark Legislation to Require Lead Certification in Rental Properties* (September 26, 2019) <http://phlcouncil.com/philadelphia-city-council-passes-landmark-legislation-to-require-lead-certification-in-rental-properties/>; Catalina Jaramillo, *City Hall is uniting around a lead poisoning law hated by landlords*, PLANPHILLY (July 29, 2019), <https://why.org/articles/city-hall-is-uniting-around-a-lead-poisoning-law-hated-by-landlords/>.

75. Benfer, *supra* note 21, at 527.

76. See *Guidelines for the Evaluation and Control of Lead-Based Paint Hazards in Housing* (2012 Edition), U.S. DEP'T OF HOUS. & URBAN DEV. (2012), https://www.hud.gov/program_offices/healthy_homes/lbp/hudguidelines; see also 40 C.F.R. § 745.227(d)(11).

77. New York City presumes lead-based paint if a child under six resides in a pre-1960 unit or in a unit built between 1960–1978 if the owner has knowledge of lead-based paint. N.Y.C. ADMIN. CODE, tit. 27, ch. 2, §§ 27-2056.1–27.2056.18 (2019).

some include civil and criminal penalties,⁷⁸ civil penalties alone,⁷⁹ and a private right of action for injunctive relief.⁸⁰

Every PRI inspection law includes exemptions. In numerous cities, a certificate of “lead-free” or multiple clearance reports over a specified length of time qualify a unit for exemption.⁸¹ Owner occupied units, units without occupants under age six, hotels, shelters, federally assisted housing, single occupancy units, elderly housing, vacation or short-term rentals, among others, are often exempt.⁸² Because many of these units are often occupied, frequented, or will eventually be occupied by children under age six, it is highly recommended that exemptions only be granted in extreme circumstances. Applying proactive rental inspection policies to all rental units can also avoid unintended consequences, such as discrimination against families with young children, a violation of the Fair Housing Act.

78. SAN DIEGO, CAL., MUNICIPAL CODE §§ 54.1013, 54.1015 (2019); D.C. CODE §§ 8-231.05, 8-231.15, 8-231.16 (2012); DETROIT, MICH., CODE OF ORDINANCES § 9-1-20 (2017); N.Y.C. ADMIN. CODE, tit. 27, ch. 2, § 27-2056.4(g) (2019); 42 R.I. GEN. LAWS ANN. §§ 42-128.1-11, 45-24.2-7, 45-24.3-18 (West. 2019); 18 VT. STAT. ANN. §1760(a) (2019).

79. MD. CODE ANN., ENV’T. §§ 6-843, 6-849, 6-850, 7-226 (West 2019); MASS. GEN. LAWS ch. 111, § 198 (2017); GRAND RAPIDS, MICH., CITY CODE § 8.503 (2018); ROCHESTER, N.Y., MUNICIPAL CODE § 90-70B (2019).

80. 42 R.I. GEN. LAWS ANN. § 42-128.1-10(b) (West. 2019).

81. SAN DIEGO, CAL., MUNICIPAL CODE § 54.1007(b) (2019); D.C. CODE § 8-231.04 (2012); MD. CODE ANN., ENV’T. § 6-803(b) (West 2019); N.J. STAT. ANN. § 52:27D-437.12 (West 2019); N.Y.C. ADMIN. CODE, tit. 27, ch. 2, § 27-2056.15(c) (2019); VT. STAT. ANN. §1759(a) (2019).

82. *See, e.g.*, MASS. GEN. LAWS ch. 111, § 199B (2017); N.J. STAT. ANN. § 52:27D-437.12 (West 2019); NEWARK, N.J., CODE § 16:3-20.2 (2019); ROCHESTER, N.Y., MUNICIPAL CODE § 90-62 (2019); 42 R.I. GEN. LAWS ANN. § 42-128.1.8(e) (West. 2019); VT. STAT. ANN. §1759(a) (2019).

Table 1⁸³

Proactive Rental Lead Hazard Inspection Requirements in the United States			
Dust Wipe & Visual Assessment	Risk Assessment	Visual Assessment Only	Lead Paint Test (XRF)
Maryland Rochester, NY Syracuse, NY Cleveland, OH Toledo, OH Lancaster, PA Philadelphia, PA Rhode Island	Washington, D.C. Detroit, MI Cleveland, OH	San Diego, CA Grand Rapids, MI Vermont Burlington, VT New York, NY	Newark, NJ Paterson, NJ Massachusetts New Jersey

A review of PRI programs demonstrates that they do not have a statistically significant impact on the availability of affordable housing. This means that the chief criticism of such programs—that they force jurisdictions to choose between protecting children and preserving affordable homes—appears to be unfounded. In a 2014 study of Rochester, New York, researchers studying landlord surveys and focus groups concluded “results suggest that the lead law has not resulted in significant additional costs to landlords nor disruption of the rental housing market.”⁸⁴ However, because so few cities and states have analyzed the effects of PRI programs on affordable housing, cities and states should prioritize financial assistance to property owners and both preserving and increasing affordable housing as a public health measure.

PRI ordinances must be carefully constructed in order to comply with constitutional requirements under federal and state law, including the Fourth Amendment prohibition against unreasonable search, state authorizing statutes, and the Equal Protection Clause.⁸⁵ Generally, PRI laws do not, on their face,

83. This table is current as of February 2020. At that time, Syracuse, New York, proposed but had yet to pass a proactive rental inspection law requiring visual assessments in rental units. Cleveland requires the owner to obtain either a dust wipe plus visual assessment or a risk assessment. Vermont requires compliance with “essential maintenance practices” that remove deteriorated visible lead-based paint prior to rental of the property. Burlington adopted local legislation requiring compliance with this provision and additional requirements. New Jersey requires the commission to conduct lead paint inspections every five years. Newark and Paterson adopted local legislation requiring a lead paint inspection and additional requirements in rental units.

84. Korfmacher, Ayoob & Morley, *supra* note 6767, at 313.

85. *See, e.g., Baker v. City of Portsmouth*, No. 1:14CV5L2, 2015 WL 5822659 (S.D. Ohio Oct.

constitute an unreasonable search under the Fourth Amendment. This finding is rooted in the right of municipalities to “regulate land use in order to maintain or improve the quality of life within their communities.”⁸⁶ To avoid violating the right to be free from warrantless searches, a PRI ordinance must provide property owners with the opportunity to participate in a precompliance review⁸⁷ or consent to inspection.⁸⁸ This may take the form of property owner consent prior to entry.⁸⁹ If a property owner or occupant refuses to permit entry, a municipality can “resort to administrative warrant mechanisms” to satisfy Fourth Amendment requirements.⁹⁰ This finding is based on the right of municipalities to “regulate land use in order to maintain or improve the quality of life within their communities.”⁹¹ For example, after the city of Detroit enacted a property maintenance code, local landlords challenged the ordinance as a requirement to “surrender [] their right to be free from warrantless searches.”⁹² As the Eastern District of Michigan noted while analyzing the PRI provision in Detroit, “there are no requirements that a landlord waive rights under the Fourth Amendment as a condition of obtaining a certificate of compliance. Certainly, the City requires rental properties to meet the [local housing] Code’s habitability standards, and the landlord must demonstrate compliance through an initial inspection. And there is nothing wrong with that.”⁹³

While a carefully drafted PRI will survive a Fourth Amendment challenge, it may be vulnerable to invalidation under state authorizing statutes and/or the Equal Protection Clause.⁹⁴ For example, a court found a Toledo lead inspection

I, 2015) (rental property owners challenging Portsmouth, Ohio ordinance requiring annual inspections).

86. 15192 Thirteen Mile Rd., Inc. v. Warren, 626 F.Supp. 803, 823 (E.D. Mich. 1985) (stating that such a right is “beyond all dispute”).

87. MS Rentals, LLC v. City of Detroit, 362 F. Supp. 3d 404, 414 (E.D. Mich. 2019).

88. Marcavage v. Borough of Landsdown, 493 F. App’x 301, 305–08 (3d Cir. 2012) (holding ordinance requiring landlords to obtain annual licenses after inspection not facially unconstitutional under Fourth Amendment because inspectors required to receive proper consent or valid search warrant, and refusal to consent not criminalized).

89. *Id.*

90. Godwin v. City of Dunn, No. 5:09-CV-381-BO, 2010 WL 2813513 (E.D.N.C. July 16, 2010); *see also* Dearmore v. City of Garland, 400 F. Supp. 2d 894, 904 (N.D. Tex. 2005) (“The court determines that in order to comply with . . . the protections of the Fourth Amendment, the Ordinance must give the landlord the opportunity to refuse to consent if the property is unoccupied and include a warrant procedure to be followed in the event the landlord refuses.”).

91. 15192 Thirteen Mile Road, 626 F.Supp. at 823 (stating that such a right is “beyond all dispute”).

92. MS Rentals, LLC, 362 F. Supp. 3d at 413.

93. *Id.* at 413 (ruling on a case in which after the city of Detroit enacted a property maintenance code, local landlords challenged the ordinance as a “requirement to ‘surrender[] their right to be free from warrantless searches’”).

94. U.S. CONST. amend. XIV, § 1 (“No State shall . . . deny to any person within its jurisdiction the equal protection of the laws.”).

regulation to be unconstitutional because Ohio state law does not authorize a municipality to enter into an agreement with a health department to “perform municipal services,” such as to administer, implement, and enforce the ordinance.⁹⁵ Even applying a rational-basis standard,⁹⁶ an Ohio court found the Toledo lead inspection ordinance violated the Equal Protection Clause because it “applied only to the owners of residential rental properties having four or less units.”⁹⁷ The court was unmoved by the City’s assertion that it could “combat the lead-paint problem on a step-by-step or piecemeal basis (starting with regulating residential rental properties containing four or less units).”⁹⁸ Ultimately, the court concluded that “limiting the Lead Ordinance’s application to rental properties comprised of four or less units, while leaving the Toledo families who live in pre-1928 rental properties having more than four units, large apartment buildings, or apartment complexes at risk of lead exposure, is not rationally, fairly, or substantially related to a legitimate governmental purpose or interest.”⁹⁹ However, in 2019, the Ohio Court of Appeals overturned the lower court decision, finding that the classifications of properties are rationally related to the ordinance’s goal of preventing lead poisoning.¹⁰⁰ Municipalities should exercise caution when enacting a PRI ordinance to ensure that the law complies with statutes regulating municipal designations of authority and does not single out a particular group of property owners without advancing a legitimate government interest.

By identifying hazards before children are exposed and develop lead poisoning, PRI can save states in direct costs related to case management and inspection after a child is determined to have an elevated blood lead level. A recent study found that if all states adopted primary prevention and eradicated lead paint hazards from older homes occupied by children in low-income families, it would result in “\$3.5 billion in future benefits, or approximately \$1.39 per dollar invested, and protect more than 311,000 children” for the 2018 birth cohort alone.¹⁰¹

95. *Mack v. City of Toledo*, Case No. CII7-4676, 35–39 (Ohio Civ. App. from Ct. Com. Pl. 2018). Here, the court discusses applicable statutes as “reflect[ing] the [Ohio] General Assembly’s failure to authorize the Health Department to perform municipal services.” *Id.* at 36. Moreover, the court agrees that “a board of health is a creature of statute with limited enumerated powers and cannot act except as enabled by statute.” *Id.* at 39. “The General Assembly or a local municipality with home rule powers may delegate their authority to *pass legislation* to local boards of health, but boards of health have no power to *enact regulations* without such a delegation.” *Id.*

96. The Toledo lead inspection ordinance neither included a suspect class nor a fundamental right. *Id.* at 42–43.

97. *Id.* at 45.

98. *Id.* at 45.

99. *Id.* at 47.

100. *Mack v. City of Toledo*, 2019-Ohio-5427, at ¶ 107, 2019 WL 7369246.

101. HEALTH IMPACT PROJECT, 10 POLICIES, *supra* note 19, at 2.

2. Point of Sale Inspections

Effective primary policy must also include point of sale lead hazard inspection. At the federal level, the Real Estate Notification and Disclosure Rule requires all sellers of pre-1978 residential real property in the United States to provide prospective buyers with: 1) a brochure on identifying and controlling lead-based paint hazards; 2) any information about known lead-based paint or lead-based paint hazards on the premises; 3) a “Lead Warning Statement” in the body of the contract; and 4) a ten-day period to conduct a paint inspection or risk assessment that may be, and is often, waived by the homebuyer.¹⁰²

However, limiting current disclosure requirements to *known* lead-based paint and lead hazards has created a perverse incentive to avoid lead hazard inspections, lest a lead-based paint that requires disclosure is discovered. As a result, residential property is being transferred without any knowledge of the potential for the property to cause lead poisoning. As the National Center for Healthy Housing noted in its *Find It, Fix It, Fund It* report, “because most homes have not been inspected, there is usually nothing to be disclosed.”¹⁰³ States can amend the real property law to require a combination of lead-based paint inspection and risk assessments to identify the presence of lead-based paint and any lead-contaminated dust, and soil, or water.¹⁰⁴ Mandatory disclosures should take a holistic approach to lead exposure, and include the presence of a lead service line and leaded plumbing and fixtures. The results should be filed with the deed before any sale contract can be executed. On the federal level, this recommendation was echoed in expert comments to EPA’s regulatory reform.¹⁰⁵ Point of sale inspections improve the transfer process by increasing notice of potential lead hazards and avoiding harm to children’s health. To reduce the cost burden on homeowners, states could provide tax relief in the transfer sale tax equivalent to the cost of the onetime inspection. Furthermore, HUD mortgage-assisted properties should be subject to the lead inspection and lead safe certification requirements, so that the federal government no longer propagates lead hazards on the residential housing market.

102. *Real Estate Disclosure about Potential Lead Hazards*, U.S. ENVTL. PROT. AGENCY, <https://www.epa.gov/lead/real-estate-disclosure> (last visited Mar. 11, 2020).

103. NAT’L CTR. FOR HEALTHY HOUS., *FIND IT, FIX IT, FUND IT: A LEAD ELIMINATION ACTION DRIVE, POLICY RECOMMENDATIONS TO CONGRESS AND THE NEW ADMINISTRATION*, § 1.2 (2017), https://nchh.org/resource-library/FFF-Action-Drive-Transition-Documents_Admin-Version.pdf.

104. *Id.*

105. *See* Evaluation of Existing Regulations, 82 Fed. Reg. 17793 (Apr. 13, 2017); *Regulatory Reform*, U.S. ENVTL. PROT. AGENCY, <https://www.epa.gov/laws-regulations/regulatory-reform> (last accessed Mar. 11, 2020).

B. Comprehensive and Accurate Identification of Hazards

1. Update Lead Hazard Standards to Protect Health

Many jurisdictions have codified or rely on the EPA's scientifically outdated lead hazard standards and clearance levels. Inspections and clearance based on these standards are incapable of identifying the majority of lead hazards that can result in lead poisoning. EPA's 2001 lead hazard standards and clearance levels were only partially updated in 2019. On July 9, 2019, EPA published a revised rule (effective January 6, 2020) that only updated lead hazard standards, leaving clearance standards well above hazard standards: "[T]his final rule revises the [dust-lead hazard standards] from 40 $\mu\text{g}/\text{ft}^2$ and 250 $\mu\text{g}/\text{ft}^2$ to 10 $\mu\text{g}/\text{ft}^2$ and 100 $\mu\text{g}/\text{ft}^2$ on floors and window sills, respectively. EPA is also finalizing its proposal to make no change to the definition of [lead-based paint] because insufficient information exists to support such a change at this time."¹⁰⁶

The 2020 rule was the product of sustained advocacy from multiple groups urging EPA to update its standards. In 2009, advocacy and healthy homes organizations, including the National Center for Healthy Housing, the Alliance for Healthy Homes, and Sierra Club petitioned EPA to lower the lead dust hazard levels.¹⁰⁷ EPA agreed that the hazard standards were outdated but did not engage in rulemaking.¹⁰⁸ In August 2016, on behalf of numerous stakeholders, Earthjustice petitioned the 9th Circuit for a writ of mandamus ordering the EPA to update their lead hazard standards.¹⁰⁹ On December 27, 2017, the 9th Circuit ordered the EPA to finally promulgate rules updating its seventeen-year-old standard based on prevailing science within ninety days.¹¹⁰ According to the court, "indeed EPA itself has acknowledged that '[l]ead poisoning is the number one environmental health threat in the U.S. for children ages 6 and younger' and that the current standards are insufficient. The children exposed to lead poisoning due to the failure of EPA to act are severely prejudiced by EPA's delay."¹¹¹ Yet, after receiving an extension,

106. Lead-Based Paint Poisoning Prevention in Certain Residential Structures, 84 Fed. Reg. 32632 (July 9, 2019) (to be codified 40 C.F.R. Part 745).

107. *Healthy Housing Groups Petition EPA to Strengthen Outdated Standards for Lead-Based Paint and Leaded Dust*, NAT'L CTR. FOR HEALTHY HOUS. (Aug. 10, 2009), <https://nchh.org/2009/08/hh-groups-petition-epa-to-strengthen-outdated-lbp-and-dust-standards/>.

108. Letter from Stephen A. Owens, Assistant Adm'r, U.S. Env'tl. Prot. Agency, to Rebecca Morley, Nat'l Ctr. for Healthy Housing, Patrick MacRoy, All. for Healthy Homes & Tom Neltner, Sierra Club 1, 1 (Oct. 22, 2009), <https://www.epa.gov/sites/production/files/2015-10/documents/epa-response.pdf>.

109. Hannah Chang, *Why Lead Standards Matter*, EARTHJUSTICE (December 27, 2017), <https://earthjustice.org/blog/2016-october/why-lead-standards-matter>.

110. Lisa Friedman, *E.P.A. Wanted Years to Study Lead Paint Rule. It Got 90 Days.*, N.Y. TIMES (Dec. 27, 2017), <https://www.nytimes.com/2017/12/27/us/epa-lead-paint.html>.

111. *In re A Community Voice*, 878 F.3d 779, 787 (9th Cir. 2017).

EPA issued a proposed rule on July 2, 2018 and its final rule on July 9, 2019 that failed to establish protective lead hazard standards.¹¹²

Earthjustice petitioned the Ninth Circuit Court of Appeals to review the EPA's rule and require the EPA to set more health protective standards.¹¹³ In a brief amicus curiae filed by the American Academy of Pediatrics, American Public Health Association, National Association of County and City Health Officials, and the Network for Public Health Law, and Dr. Bruce Lanphear, amici stated that "[w]ithout further amendment, the current rule, which is based on antiquated and unprotective standards, will result in the preventable lead poisoning and permanent brain damage of children throughout the country."¹¹⁴

However, many states continue to follow or have adopted EPA's outdated 2001 standards in their regulations. States and cities should take steps to surpass the EPA's response and set standards that reflect health-based thresholds for lead hazards and clearance requirements.¹¹⁵ For example, New York City recently enacted legislation lowering the dust hazard levels to 5 µg/ft² on floors, 40 µg/ft² for interior window sills, and 100 µg/ft² for window wells.¹¹⁶ As the Petitioners in the 9th Circuit case urged, clearance standards should be set as low as detectable and dust-lead and dust-lead hazard standards should be set at 5 µg/ft² on floors and 40µg/ft² on window sills. In addition, the Petitioners urged EPA to update the outdated definition of lead-based paint to at least paint containing lead in excess of 0.06 percent, and ideally as low as the Consumer Product Safety Commission definition of 0.009 percent lead content. Soil lead hazard standards should also

112. *Review of the Dust-Lead Hazard Standards and the Definition of Lead-Based Paint*, EPA–HQ–OPPT–2018–0166, July 9, 2019. See also Brief Amici Curiae of the American Academy of Pediatrics et al., *In re A Community Voice*, et al. v. U.S. Environmental Protection Agency, 9th Cir. No 19-71930, Jan. 16, 2020.

113. Petition for Review at 1–2, *In re A Community Voice*, 878 F.3d 779 (2019) (No. 19-____), available at <https://earthjustice.org/sites/default/files/files/Petition%20for%20Review%20Final.pdf>.

114. Brief Amici Curiae of the American Academy of Pediatrics et al., at 7–8, *In re A Community Voice*, 878 F.3d 779 (9th Cir. 2020) (No. 19-71930), available at https://www.apha.org/-/media/files/pdf/advocacy/briefs/200116_epa_lead_hazard_rule_brief.ashx?la=en&hash=123D2F06A1A98ED51255EB212168317585662E69.

115. As addressed by petitioners to EPA regarding the rulemaking, the new rule should have set clearance standards for dust-lead and dust-lead hazard standards at 5 µg/ft² on floors; revised the definition of lead-based paint at least to paint containing lead in excess of 0.06 percent, and potentially as low as 0.009 percent; and revised the soil lead hazard standards to reflect at least the current blood lead reference level set by the CDC. See *Review of the Dust-Lead Hazard Standards and the Definition of Lead-Based Paint*, 83 Fed. Reg. 30889 (July 2, 2018) (to be codified 40 C.F.R. pt. 745). See also Sherry L. Dixon et al., *Exposure of U.S. Children to Residential Dust Lead, 1999–2004: II. The Contribution of Lead-Contaminated Dust to Children's Blood Lead Levels*, 117 ENVTL. HEALTH PERSPS. 468, 468 (2008) (concluding that "[l]owering the floor [lead] standard below the current standard of 40 µg/ft² would protect more children from elevated [lead]"); Bruce P. Lanphear, *Screening Housing to Prevent Lead Toxicity in Children*, 120 PUB. HEALTH REPS. 305, 308 (2005).

116. N.Y.C. ADMIN. CODE § 27-2056.2(8)(a) (enacted by City Local Law 66 of 2019).

reflect at least the current blood lead reference level set by the CDC.¹¹⁷

In addition, EPA has thus far failed to lower lead in drinking water standards to a health-based standard. In EPA's latest proposed updates to the Lead and Copper Rule the action level remains at 15 parts per billion (ppb) despite a non-enforceable Maximum Contaminant Level Goal of 0 ppb.¹¹⁸ Canada recently set a level of 5 ppb as the maximum contaminant level for lead in drinking water.¹¹⁹ The World Health Organization established a maximum level of 10 ppb, noting, however, that this level was provisional and not fully protective.¹²⁰

2. Identify All Sources of Lead in the Environment

To protect children from harm, states and local jurisdictions must address all sources of lead in the environment. Many everyday products contain lead.¹²¹ Sources of exposure outside of lead-based paint hazards, such as lead in solder, pipes, service lines, consumer products, imported products, emissions, non-commercial airplane fuel, ammunition, among others, can contribute significantly to elevated blood lead levels in children. While many states merely include warnings on agency websites to notify consumers of potential lead hazards, California laws outright ban lead in select consumer products. For example, California restricts the use of leaded ammunition, lead in brake pads, and excess amounts of lead in paint and ceramics.¹²²

Neighborhood location directly affects lead exposure risks for residents and underscores the importance of community wide interventions. Emissions and contamination from former lead smelting sites, secondary smelters, battery recycling plants, Superfund sites, and other hazardous waste facilities cause

117. Review of the Dust-Lead Hazard Standards and the Definition of Lead-Based Paint, 83 Fed. Reg. 30889 (July 2, 2018) (to be codified 40 C.F.R. pt. 745).

118. *EPA Proposes Updates to Lead and Copper Rule to Better Protect Children and At-Risk Communities*, U.S. ENVTL. PROT. AGENCY, October 10, 2019, <https://www.epa.gov/newsreleases/epa-proposes-updates-lead-and-copper-rule-better-protect-children-and-risk-2>.

119. Guidelines for Canadian Drinking Water Quality: Guideline Technical Document – Lead, March 8, 2019, available at <https://www.canada.ca/en/health-canada/services/publications/healthy-living/guidelines-canadian-drinking-water-quality-guideline-technical-document-lead.html>.

120. Lead in Drinking-water, Background document for development of WHO *Guidelines for Drinking-water Quality*, available at https://www.who.int/water_sanitation_health/dwq/chemicals/lead.pdf.

121. *Childhood Lead Poisoning Prevention: Sources of Lead*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/nceh/lead/tips/sources.htm> (last accessed Mar. 11, 2020).

122. CAL. CODE REGS. tit. 14, § 250.1 (2019); DEP'T OF TOXIC SUBSTANCES CONTROL, SENATE BILL (SB) 774 AND CHANGES TO THE TOXICS IN PACKAGING PREVENTION ACT 1, 1–2 (2009), https://dtsc.ca.gov/wp-content/uploads/sites/31/2017/02/TIP_FS_SB-774_Changes.pdf; *Brake Pad Legislation*, DEP'T OF TOXIC SUBSTANCES CONTROL, <https://dtsc.ca.gov/scp/brake-pad-legislation/> (last accessed Mar. 11, 2020).

elevated lead levels and other detrimental health outcomes for local residents.¹²³ Neighborhoods close to these environmental hazards typically have a higher percentage of nonwhite residents compared to the nation as a whole, meaning that these hazards disproportionately affect communities of color.¹²⁴ Other sources of exposure such as truck wheel weights also add a toxic burden throughout the country; the United States Geological Survey estimates wheel weights add 4.4 million pounds of lead to communities every year.¹²⁵

Proximity to certain airfields also affects lead exposure. While the 1990 Clean Air Act amendments banned leaded gasoline in cars, leaded gasoline is often used in piston engine aircrafts.¹²⁶ The EPA estimates that half of lead emissions from such aircraft stay in the vicinity of airports that serve them.¹²⁷ One study found that children living within 0.6 miles of an airport had blood lead levels that were 5.7 percent higher than children living 2.5 miles from the airport.¹²⁸ Local jurisdictions can impose fees on airports serving piston engine aircraft to finance cleanup in nearby neighborhoods, schools, and parks and to incentivize the phasing out of leaded aircraft fuel.¹²⁹

The Flint crisis focused national attention on exposure to lead in water.¹³⁰ Drinking water contamination can occur in multiple ways: corrosion of leaded service lines (“LSL”s), brass plumbing fixtures, and lead solder.¹³¹ To correct lead hazards in drinking water, states and localities should require water utilities to submit plans for the *full* replacement of LSLs across the nation.¹³² Full LSL replacement is a health equity issue. Federal, state and local investment is needed

123. See generally EMILY COFFEY ET AL., POISONOUS HOMES: THE FIGHT FOR ENVIRONMENTAL JUSTICE IN FEDERALLY ASSISTED HOUSING (2020), available at https://www.povertylaw.org/wp-content/uploads/2020/06/environmental_justice_report_final-rev2.pdf.

124. EC/R INCORPORATED & EPA CONTRACT, RISK AND TECHNOLOGY REVIEW — FINAL ANALYSIS OF SOCIO-ECONOMIC FACTORS FOR POPULATIONS LIVING NEAR SECONDARY LEAD SMELTING FACILITIES 1, 9 (2011), <https://earthjustice.org/sites/default/files/Leadsmeltersocioeconomicanalysis.pdf>.

125. *Little Lobbyists for Big Change: A Team of Amazing Kids Battle Lead Contamination*, EARTHJUSTICE, <https://earthjustice.org/features/little-lobbyists-for-big-change>.

126. “Leaded fuel used by piston engine aircraft is the nation’s largest source of lead emissions into the air, with approximately 167,000 aircraft emitting about 450 tons a year.” HEALTH IMPACT PROJECT, 10 POLICIES, *supra* note 19, at 63.

127. Advance Notice of Proposed Rulemaking on Lead Emissions from Piston-Engine Aircraft Using Leaded Aviation Gasoline, 75 Fed. Reg. 22439 (April 28, 2010) (to be codified 40 C.F.R. Part 87).

128. HEALTH IMPACT PROJECT, 10 POLICIES, *supra* note 19, at 64.

129. *Id.* at 82.

130. See generally HANNA-ATTISHA, *supra* note 21.

131. HEALTH IMPACT PROJECT, 10 POLICIES, *supra* note 19, at 23.

132. Michigan mandates lead line inventory, better sampling to detect lead in water, phased in decrease in action level, and removal of lead service lines over the next twenty years. See generally Graham Sustainability Institute, *What You Need to Know About Michigan’s 2018 Lead and Copper Rule*, available at <http://graham.umich.edu/project/revised-lead-and-copper-rule>.

to ensure that low-income residents and renters are not disproportionately by lead in drinking water due to partial LSL replacement or lack of LSL replacement. In addition, the EPA's Lead and Copper Rule requires "corrosion control" for reducing lead in water.¹³³ However, a Natural Resources Defense Council investigation indicated that "over 18 million people were served by 5,363 community water systems that violated the [EPA's] Lead and Copper Rule."¹³⁴ Nearly ninety percent of reported violations did not see any formal enforcement action from either the state or EPA.¹³⁵ States should heighten enforcement of the Lead and Copper Rule to prevent lead in drinking water as an integral part of a primary prevention system.

C. Using Technology & Data to Identify and Remove Lead Hazards and Prevent Future Harm

Data collection and transparency are crucial to mitigating exposure to lead hazards. A comprehensive system for recording and analyzing test results will allow states to identify hotspots, target preventative measures, and provide proper care and treatment for children with elevated blood lead levels. By engaging in systematic data collection and analysis, states will also be able to more quickly identify and eliminate hazards after a child tests positive for an elevated blood lead level.

1. Data Collection

Comprehensive lead surveillance programs provide information on the extent of elevated blood lead levels in a jurisdiction. The Flint water crisis was uncovered using aggregated electronic medical records to analyze children's blood lead levels, which revealed that EBLR rates increased exponentially in 2014.¹³⁶ States should use available data from sources such as laboratories, hospitals, and the CDC to ensure they have the most comprehensive surveillance system available to identify children and areas of need before the harm proliferates. Providing

133. *Drinking Water Requirements for States and Public Water Systems: Lead and Copper Rule*, U.S. ENVTL. PROT. AGENCY, <https://www.epa.gov/dwreginfo/lead-and-copper-rule> (last accessed Mar. 11, 2020) (40 C.F.R. Part 141 Subpart I).

134. ERIK OLSON & KRISTI PULLEN FEDINICK, NAT. RES. DEF. COUNCIL, WHAT'S IN YOUR WATER? FLINT AND BEYOND: ANALYSIS OF EPA DATA REVEALS WIDESPREAD LEAD CRISIS POTENTIALLY AFFECTING MILLIONS OF AMERICANS 1, 5 (2016), <https://www.nrdc.org/sites/default/files/whats-in-your-water-flint-beyond-report.pdf>.

135. *Id.* at 6.

136. David Wahlberg, *Flint Doctor Used Epic Systems Records to Expose Lead Crisis*, WIS. ST. J. (Jan. 30, 2016), http://host.madison.com/wsj/news/local/health-med-fit/flint-doctor-used-epic-systems-records-to-expose-lead-crisis/article_cf462592-f27b-5ed0-a2ff-33232902ab74.html; see also HANNA-ATTISHA, *supra* note 21.

geographic data allows states to identify specific high-risk communities that require intervention on a community-wide level.

In addition to collection, jurisdictions should make some of this data available to community members to promote transparency about risks of lead poisoning and the location of potential lead hazards. For example, some states – including Connecticut and Massachusetts – publish data annually on screening rates and the prevalence of lead poisoning at the county level. Providing neighborhood-level data would increase the utility of such reports. Often the highest number of elevated blood lead levels in an area can be traced to one census tract or neighborhood.¹³⁷

Jurisdictions can also use data to provide information to citizens on lead-safe housing. Massachusetts and Rhode Island maintain registries of lead-safe homes or homes with lead-safe certificates.¹³⁸ This allows residents to identify safe and healthy housing as part of the home selection process, thereby avoiding exposure to lead hazards.¹³⁹

2. Leveraging Technology to Identify Communities and Children at Risk of Lead Exposure

Jurisdictions can use technology to identify children at risk of exposure to lead hazards. Critically, these techniques may allow states and health providers to intervene before a child suffers irreversible harm. In particular, geographic information systems (GIS) and predictive modeling allow public health departments to identify at-risk children. In predictive modeling, researchers use available data on blood lead level tests and housing inspection reports in conjunction with current census information to create a model that determines lead poisoning risk scores for individual children.¹⁴⁰ Incorporating GIS into childhood lead exposure programs significantly enhances “identifying lead hazards in the environment and determining at risk children.”¹⁴¹

137. See Joshua Schneyer & M.B. Pell, *Special Report: Flawed CDC Report Left Indiana Children Vulnerable to Lead Poisoning*, REUTERS (Sept. 28, 2016), <https://www.reuters.com/article/us-usa-pollution-report-specialreport/special-report-flawed-cdc-report-left-indiana-children-vulnerable-to-lead-poisoning-idUSKCN11Y1BH>.

138. See *Lead Safe Homes*, MASS. DEPT. OF HEALTH & HUMAN SERVS., <https://eohhs.ehs.state.ma.us/leadsafehomes/default.aspx>; *Find Lead Property Violations and Certifications*, R.I. DEPT. OF HEALTH, <https://health.ri.gov/find/environmentallead/propertystatus/>.

139. See Benfer & Gold, *supra* note 53, at S20 (noting that “the ability to use disclosed information to make decisions is severely limited for low-income residents” due to a dearth of affordable lead-safe housing options).

140. Eric Potash et al., *Predictive Modeling for Public Health: Preventing Childhood Lead Poisoning*, KDD '15: PROCEEDINGS OF THE 21ST ACM SIGKDD INTERNATIONAL CONFERENCE ON KNOWLEDGE DISCOVERY AND DATA MINING 2039, 2046 (2015).

141. Cem Akkus & Esra Ozdenerol, *Exploring Childhood Lead Exposure Through GIS: A*

The Chicago Department of Public Health (CDPH) used the predictive modeling results to develop a three-pronged strategy to prevent at-risk children from becoming exposed to lead hazards. First, CDPH used area billboards “to encourage [pregnant women and parents of young children] to request home inspections” to identify sources of lead in the home.¹⁴² Second, CDPH provided risk scores to doctors and health care providers to target patients with acute risks of lead poisoning. Finally, “CDPH recruit[ed] health and social service providers to facilitate lead-based paint hazard inspections by city inspectors.”¹⁴³ Health care providers can also use a patient’s risk score to educate the patient about risk-reducing practices, such as requesting a lead inspection.¹⁴⁴ Finally, to address sources of lead poisoning in the home, CDPH developed “a program of outreach and education” to landlords and housing providers.¹⁴⁵ This included informing landlords of the risk scores of their property and encouraging them to develop and execute a plan to eliminate hazards.¹⁴⁶ The risk score also allowed CPDH to prioritize free inspections for low-income homeowners.¹⁴⁷

A healthcare system’s electronic medical record (EMR) software can also be leveraged to identify patients at-risk of elevated blood lead levels.¹⁴⁸ An EMR tracks all patient information and data, allowing health care providers to easily input and view the information in one portal. At Erie Family Health Centers in Chicago, Illinois, providers receive an EMR alert if a pediatric patient resides in a home that previously housed a child with an elevated blood lead level.¹⁴⁹ The note-based reminder system in the EMR can increase the rates at which providers educate families about lead poisoning and order blood lead level tests for their patients.¹⁵⁰ At Jefferson Family Medicine Associates in Philadelphia, Pennsylvania, implementing this system increased the rate at which providers order blood lead level tests among children between the age of twelve months to

Review of the Recent Literature, 11 INT’L J. ENVTL. RESEARCH & PUB. HEALTH 6314, 6314–15 (2014) (“The use of GIS in environmental risk factor studies on childhood lead exposure became a focus of research activity in the late 1990s. This prompted the CDC to develop a guideline for the use of GIS in childhood lead poisoning studies in 2004.”).

142. Potash et al., *supra* note 140, at 2046.

143. *Id.*; see also MILBANK MEMORIAL FUND, CASE STUDIES: THREE PROJECTS RECEIVE INAUGURAL STATE AND LOCAL INNOVATION PRIZE 1, 3–5 (2018), <https://www.milbank.org/wp-content/uploads/2018/07/MMF-AH-Innovation-Prize-FINAL-1.pdf>.

144. Potash et al., *supra* note 140, at 2046.

145. *Id.*

146. *Id.*

147. *Id.*

148. For information about data sharing agreements for lead poisoning prevention, see DATA ACROSS SECTORS FOR HEALTH, A LEGAL APPROACH TO SHARING HEALTH & EDUCATION DATA 1, 4–5 (2018), http://dashconnect.org/wp-content/uploads/2018/05/DASH-Bright-Spot_Chicago.pdf.

149. MILBANK MEMORIAL FUND, *supra* note 143, at 3.

150. Kathryn McGrath et al., *EMR-Based Intervention Improves Lead Screening at an Urban Family Medicine Practice*, 48 FAM. MED. 801, 803 (2016).

six years from twenty-one percent to forty-nine percent of patients.¹⁵¹ By identifying patients with EBLs, providers can more quickly prescribe interventions to mitigate the harmful effects of lead exposure.

III. SECONDARY PREVENTION STRATEGIES TO IDENTIFY AND IMMEDIATELY ELIMINATE CHRONIC LEAD POISONING

Secondary prevention strategies are designed to identify a problem at its earliest stages,¹⁵² before injury becomes severe. While states and cities adopt and implement primary prevention strategies, and because no state is yet able to prevent all cases of lead poisoning, it is necessary for states and local governments to improve secondary prevention measures. These include universal screening, screening through Medicaid, and updating the definition of lead poisoning, as well as the actions elevated blood lead levels trigger.

A. Universal Screening

Currently, not all children are screened for lead poisoning; available blood lead surveillance data is not representative of lead poisoning rates in the United States or even an entire state or county.¹⁵³ Presently, the CDC recommends that states develop statewide blood lead screening plans based on local data and conditions.¹⁵⁴ As recently as the 1990s, the CDC recommended universal screening for all U.S. children, including those not enrolled in Medicaid. Today, the CDC's guidelines recommend universal screening for communities with at least 27% pre-1950 housing (See Table 2).¹⁵⁵ Because blood lead testing is initiated by the health care provider, states must have clear and widely distributed requirements for screening children. Most states only require blood lead level screenings among high-risk populations or regions, which creates gaps in prevention and treatment

¹⁵¹ *Id.*

¹⁵² See *Primary, Secondary and Tertiary Prevention*, *supra* note 26.

¹⁵³ *Childhood Lead Poisoning Prevention: CDC National Childhood Blood Lead Surveillance Data*, CTRS. FOR DISEASE CONTROL & PREVENTION, cdc.gov/nceh/lead/data/national.htm (last visited Mar. 11, 2020).

¹⁵⁴ CTRS. FOR DISEASE CONTROL & PREVENTION, SCREENING YOUNG CHILDREN FOR LEAD POISONING: GUIDANCE FOR STATE AND LOCAL PUBLIC HEALTH OFFICIALS 1, 31 (1997), https://www.cdc.gov/nceh/lead/docs/cdc_13364_1997.pdf.

¹⁵⁵ ADVISORY COMM. ON CHILDHOOD LEAD POISONING PREVENTION, *supra* note 20, at 23. However, the U.S. Preventive Services Task Force (USPSTF) has found that, although elevated lead levels cause harm to children and lead screening tests are accurate, evidence for treating screen-detected individuals to be virtually nonexistent. On this basis, the USPSTF concluded that the evidence was insufficient to assess the balance of benefits and harms of screening for lead levels in children. Michael Silverstein, Heather E. Hsu & Alastair Bell, *Addressing Social Determinants to Improve Population Health: The Balance Between Clinical Care and Public Health*, 322 JAMA 2379 (2019).

in other parts of the state.¹⁵⁶ Only a fraction of states currently require universal screening, including all of New England (Vermont, New Hampshire, Maine, Massachusetts, Connecticut, and Rhode Island), New Jersey, New York, Maryland, Delaware, Iowa, Louisiana, and the District of Columbia.¹⁵⁷ States that require universal screening typically prioritize children under the age of three, though some mandate screening for older children in high-risk areas.¹⁵⁸

However, even areas with universal screening requirements can have low compliance rates that reflect lack of enforcement and inadequate incentives.¹⁵⁹ Since Connecticut adopted universal screening in 2008, which went into effect in 2009, screening rates for children 9-35 months steadily increased from just below 50% to 74.1% in 2015. To encourage high screening rates, “Connecticut contracts with regional treatment centers [Connecticut Children’s Medical Center in Hartford and Yale-New Haven Hospital in New Haven], located in healthcare systems, that undertake provider and community education events, free medical consultation services, and other measures aimed at identification and primary prevention.”¹⁶⁰ These regional treatment centers, with a dedicated presence in large healthcare systems, act as liaisons between the state, health care providers, and patients to encourage robust testing. Maryland employs a targeted statewide lead exposure risk analysis model to inform their universal screening mandate.¹⁶¹

To improve rates of testing, states should increase outreach to hospitals, health providers, community health centers, and parents. States should offer blood lead tests at clinics; Women, Infant and Children (WIC) offices; daycares, and schools,

156. GREEN & HEALTHY HOMES INITIATIVE, STRATEGIC PLAN, *supra* note 70, at 16.

157. See JENNIFER DICKMAN, CHILDREN AT RISK: GAP IN STATE LEAD SCREENING POLICIES (2017), https://saferchemicals.org/wp-content/uploads/2017/01/saferchemicals.org_children-at-risk-report.pdf. Since the Safer Chemicals guide was published, New Hampshire and Maine began to require universal testing with the passage of Senate Bill 247 in February 2018, and 2019 respectively (jurisdictions requiring universal testing are Maine, Massachusetts, Connecticut, Vermont, Rhode Island, Iowa, New York, Maryland, New Jersey, Louisiana, Delaware, New Hampshire, and Washington, DC). See HEALTH JUSTICE INNOVATIONS, COMPARATIVE ASSESSMENT OF LEAD POISONING SCREENING PRACTICES IN MAIN & NEW ENGLAND I, 7–17 (2019), <https://mainehousingcoalition.org/wp-content/uploads/2019/08/Lead-Screening-Report-Final-Full-Report.pdf>.

158. States should also ensure that private health insurance companies cover the cost of mandatory lead testing. For example, when Connecticut mandated blood lead level screening for all one and two-year-old children, CONN. GEN. STAT. § 19a-111g, it also updated CONN. GEN. STAT. § 38a-490d, requiring health insurance policies to cover blood lead tests. For an overview of universal screening practices in New England states, see HEALTH JUSTICE INNOVATIONS, *supra* note 157, at 13–17.

159. See *id.* at 15–17.

160. *Id.* at 15.

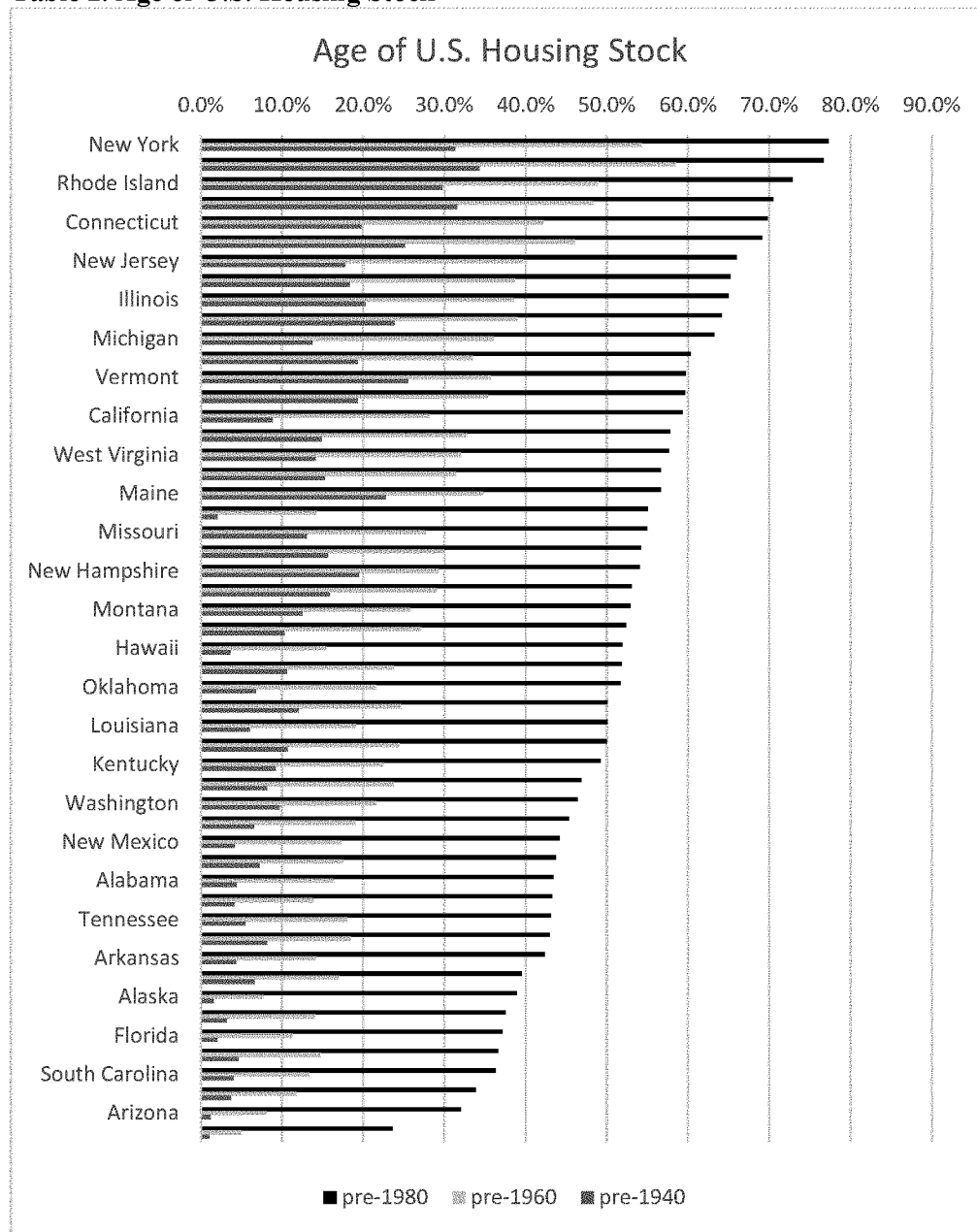
161. *Maryland Targeting Plan for Areas At Risk for Childhood Lead Poisoning*, MD. DEP’T OF HEALTH AND MENTAL HYGIENE (October 2015), available at <https://phpa.health.maryland.gov/IDEHSharedDocuments/MD%202015%20Lead%20Targeting%20Plan.pdf>.

as well as allow for mobile health units that can offer portable test options, especially in at-risk neighborhoods.¹⁶² One such portable device is the LeadCare II POC instrument, which entails a capillary blood draw (finger prick) and provides rapid results, does not require specialized skill for use, and is relatively affordable.¹⁶³ To identify children with lead poisoning at the earliest possible point of exposure, states with high rates of pre-1950 and pre-1978 housing stock should adopt universal screening policies. For these states, the policy becomes a part of routine well child visits, similar to immunizations, and leaves nothing to individual assessment, assumptions about lead poisoning risk, or chance.¹⁶⁴

¹⁶² HEALTH IMPACT PROJECT, 10 POLICIES, *supra* note 19, at 83–84.

¹⁶³ Jacquelyn Mason et al., *Response to the U.S. FDA LeadCare Testing Systems Recall and CDC Health Alert*, 25 J. PUB. HEALTH MGMT. & PRAC., S91, S95 (2019).

¹⁶⁴ For an overview of state laws and best practices, *see* HEALTH JUSTICE INNOVATIONS, *supra* note 157, at 19.

Table 2. Age of U.S. Housing Stock¹⁶⁵

165. AMERICAN COMMUNITY SURVEY 2018, U.S. CENSUS BUREAU, <https://www.census.gov/acs/www/data/data-tables-and-tools/data-profiles/> (last accessed Mar. 11, 2020).

B. State Medicaid Screening

State Medicaid agencies can leverage existing resources and standards to identify and treat children exposed to lead hazards. The U.S. Department of Health and Human Services requires all Medicaid-eligible children to receive a blood lead test at ages twelve months and twenty-four months. Any child between thirty-six months and seventy-two months with no record of a blood lead test must also be screened.¹⁶⁶ In some states, State Medicaid agencies establish additional screening requirements for at-risk children.¹⁶⁷ Yet, based on 2016 data reported to CMS, nationwide, only about 25% of Medicaid eligible children age two and below received their required screening for EBLLs.¹⁶⁸ States have generally failed in their duty to affirmatively conduct outreach efforts to inform parents of available Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) services and the importance of early detection, as well as in their duty to provide the necessary administrative support (scheduling appointments prior to screening deadlines, arranging transportation services, and providing written materials in multiple languages).¹⁶⁹

In addition, if a child has an elevated blood lead level, Medicaid provides comprehensive coverage for any service that is “medically necessary to correct or ameliorate defects in physical and mental illnesses or conditions . . . whether or not such service is otherwise covered under the state plan.”¹⁷⁰ This includes investigations in the child’s home.¹⁷¹ States also have an obligation to ensure that all Medicaid-eligible children under age twenty-one receive treatment and care for lead poisoning (even from past exposures), and that all Medicaid beneficiaries suffering from the long-term effects of lead poisoning receive appropriate treatment and care (even those over the age 21).¹⁷²

Given their insured population, state Medicaid agencies are well placed to

166. STATE MEDICAID MANUAL § 5123.2(D)(1) (CTRS. FOR MEDICARE & MEDICAID SERVS.).

167. *See, e.g.*, IND. HEALTH COVERAGE PROGRAMS, EARLY AND PERIODIC SCREENING, DIAGNOSTIC, AND TREATMENT (EPSDT)/HEALTHWATCH SERVICES 1, 25 (2019), <https://www.in.gov/medicaid/files/epsdt.pdf>.

168. *Early and Periodic Screening, Diagnostic, and Treatment*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.medicaid.gov/medicaid/benefits/epsdt/index.html> (Annual EPSDT Participation Report FY 2016, CMS Form 416).

169. 42 U.S.C. § 1396a(a)(43)(A); 42 C.F.R. §§ 441.50–441.62.

170. Vikki Wachino, Dir., Ctr. for Medicaid and CHIP Servs., *Coverage of Blood Lead Testing for Children Enrolled in Medicaid and the Children’s Health Insurance Program* 1, 2 (Nov. 30, 2016), <https://www.medicaid.gov/sites/default/files/federal-policy-guidance/downloads/cib113016.pdf>.

171. *Id.*

172. 42 U.S.C. § 1396d(r)(5) (2018).

identify children at risk of lead exposure. Medicaid can collaborate with other state agencies such as the health and housing departments, health care providers, other groups such as WIC clinics, community health clinics, and school-based health centers. Further, Medicaid should invest in data collection and create a database of all Medicaid beneficiaries in at-risk areas (such as those near Superfund sites). And finally, agencies can ensure staff and services are available for treatment and care of children and adults with elevated blood lead levels, as well as invest in case management and early intervention and special education programs.

C. Definition of Lead Poisoning and Action Levels

States should amend their lead poisoning definitions by tying their action levels to the CDC's reference level. The CDC's reference level is currently set at 5 µg/dL; this level is meant to be revised to lower levels at a regular basis.

In 1988, with the passage of the Lead Contamination Control Act, Congress authorized the CDC to create a comprehensive childhood lead poisoning program.¹⁷³ The program was meant to enhance national efforts to address lead poisoning, by (1) developing policies to prevent poisoning; (2) educating the public and health care providers; (3) providing funding to state and local health departments for lead poisoning services (including screening and environmental investigation); and (4) supporting research on the effectiveness of policies.¹⁷⁴ The CDC definition of lead poisoning has evolved over time with advances in the science of lead hazards. In 2012, the CDC revised its guidelines, replacing the 10 µg/dL "blood lead 'level of concern'" with the "reference value" of 5 µg/dL.¹⁷⁵ The justification for the new approach was the CDC's finding that there is no safe level of lead poisoning. Ideally, the reference value will continue to decrease as lead poisoning rates decline throughout the United States. For this reason, the CDC, American Academy of Pediatrics, and the Green & Healthy Homes Initiative have advised states and local governments to engage in primary prevention and, at a minimum, adopt the CDC's reference level as the statewide lead poisoning action level.¹⁷⁶ More than half of U.S. states define EBLL (or lead poisoning) for children

173. ADVISORY COMM. ON CHILDHOOD LEAD POISONING PREVENTION, *supra* note 20, at 1.

174. *Id.*

175. *Child Lead Poisoning Prevention: Blood Lead Levels in Children*, CTNS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/nceh/lead/acclpp/blood_lead_levels.htm. The new "reference level" standard is tied to the 97.5th percentile of the NHANES blood lead level distribution in children 1-5 years old. The CDC has stated its intention to update this limit every four years. Based on this assertion, the CDC is overdue in updating the reference level to 3.5 µg/dL. *See also* Benfer, *supra* note 21, at 499.

176. The Green & Healthy Homes Initiative warned that "failure to follow the CDC guidelines will potentially enable millions of poisoned children to go undetected and untreated." GREEN & HEALTHY HOMES INITIATIVE, STRATEGIC PLAN, *supra* note 70, at 14.

as ≥ 5 $\mu\text{g}/\text{dL}$ or use the CDC reference level.¹⁷⁷ However, while the definition conforms to current CDC standard, only Maine,¹⁷⁸ Maryland,¹⁷⁹ Massachusetts,¹⁸⁰

177. These states include California, District of Columbia, Florida, Idaho, Illinois, Kentucky, Maine, Maryland, Massachusetts, Minnesota, Missouri, Montana, New Hampshire, New Jersey, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Texas, Virginia, Washington, West Virginia, and Wisconsin. *See* Cal. Health & Safety Code § 105280; D.C. Code § 8-231.01(13); Fla. Stat. Ann. § 381.983; Idaho Admin. Cod. r. 16.02.10.380; Ill. Admin. Code. tit. 77, 845.20; Ky. Rev. Stat. An. § 211.900; Me. Rev. Stat. Ann. tit. 22 §1315 (5C); Md. Code Regs. 10.11.04.02.04; 105 CMR 460.020; Minn. Stat. Ann. § 144.9501(Subd. 9); Mo. Code Regs. Ann. tit. 19, § 20-8.030.1(M); Mont. Admin. R. 37.114.203(ai); N.H. Rev. Stat. Ann. § 130-A:6-b; N.J. Admin. Code 8:51-1.4; N.Y. Pub. Health Law § 1370; N.C. Gen. Stat. § 130A-131.7(5); Ohio Admin. Code 3701-30-01(O); Okla. Admin. Code § 310:512-1-4; Or. Admin. R. 333-017-0000(18); 28 Pa. Code. 27.34; 216 R.I. Code R. § 050-15-3, Section 3.3(A)(44); S.C. Code Ann. § 44-53-1320 (uses standard from Dept Health Env Control); Tex. Health & Safety Code § 88.001; Va. Code Ann. § 32.1-46.1; Wash. Admin. Code 246-101-010; W. Va. Code § 16-35-3; Wis. Stat. Ann. § 254.11(9). In addition, according to interviews with state Public Health officials and guidance posted on state Department of Health websites, Arkansas, Delaware, Hawaii, Louisiana, Michigan, Mississippi, South Dakota, Tennessee, and Utah consider a blood lead level of ≥ 5 $\mu\text{g}/\text{dL}$ to constitute lead poisoning in practice, despite the fact that the respective state statutes do not yet define it as such.

178. Me. Rev. Stat. tit. 22, § 1320-A. (“Except in the case of an owner-occupied, single-family residence, the department shall within 30 days inspect all dwelling units in a dwelling when: . . . Lead poisoning [is] found. A case of lead poisoning has been found in any dwelling unit within the dwelling; . . . [t]he department may, at its discretion, inspect an owner-occupied single-family residence whenever a lead-poisoned child has been identified as residing in or receiving care in that residence.”).

179. MD. CODE REGS. 10.09.23.04. However, it should be noted that this is only for Medicaid recipients. Early Periodic Screening, Diagnostic, and Treatment (EPSDT) program from Medicaid recipients covers medically necessary screening services for environmental lead investigations when there is a BLL ≥ 5 $\mu\text{g}/\text{dL}$).

180. 105 MASS. CODE. REGS. 460.710. (“All inspections or lead determination enforcement procedures shall be carried out according to the following: . . . (b) Dwelling units in which a child with a blood lead level of concern resides. . . . (c) Dwelling units in which a child younger than six years old lives for which an inspection is requested by the occupant.”) It should be noted that Massachusetts defines “Blood Lead Level of Concern” as “a concentration of lead in whole venous blood from 5 to less than 10 micrograms per deciliter in a child less than six years old.” As a result, if a child over six years old has a blood lead level of 5 micrograms per deciliter, the statute does not mandate physical inspection. 105 MASS. CODE. REGS. 460.020.

New Hampshire,¹⁸¹ District of Columbia,¹⁸² North Carolina,¹⁸³ Illinois,¹⁸⁴ New York,¹⁸⁵ and New Jersey,¹⁸⁶ mandate physical inspection of the home for lead hazards when a child's EBL is ≥ 5 $\mu\text{g}/\text{dL}$ or reaches the CDC reference level after one or two tests, depending on the state.

Other states adopt the following approaches: (1) optional investigation at the

181. N.H. REV. STAT. ANN. § 130-A:5. ("The commissioner shall investigate cases of lead poisoning in children reported under RSA 141-A whose blood lead level meets or exceeds 7.5 micrograms per deciliter of whole venous blood . . . Such investigations shall include, but not be limited to: . . . (b) Inspections of dwellings or dwelling units or of any child care facility, and testing environmental samples.") However, effective July 1, 2021, the blood lead level that triggers investigation will be lowered to 5 micrograms per deciliter of whole venous blood.

182. D.C. Code § 8-231.03(a). ("(a) Whenever a child under age 6 with an elevated blood lead level resides in, or regularly visits a dwelling or unit or child-occupied facility in the District . . . the Mayor shall conduct a risk assessment of the appropriate properties.") A "risk assessment" is defined as "an on-site investigation to determine and report the existence, nature, severity, and location of conditions conducive to lead poisoning." D.C. Code § 8-231.01(36). It should be noted, therefore, that if a child over six years has a blood lead level of 5 micrograms per deciliter or greater, the statute does not mandate physical inspection.

183. N.C. GEN. STAT. § 130A-131.9A(a1). ("When the Department learns of an elevated blood lead level, the Department shall, upon informed consent, investigate the residential housing unit where the child or pregnant woman with the elevated blood level resides. When consent to investigate is denied, the child or pregnant woman with the elevated blood lead level cannot be located, or the child's parent or guardian fails to respond, the Department shall document the denial of consent, inability to locate, or failure to respond.")

184. ILL. ADMIN. CODE tit. 77, § 845.85. ("(1) An EBL inspection to determine the source of lead exposure shall be conducted under any of the following circumstances: (A) If a child or pregnant person who is an occupant or frequent visitor of a regulated facility has an EBL; . . . (2) An EBL inspection of a regulated facility to determine the source of lead poisoning as required by this Section shall be conducted and shall consist of at least the following: . . . (B) A visual assessment of the condition of the building; . . . (C) Environmental sampling.").

185. The New York State Department of Health has statutory authority to promulgate and enforce regulations for follow up of children and pregnant women who have elevated blood lead levels. N.Y. Pub. Health Law § 1370-a. The New York State Department of Health requires a home visit when a child has an elevated blood lead level. *Childhood Lead Poisoning Prevention*, N.Y. STATE DEP'T OF HEALTH (Jan. 2020), <https://www.health.ny.gov/environmental/lead/>. See also *What Your Child's Blood Lead Test Means*, N.Y. STATE DEP'T OF HEALTH, <https://www.health.ny.gov/publications/2526.pdf>.

186. N.J. Admin. Code § 8:51-2.4(b). ("Whenever a child has a confirmed blood lead level of five $\mu\text{g}/\text{dL}$ or greater, a public health nurse shall perform case management consisting of: (1) A home visit . . . (3) In the case of a child with two confirmed blood lead levels of five to nine $\mu\text{g}/\text{dL}$ or one confirmed blood lead level of 10 to 44 $\mu\text{g}/\text{dL}$, a review of the lead Hazard Assessment Questionnaire . . . with the lead inspector/risk assessor certified by the Department to ensure that the child's environment has been evaluated for non-paint lead hazards and that the environmental evaluation has been performed."). See also *Childhood Lead*, N.J. DEP'T OF HEALTH (Aug. 28, 2019), <https://www.state.nj.us/health/childhoodlead/testing.shtml>; N.J. STAT. § 26:2-137.3 (2017). New Jersey ties its action level to the CDC's reference level, rather to any specific number. When the CDC further lowers the action level, New Jersey's level will also be lowered without the need for any additional legislative action.

CDC reference value or at $\geq 5 \mu\text{g/dL}$;¹⁸⁷ or (2) optional investigation at any level;¹⁸⁸ or (3) case management or monitoring at the CDC reference value and environmental investigations for lead hazards at EBLs two to five times the CDC reference value.¹⁸⁹ For example, several states still conduct investigations only at blood lead levels greater than $20 \mu\text{g/dL}$ or at 15 to $20 \mu\text{g/dL}$ in two tests taken several months apart.¹⁹⁰ These requirements are based on the CDC's 1991 recommendations and no longer comply with medical or scientific

187. These states include Idaho, South Carolina, and Wisconsin. *See, e.g.*, IDAHO ADMIN. COD. r. 16.02.10.380 ("Each reported case of lead poisoning *may* be investigated") (emphasis added); S.C. Code Ann. § 44-53-1390 ("When the department is notified of a lead poisoning case, the department . . . with the consent of the householder or his agent, *may* enter a dwelling, dwelling unit, or childcare facility at reasonable times and in a reasonable manner for the purpose of conducting a lead-based hazard investigation") (emphasis added); Stat. Ann. § 254.166 ("The department *may*, after being notified that an occupant of a dwelling or premises who is under 6 years of age has blood lead poisoning or lead exposure, present official credentials to the owner or occupant of the dwelling or premises, or to a representative of the owner, and request admission to conduct a lead investigation of the dwelling or premises") (emphasis added).

188. These states include Alaska, Minnesota, and Rhode Island. *See, e.g.*, Alaska Admin. Code tit. 7, § 27.016 ("A public health agent may conduct an administrative inspection of any establishment and examine the records of any establishment that may involve a threat to public health in the conduct of an epidemiological investigation"); Minn. Stat. Ann. § 144.9504 ("Within the limits of available local, state, and federal appropriations, an assessing agency may also conduct a lead risk assessment for children with an elevated blood lead level"); 216 R.I. Code R. § 050-15-3, Section 3.5.1 ("(A) Initiation of a Lead Inspection. (1) A lead inspection may be initiated by any of the following persons: a. a property agent; b. a tenant; c. a child care provider; d. a buyer under a contract for the purchase and sale of real estate; e. a mortgagee or property and casualty insurer; f. a funding agency; g. a municipality or public housing authority; h. a lead center; or i. the [Health] Department. (B) Purpose of a Lead Inspection. (1) A lead inspection may be initiated for a variety of reasons, including . . . c. To identify lead hazards and recommend treatment options to correct those hazards").

189. These states include Ohio, Oklahoma, and West Virginia. *See, e.g.*, Ohio Admin. Code, § 3701-30-07 ("(A) For children with a blood lead level of five micrograms per deciliter or greater but less than ten micrograms per deciliter the director shall cause the completion of a comprehensive questionnaire on a form prescribed the director . . . (B) For children with a blood lead level of ten micrograms per deciliter or greater the director shall conduct an on-site investigation of a residential unit, child care facility or school"); Okla. Admin. Code § 310:512-3-4.1 ("(C) For each child who has an elevated blood lead level at or above the reference level, the health care provider shall take those actions that are reasonably and medically necessary and appropriate based upon the child's blood lead level to reduce, to the extent possible, the child's blood lead level below the reference level. Such actions may include the following: . . . (5) Referral to the Department for an environmental investigation for a single venous blood lead test result equal to or greater than $20 \mu\text{g/dL}$ "; W. Va. Code § 64-42-5 ("(5.2) The health care provider shall provide all information concerning a child's blood lead level to the legal parent or guardian and other agencies involved in lead poisoning testing . . . (5.3.b) Children with two (2) consecutive blood lead levels of greater than or equal to fifteen (15) micrograms per deciliter, and children with blood lead levels of greater than or equal to twenty micrograms per deciliter shall be referred to environmental assessment and nurse home visits.").

190. These states include Connecticut, Iowa, and Vermont. *See, e.g.*, Conn. Gen. Stat. § 19a-111; Iowa Admin. Code r. 641-68.3; 13-140-055 Vt. Code R. § 3.

recommendations.¹⁹¹

Several states do not have any lead poisoning laws or regulations, or have very limited guidance for lead poisoning.¹⁹² Until true primary prevention measures are implemented, it is paramount that states adopt lead poisoning definitions that are consistent with the CDC recommendations. In the absence of robust state laws, cities and municipalities should adopt stronger thresholds.

IV. INCREASED FUNDING AND COMPLIANCE

The effectiveness of any primary or secondary lead poisoning prevention program is dependent upon adequate funding and accountability. To raise revenue, states can draw from federal sources, local partners, as well as tax and fee structures. Robust enforcement of state and federal laws, as well as remedies tied to the property can help states achieve compliance and safeguard children.

A. Raising Revenue

Eliminating exposure to lead hazards requires increasing funding for primary prevention measures. Childhood lead poisoning imposes “significant costs to taxpayers.”¹⁹³ These costs are the result of direct health care expenditures, as well as societal and behavioral costs in special education, crime, and lifetime earning losses caused by lead poisoning.¹⁹⁴ Given these costs, each dollar invested in lead hazard control produces a significant return on investment.¹⁹⁵ A 2017 study released by the Health Impact Project, a collaboration between the Pew Charitable Trusts and the Robert Wood Johnson Foundation found that “removing leaded drinking water service lines from the homes of children born in 2018 would . . .

191. In 1991, the CDC published a guide for Preventing Lead Poisoning in Young Children that recommended inspection and remediation at 20 µg/dL or 15 to 19 µg/dL in two tests taken three to four months apart. CTRS. FOR DISEASE CONTROL & PREVENTION, PREVENTING LEAD POISONING IN YOUNG CHILDREN (1991) <https://wonder.cdc.gov/wonder/prevguid/p0000029/p0000029.asp> (“If the blood lead level is 15-19 µg/dL, the child should be screened every 3-4 months, the family should be given education and nutritional counseling as described in Chapter 4, and a detailed environmental history should be taken to identify any obvious sources or pathways of lead exposure. When the venous blood lead level is in this range in two consecutive tests 3-4 months apart, environmental investigation and abatement should be conducted, if resources permit.”).

192. These states include Kansas, South Dakota, and Wyoming. *See, e.g.*, KAN. ADMIN. REGS. §28-72-1.

193. HEALTH IMPACT PROJECT, 10 POLICIES, *supra* note 19, at 1.

194. CINDY MANN, KINDA SERAFI & ARIELLE TRAUB, LEVERAGING CHIP TO PROTECT LOW-INCOME CHILDREN FROM LEAD (Feb. 2, 2017), <https://www.manatt.com/Insights/White-Papers/2017/Leveraging-CHIP-to-Protect-Low-Income-Children-fro>.

195. Anne Marie Costello, Ctr. for Medicaid and CHIP Svcs., Maryland Approval Letter (June 15, 2017), <https://www.medicaid.gov/CHIP/Downloads/MD/MD-17-0001-LEAD.pdf>; Timothy Hill, Ctr. for Medicaid and CHIP Svcs., Michigan Approval Letter (Nov. 14, 2016), <https://www.medicaid.gov/sites/default/files/CHIP/Downloads/MI/MI-16-0017.pdf>.

yield \$2.7 billion”¹⁹⁶ in future benefits. Further, policies that “eradicat[e] lead paint hazards from older homes of children from low-income families would provide \$3.5 billion in future benefits.”¹⁹⁷ Finally, requiring contractors to comply with the EPA’s rule that requires lead-safe renovation, repair, and painting practices would yield \$4.5 billion in future benefits.¹⁹⁸ When considering lead poisoning levels below the CDC reference value, it is estimated that the costs to society associated with lead poisoning are as high as \$84 billion.¹⁹⁹

In October 2016, the Green and Healthy Homes Initiative released a Strategic Plan to End Childhood Lead Poisoning estimating that: to effectively address lead poisoning nationally, an investment of \$2.5 billion dollars each year for the next five years is necessary.²⁰⁰ The societal benefits of prevention far outweigh the upfront costs associated with lead poisoning among children. In addition to the measures outlined below for funding lead poisoning prevention, lead paint manufacturers must be held responsible for funding abatement of lead hazards.

1. Medicaid & CHIP

Several Medicaid programs can be strategically leveraged to address lead poisoning. For example, states such as Rhode Island and Missouri offer Medicaid-reimbursable managed care plans and case management services for children with elevated blood lead levels.²⁰¹

The Children’s Health Insurance Program (CHIP)²⁰² provides an option for additional funding.²⁰³ The Health Services Initiative (HSI), a “long-standing but

196. HEALTH IMPACT PROJECT, 10 POLICIES, *supra* note 19, at 2.

197. *Id.*

198. *Id.*

199. *New Online Tool Calculates the Cost and Economic Benefits of Preventing Childhood Lead Exposure in the United States*, ALTARUM (May 30, 2019), <https://altarum.org/news/new-online-tool-calculates-cost-and-economic-benefits-preventing-childhood-lead-exposure-united>.

200. GREEN & HEALTHY HOMES INITIATIVE, STRATEGIC PLAN, *supra* note 70, at 18 (1.1 million at risk homes, 220,000 homes per year, \$11,300 to fully abate each home); NAT’L CTR. FOR HEALTHY HOUSING, FIND IT, FIX IT, FUND IT, *SUPRA* NOTE 103, at 3.2. Existing sources of federal funding for lead-based projects include HUD’s Lead-Based Paint Hazard Control and Lead Hazard Reduction Demonstration Grants, HUD’s Choice Neighborhoods Grants, HUD’s Community Development Block Grants, DHHS’s Community Services Block Grants, EPA’s Drinking Water State Revolving Loan & Water Infrastructure Finance and Innovation Act Grants, and DOE’s Weatherization Assistance Program Grants. However, additional support from federal, state and local governments, as well as from the private sector are necessary to finally eliminate childhood lead poisoning.

201. GREEN & HEALTHY HOMES INITIATIVE, LEAD FUNDING TOOLKIT 1, 34 (2019), https://www.greenandhealthyhomes.org/wp-content/uploads/Lead-Funding-and-Financing-Toolkit-5-29-19_final.pdf.

202. *Id.* at 37 (“The Children’s Health Insurance Plan (CHIP) uses federal and state funds to provide health coverage to over 9 million eligible children through Medicaid and other CHIP-specific programs.”).

203. Kate Honsberger, Liz McCaman & Karen Vanladeghem, *State Strategies to Improve*

relatively underutilized CHIP provision,” offers states enhanced federal matching for programs that help low-income children.²⁰⁴ While CHIP’s federal match rate is already 65-82%, HSI programs receive a minimum 88% of program cost from the federal government.²⁰⁵

As of 2019, at least four states – Maryland, Michigan, Indiana, and Ohio – implement HSI programs that address lead poisoning. Each state’s program provides additional funding for lead hazard abatement.²⁰⁶ In addition, Maryland’s HSI program funds lead hazard home assessments for children with a blood lead level above 5 µg/dL.²⁰⁷ In Ohio, HSI also allows for the establishment of an online lead-safe housing registry.²⁰⁸ In Michigan, the program is primary prevention such that children on Medicaid and CHIP are eligible for free home inspection and abatement.²⁰⁹

2. Health Care Providers, Systems, and Hospitals as Investors in Lead Poisoning Prevention and Community Health

Often, the role of health care providers and hospitals in lead poisoning prevention is limited to patient education and managing elevated blood lead level cases. Providers routinely screen admitted children, provide chelation treatment for the most severe cases of poisoning, and notify local health departments of other cases, with little opportunity for follow-up. Health care providers, systems, and hospitals could make a major contribution to lead poisoning prevention by treating the community as the patient. In contemplating the future of health care, scholars often use the hub-and-spoke analogy. There are two visions for such a system. First, the health care organization could be the hub with various community-based organizations as spokes. Alternatively, health care organizations could be one of the spokes with another entity as the hub.²¹⁰ In both models, scholars imagine

Childhood Lead Screening and Treatment Services under Medicaid and CHIP (April 2018), <https://www.nashp.org/wp-content/uploads/2018/04/Childhood-Lead-Screening.pdf>.

204. MANN, SERAFI & TRAUB, *supra* note 194, at 1.

205. *Id.* at 2.

206. Costello, *supra* note 195; Anne Marie Costello, Ctr. for Medicaid and CHIP Svcs., Ohio Approval Letter (Dec. 5, 2017), <https://www.medicaid.gov/CHIP/Downloads/OH/OH-17-0038.pdf>; Timothy Hill, Ctr. for Medicaid and CHIP Svcs., Michigan Approval Letter (Nov. 14, 2016), <https://www.medicaid.gov/CHIP/Downloads/MI/MI-16-0017.pdf>; Anne Marie Costello, Ctr. for Medicaid and CHIP Svcs., Indiana Approval Letter (Sept. 29, 2017), <https://www.medicaid.gov/CHIP/Downloads/IN/IN-17-0000-0002.pdf>.

207. Costello, Ctr. for Medicaid and CHIP Svcs., Maryland Approval Letter (June 15, 2017), <https://www.medicaid.gov/CHIP/Downloads/MD/MD-17-0001-LEAD.pdf>.

208. Anne Marie Costello, Ctr. for Medicaid and CHIP Svcs., Ohio Approval Letter (Dec. 5, 2017), <https://www.medicaid.gov/CHIP/Downloads/OH/OH-17-0038.pdf>.

209. CTR. FOR MEDICARE & MEDICAID SERVICES, Michigan Health Services Initiative (Nov. 14, 2016), <https://www.cms.gov/newsroom/fact-sheets/michigan-health-services-initiative>.

210. Lauren Taylor, Andrew Hyatt & Megan Sandel, *Defining The Health Care System’s Role*

health care organizations working in concert with community groups, allocating, and receiving resources to address the root cause of health issues. Hospitals and health systems could reduce lead poisoning by engaging in predictive modeling, matching past lead poisoning cases with patient addresses, determining the community health needs in their service areas, and investing in lead hazard identification and reduction.

While health care providers, scholars, and advocates recognize the importance of addressing social determinants of poor health, like housing conditions, investment in programs that target the root cause of diseases is limited. For example, publicly-financed health care services often restrict the use of funds for preventive interventions, such as lead abatement.²¹¹ At the same time, community-based public health initiatives often have fragmented funding sources, making it difficult to sustain interventions.²¹² The lack of coordination between health care providers and public health programs, and disparity in adequate funding, have led to high health costs with little to show for it.²¹³ Increased funding for lead poisoning prevention programs means not only providing additional dollars, but also improving how the money is spent to maximize benefits. This will avoid “an imbalance of high health spending and poor health outcomes.”²¹⁴

Hospitals are well-positioned to prioritize lead poisoning prevention on a community wide level. Under the Affordable Care Act, in order to maintain their tax-exempt status, nonprofit hospitals are required to regularly assess the social, economic, environmental, and health challenges facing their communities. Tax-exempt hospitals must file a Community Health Needs Assessments (CHNA) with the Internal Revenue Service.²¹⁵ To conduct a CHNA, a hospital must define the

In Addressing Social Determinants And Population Health, HEALTH AFFAIRS BLOG (Nov. 17, 2016), <https://www.healthaffairs.org/doi/10.1377/hblog20161117.057601/full/>.

211. Andrew Olson et al., *State Play Book: Pay for Success Financing – How to Use Innovative Financing to Fund Innovation in Medicaid Value-Based Purchasing Programs* (May 2017), <https://www.greenandhealthyhomes.org/publication/state-playbook-pay-for-success-financing-how-to-use-innovative-financing-to-fund-innovation-in-medicaid-value-based-purchasing-programs/>.

212. CHANGELAB SOLUTIONS, FINANCING PREVENTION: HOW STATES ARE BALANCING DELIVERY SYSTEM & PUBLIC HEALTH ROLES 1, 10 (Apr. 2014), http://www.changelabsolutions.org/sites/default/files/Financing_Prevention-NASHP_FINAL_20140410.pdf.

213. *Id.* (“In 2012, health expenditures accounted for 17.2 percent of the United States’ gross domestic product. Compared to other industrialized nations, the United States spends two-and-a-half times more per person on health care. At the same time, the United States ranks below other industrialized nations in health status, ranking 26th in life expectancy among Organization for Economic Co-operation and Development (OECD) nations in 2011.”).

214. *Id.*

215. TYLER NORRIS & TED HOWARD, DEMOCRACY COLLABORATIVE, CAN HOSPITALS HEAL AMERICA’S COMMUNITIES?: “ALL IN FOR MISSION” IS THE EMERGING MODEL FOR IMPACT 1, 13 (2015), <https://community-wealth.org/sites/clone.community-wealth.org/files/downloads/CanHospitalsHealAmericasCommunities.pdf>; *see also* McGinnis et al.,

community, solicit input from people who “represent the broad interests of its community,” document findings, develop a strategy to address needs, and make a report available to the public.²¹⁶ The healthcare field can also work with state agencies to collect and analyze data that can help identify the most vulnerable neighborhoods in a community.²¹⁷ The CHNA presents an opportunity for hospitals to prioritize lead poisoning as a community health need and to build a strong community coalition, including community health centers, civic and faith-based organizations, community businesses, education and social service agencies, legal aid organizations, community members, and others.²¹⁸ Hospitals and health systems whose footprints of service overlap can also conduct joint CHNA’s. In Philadelphia, for example, major health systems conducted a joint CHNA in 2019 with a community development organization as the facilitator, which resulted in aligned priorities for investment.²¹⁹ Federal funds are available under a Prevention and Public Health Fund to “help reshape the physical and social environments of communities that face multiple long-standing impediments to healthier living.”²²⁰

The Hospital Community Benefit program, which requires nonprofit hospitals to invest in their local communities, can also be used to address the underlying causes of social determinants of poor health, including lead poisoning.²²¹ This is exactly the type of intervention needed to eliminate lead poisoning in the communities most at risk. Hospitals should identify exposure to lead hazards as a health priority in their communities and devote funding to address lead hazards before children are harmed and require medical treatment. For example, Dignity Health in San Francisco, California provided loans to affordable housing

supra note 57, at 83.

216. 79 Fed Reg. 78,962 (Dec. 31, 2014).

217. *Community Health Needs Assessments*, COMMUNITY COMMONS, <https://www.communitycommons.org/collections/Community-Health-Needs-Assessments> (last visited Mar. 10, 2020).

218. SARA ROSENBAUM, GEORGE WASHINGTON UNIV. SCH. OF PUB. HEALTH & HEALTH SVCS., DEP’T OF HEALTH POL’Y, PRINCIPLES TO CONSIDER FOR THE IMPLEMENTATION OF COMMUNITY HEALTH NEEDS ASSESSMENT PROCESS 1, 4 (June 2013), https://nnphi.org/wp-content/uploads/2015/08/PrinciplesToConsiderForTheImplementationOfACHNAProcess_GWU_20130604.pdf.

219. *Southeastern Pennsylvania Community Health Needs Assessment*, CITY OF PHILADELPHIA (July 1, 2019) <https://www.phila.gov/documents/regional-community-health-needs-assessment/>.

220. Miller, Sadegh-Nobari & Lillie-Blanton, *Healthy Starts for All*, *supra* note 55, at S31.

221. See National Center for Healthy Housing, *Hospital Community Benefits*, available at <https://nchh.org/tools-and-data/financing-and-funding/healthcare-financing/hospital-community-benefits/> (“Nonprofit hospital organizations are required by federal tax law to spend some of their surplus on ‘community benefits,’ which are goods and services that address a community need.”); see also Green and Healthy Homes Initiative, *Hospital Community Benefits*, available at https://www.greenandhealthyhomes.org/toolkit_resource/hospital-community-benefits/ (“However, according to the guidelines of the ACA, Community Benefit funds can be used to address the upstream causes of poor health outcomes, or social determinants of health. These include housing conditions, specifically lead-based paint hazards that lead to lead poisoning.”).

developers in California, including a \$1.2 million bridge loan in 2018 for a community revitalization project.²²² While this project did not specifically address lead poisoning prevention, it is an example of a hospital recognizing the effect of housing on health, and directing community benefit funds to the address the underlying cause of negative health outcomes among their patient population. Given that hospitals spend \$340 billion each year on goods and services,²²³ redirecting even a tiny fraction of that to lead poisoning prevention could have an enormous impact on lead poisoning rates in the community. Health care providers can also access federal funding streams, such as community transformation grants, may be used on a local level by “community-based organizations for the implementation, evaluation, and dissemination of evidence-based community” prevention measures.²²⁴

Hospital-based services can also be leveraged to address lead poisoning. For example, medical-legal partnerships (MLPs),²²⁵ wherein legal services are embedded into the health system, allow providers and lawyers to collaborate in order to identify and address the underlying social or environmental causes of a patient’s health issue.²²⁶ MLPs often identify systemic issues affecting numerous patients that can be addressed through community-wide measures.²²⁷ For example, a Chicago MLP identified a pattern of lead poisoning cases in federally assisted housing due to an antiquated federally policy. To address the issue, the providers and attorneys partnered with numerous national nonprofits and scientists, including the authors of this article, to successfully petition the U.S. Department of Housing and Urban Development for rulemaking that resulted in updates to the federal Lead Safe Housing Rule.²²⁸ Similarly, patient navigation programs also can

222. GREEN & HEALTHY HOMES INITIATIVE, LEAD FUNDING TOOLKIT, *supra* note 201, at 39.

223. Benfer & Gold, *supra* note 53, at S47.

224. 42 U.S.C. § 300u-13(a) (2018).

225. See NAT’L CTR. FOR MEDICAL-LEGAL PARTNERSHIP, <https://medical-legalpartnership.org> (last visited Mar. 10, 2020).

226. See generally Emily A. Benfer, Abbe R. Gluck & Katherine L. Kraschel, *Medical-Legal Partnership: Lessons from Five Diverse MLPs in New Haven, Connecticut*, 46 J. L. MED. ETHICS 602 (2018).

227. National Center for Medical-Legal Partnership, *Applying the Medical-Legal Partnership Approach Population Health, Pain Points and Payment Reform* 1, 6 (Oct. 2016), <https://medical-legalpartnership.org/wp-content/uploads/2016/10/Applying-the-MLP-Approach-to-Population-Health-October-2016.pdf> (“In an MLP, legal professionals work on-site together with health care providers to address and treat the most complex social determinants, which require legal solutions.”; *id.* at 7 (describing the intersection of medical and legal assistance as applied to issues faced by asthmatic children, seniors with diabetes, and children with sickle-cell anemia). [EE the “*id.* at 7” part of the parenthetical refers to the same source cited in this footnote – is this the correct way to cite according to Bluebook style?]

228. See Benfer, *supra* note 21; Kate Marple & Erin Dexter, National Center for Medical-Legal Partnership, *Patients-to-Policy: Keeping Children Safe from Lead Poisoning* (Apr. 18, 2018), <https://medical-legalpartnership.org/mlp-resources/keeping-children-safe-from-lead-poisoning/>.

be used to strengthen communities. Navigators work directly with patients to help “navigate” them through the increasingly complex healthcare system.²²⁹ They provide patients with “care continuity, and comprehensiveness,” and address socio-economic and environmental determinants of health in ways that traditional hospital models do not.²³⁰

In Los Angeles, this patient navigator system took on another role: training members of the community most affected by societal problems to become navigators themselves. Through Medi-Cal’s Whole Person Care (WPC) program, Los Angeles County built a Training Institute that employs and trains community health workers (CHWs) from low-income communities—“those with life experiences shared by the target population.”²³¹ This model can be adapted to address lead poisoning in other states and municipalities. Focusing on the elimination of childhood lead poisoning would increase demand for nurses, inspectors, and abatement workers.²³² These jobs could be prioritized for low-income residents of high-risk communities.²³³ Implementing a navigator program, community members could be trained in lead screening, case management, inspections, and abatement. These workers would be able to work closely with fellow community members to educate them of the risks of lead poisoning, the importance of screening, and the proper procedure for inspections, abatements, and re-inspection. Navigators could help community members understand the need for and their rights to inspections and abatement. With their close ties to the community, navigators would provide continuous support and follow-through and remain invested in keeping the community strong and healthy.

3. Regional Financial Institutions

Regional financial institutions are well-positioned to provide funding to lead poisoning prevention. Such entities are situated within the affected community and can provide grants, low-interest loans, or other financing to assist property owners in making their properties lead safe.²³⁴ For example, in Milwaukee, Wisconsin, a

229. Ruta K. Valatis et al., *Implementation and Maintenance of Patient Navigation Programs Linking Primary Care with Community-Based Health and Social Services: A Scoping Literature Review*, 17 BMC HEALTH SERVICES RESEARCH 1 (2017).

230. *Id.* at 2.

231. L.A. County Dep’t of Health Services, WHOLE PERSON CARE – LOS ANGELES 14 (May 18, 2017), [https://www.dhcs.ca.gov/provgovpart/Documents/Whole%20Perons%20Care/WPC%20Updates_Apps%20and%20Memos/LosAngelesWPCApplicationFINAL\(2\).pdf](https://www.dhcs.ca.gov/provgovpart/Documents/Whole%20Perons%20Care/WPC%20Updates_Apps%20and%20Memos/LosAngelesWPCApplicationFINAL(2).pdf).

232. HEALTH IMPACT PROJECT, 10 POLICIES, *supra* note 19, at 47. *See also* NAT’L CTR. FOR HEALTHY HOUSING, FIND IT, FIX IT, FUND IT, *supra* note 103.

233. HEALTH IMPACT PROJECT, 10 POLICIES, *supra* note 19, at 47.

234. KENT GARDNER, CTR. FOR GOVERNMENTAL RESEARCH, RENEWING OUR PLEDGE: A PATH TO ENDING LEAD POISONING OF BUFFALO’S MOST VULNERABLE CITIZENS 1, 44 (2017), <https://cfgrb.org/wp-content/uploads/2018/07/buffalo-lead-action-plan-final-report.pdf>.

regional bank has established a Target Area Home Improvement Program and provides matching loan of up to \$6,000 per unit to lead abatement grant recipients in low-income neighborhoods.²³⁵ Similarly, in Nebraska, the Omaha Healthy Kids Alliance is working with banks to provide low-interest loans for lead remediation up to \$10,000.²³⁶

4. *Pay for Success*

Pay for Success programs are a useful tool for investing in innovative lead poisoning prevention strategies — especially for strategies with high upfront costs or implementation challenges.²³⁷ In a Pay for Success model, “private funders provide working capital to scale an evidence-based intervention through an agreement tying their repayment to outcomes produced by the intervention.”²³⁸ States can work with partner-managed care entities to create value-based purchasing (VBP) agreements. Through VBP agreements, outside parties, such as foundations,²³⁹ provide start-up funds to deliver services. After implementation, the managed care entity evaluates the program and makes a value-based payment to the outside investor based on predetermined factors. For example, in late 2017, groups in Cleveland, Ohio began structuring a pay for success transaction to remediate 10,000 homes in ten years. “It is one of the largest PFS transactions in development, with initial figures projecting a \$200 million return on a \$159 million upfront investment.”²⁴⁰

235. *Id.*; DELTA & U.S. ENVTL. PROT. AGENCY, CREATIVE FUNDING STRATEGIES FOR REMEDIATION OF LEAD AND OTHER HEALTHY HOUSING HAZARDS: A GUIDE FOR INCREASING PRIVATE-SECTOR FINANCING, U.S. ENVIRONMENTAL PROTECTION AGENCY 17 (2010), <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.592.9840&rep=rep1&type=pdf>.

236. KENT GARDNER, *supra* note 234, at 44.

237. CTRS. FOR DISEASE CONTROL & PREVENTION, PAY FOR SUCCESS: A HOW-TO GUIDE FOR LOCAL GOVERNMENT FOCUSED ON LEAD-SAFE HOMES 1, 9 (Apr. 2017), https://www.cdc.gov/nceh/lead/docs/pay_for_success_guide.pdf.

238. GREEN & HEALTHY HOMES INITIATIVE, LEAD FUNDING TOOLKIT, *supra* note 201, at 39 (Pay for Success financing models may also be known as “social impact bonds”).

239. Pay for Success programs offer valuable opportunities for public-private partnerships. In a 2009 study, researchers commented on the shared goals of foundations and government agencies. For example, in 2006, private foundations spent about \$28 billion on programs in health, education, development, the environment, human services, and relief. The U.S. government spent about \$720 billion in these same six categories. At the same time, both foundations and governments have much to learn from the other. The report stated: “A potentially important benefit of interactions and partnerships between the federal government and foundations is the opportunity they create for sharing emerging innovations that may strengthen philanthropic efforts.” A great deal of good can come from partnerships between public agencies and private organizations. *See* ANN E. PERSON ET AL., MAXIMIZING THE VALUE OF PHILANTHROPIC EFFORTS THROUGH PLANNED PARTNERSHIPS BETWEEN THE U.S. GOVERNMENT AND PRIVATE FOUNDATIONS (May 2009), <https://aspe.hhs.gov/system/files/pdf/75776/report.pdf>.

240. GREEN & HEALTHY HOMES INITIATIVE, LEAD FUNDING TOOLKIT, *supra* note 201, at 40.

The potentially long period for return on investment and the disparate cost centers that would be impacted by successful reductions in lead exposure can present unique challenges to Pay for Success as a model for all types of lead interventions. However, these arrangements can fund services “while mitigating the risk of program success for the taxpayer and managed care entities responsible for publicly-financed health care expenditures.”²⁴¹ Managed care entity partners have the flexibility to experiment with different service delivery options and keep programs that are effective, as well as borrow from other states’ models.

Where the home and adjacent environment (airports, hazardous waste facilities, leaded service lines, etc.) are the major sources of exposure, Pay for Success programs that focus on community-based interventions can address a greater number of health issues, including social determinants of health. Whereas traditional health care models focus on hospitals and doctors’ offices, Pay for Success models, which focus on high-risk communities, leverage funding dollars to be used more efficiently for primary prevention. In 2008, Trust for America’s Health estimated that nationwide investment in evidence-based community-level prevention programs could result in savings of \$5.60 for every \$1 spent.²⁴² States can encourage such Pay for Success programs by amending managed-care contracts to allow for VBP agreements, provide economic motives for innovation, and ensure that there is infrastructure and administrative support for such programs.²⁴³

5. Taxes & Fees to Increase Lead Poisoning Prevention Funds

States and cities “can utilize taxpayer dollars and allocate funds from their annual general fund or other operating budgets”²⁴⁴ or impose fees on various entities that can be used for lead hazard remediation.” For example, Illinois’ state budget demarcates funds for the Clear-Win Program. Through the program, the Illinois Department of Public Health “partner[s] with the Illinois Housing Development Authority and the Department of Commerce and Economic Opportunity in hiring local contractors to remove sources of lead exposure from the residences of children with elevated blood lead levels.”²⁴⁵ The program has

241. Olson et al., *supra* note 211.

242. TRUST FOR AMERICA’S HEALTH, PREVENTION FOR A HEALTHIER AMERICA: INVESTMENTS IN DISEASE PREVENTION YIELD SIGNIFICANT SAVINGS STRONGER COMMUNITIES 1 (July 2008), https://www.preventioninstitute.org/sites/default/files/publications/Prevention%20for%20a%20Healthier%20America_0.pdf; CTRS. FOR DISEASE CONTROL & PREVENTION, PAY FOR SUCCESS, *supra* note 237, at 25–26.

243. Olson et al., *supra* note 211.

244. GREEN & HEALTHY HOMES INITIATIVE, LEAD FUNDING TOOLKIT, *supra* note 201, at 24.

245. *Illinois Department of Public Health: Moves to Lower Action Level for Lead in Blood*, PRAIRIE STATE WIRE (Aug. 31, 2018), <https://prairiestatewire.com/stories/511550713-illinois-department-of-public-health-moves-to-lower-action-level-for-lead-in-blood>; Benfer & Gold, *supra*

been remarkably effective, reducing the average lead dust level of interior floors by 44%, interior sills by 88%, and exterior troughs by 98% and resulting in a net monetary benefit of \$2,460,378.²⁴⁶

States can also enact various fees or taxes to generate funding for lead poisoning prevention, such as charging paint manufacturers per gallon of paint sold. For example, through the PaintCare Program, states²⁴⁷ have established fees on each container of architectural paint sold in the state.²⁴⁸ PaintCare uses these fees to fund paint stewardship programs in participating jurisdictions, which allow consumers to “take their unwanted, leftover paint” to specified drop-off sites for “reuse, recycling, energy recovery, or safe disposal.”²⁴⁹ In New Jersey, the state funds its Lead Hazard Control Assistance Fund through sales taxes collected on paint or other surface coating materials; a minimum of \$7 million per year, and a maximum of \$14 million per year is set aside from such sales tax revenue.²⁵⁰ Since 2006, Maine has required companies that sell more than 1,800 gallons of paint in a calendar year to pay 25 cents per gallon of paint sold. The fee will be repealed when the Commissioner of Health and Human Services certifies a period of 24 months has elapsed since a child with an elevated blood lead level has been identified in the state.²⁵¹

Fees can also be imposed on manufacturers and entities involved with the production or sale of lead-based products, including petroleum. In California,²⁵² this type of fee generated \$20.6 million in the 2015 fiscal year.²⁵³ Every employer in an industry category identified as having a potential for occupational lead poisoning or lead or lead-containing materials present in their business must

note 53, at S31.

246. *Comprehensive Lead Education and Reduction Through Window Replacement (CLEAR WIN)*, NAT’L CTR. FOR HEALTHY HOUS., <https://nchh.org/research/clear-win/>.

247. *Overview*, PAINTCARE, <http://www.paintcare.org/about/#/overview> (These states include California, Colorado, Connecticut, Washington, DC, Maine, Minnesota, New York, Oregon, Rhode Island, Vermont, and Washington.).

248. *Id.* (The fees range depending on how much paint is purchase. For example, most jurisdictions charge nothing for a half pint or smaller, but over a dollar for larger than one gallon of paint).

249. *Id.*

250. S1348, 210th Leg., (N.J. 2004), (“Legislative Fiscal Estimate”), https://www.njleg.state.nj.us/2002/Bills/S1500/1348_E1.HTM.

251. ME. REV. STAT. ANN. tit. 22 § 1322-F; *Frequently Asked Questions on the Lead Poisoning Prevention FEE*, MAINE DEP’T OF HEALTH & HUMAN SERVS. https://www.maine.gov/dhhs/mecdc/environmental-health/eohp/lead/documents/LPPF_PaintFee_FAQ.pdf (last visited Mar. 12, 2020).

252. HEALTH IMPACT PROJECT, 10 POLICIES, *supra* note 19, at 62.

253. California State Board of Equalization, *California State Board of Equalization Annual Report FY 2013–14: Supporting Our Communities: Funding a Better Quality of Life*, https://digitalcommons.law.ggu.edu/cgi/viewcontent.cgi?article=1288&context=caldocs_agencies (last visited Mar. 12, 2020).

register and pay the fee. Under the program, employers may be exempted from payment if they demonstrate that lead is not present in their places of employment.²⁵⁴ Not only does this approach raise revenue for lead poisoning prevention, but the exemption further incentivizes employers to remediate lead exposure for primary prevention efforts.

Homeowners' insurance and professional licenses connected to residential property are another fee-based system. Massachusetts imposes surcharges of \$25 to \$100 on the annual fees of certain professional licenses, including for real estate brokers, property and casualty insurance agents, mortgage brokers and lenders, small loan agencies, and individuals who perform lead inspections.²⁵⁵ In 2018, Connecticut enacted a law imposing a \$12 surcharge on homeowners' insurance to fund their healthy homes program, thereby increasing funding for lead poisoning prevention that can reduce health and safety hazards in residential dwellings in the state.²⁵⁶ Finally, fees can be assessed as penalties for violations of lead poisoning prevention laws and regulations. New Jersey currently collects \$3 million annually in penalties, enough to sustain its program.²⁵⁷

Various cities also collect fees as part of their rental registration programs, portions of which could also be directed towards lead poisoning prevention activities. Los Angeles, California enacted a housing ordinance that imposes a \$24.51 annual fee upon owners of rental properties built on or before October 1, 1978 with two or more units in order to cover the cost of the city's systematic code inspection program.²⁵⁸ The City of Buffalo's Rental Registration program, implemented in 2005, requires the registration of all non-owner-occupied single- and two-family homes.²⁵⁹ When properly enforced, rental property owners would be required to pay a fee ranging from \$20 to \$50,²⁶⁰ which could then be used to fund lead poisoning prevention programs. Significant fees can be collected from penalties for violations of existing laws. For example, in Buffalo, the annual registration fee for rental properties doubles 30 days after the due date has passed,

254. CAL. HEALTH & SAFETY CODE § 105185–105195; *Occupational Lead Poisoning Prevention Fee – Frequently Asked Questions (FAQs)*, CAL. DEP'T OF TAX & FEE ADMIN., <https://www.cdtfa.ca.gov/taxes-and-fees/occ-lead-pois-prev-prgrm-faq.htm> (last visited Mar. 12, 2020).

255. HEALTH IMPACT PROJECT, 10 POLICIES, *supra* note 19.

256. CONN. PUB. ACT NO. 18-160; CONN. PUB. ACT NO. 18-52.

257. ALL TO END CHILDHOOD LEAD POISONING, TEN EFFECTIVE STRATEGIES FOR PREVENTING CHILDHOOD LEAD POISONING THROUGH CODE ENFORCEMENT 1, 12 (April 25, 2002), <http://portal.hud.gov/hudportal/documents/huddoc?id=codeenforcementstrategies.doc>. [hereinafter TEN EFFECTIVE STRATEGIES]

258. L.A. Municipal Code. § 151.05; *see also* Los Angeles Housing and Community Investment Department, Annual RSO/SCEP [Systematic Code Enforcement Program] Bill, available at <https://hcidladev.lacity.org/Annual-RSO-SCEP-Bill>.

259. City of Buffalo Code § 264-3.

260. City of Buffalo Code § 264-21.

and an additional fine in the amount of \$75.00 is imposed 60 days after.²⁶¹

States can also access funds from sources such as state attorney general settlement funds. “Attorney General settlements are a non-traditional source of funding that can be used to fund lead remediation . . . Attorneys General determine allowable uses for the settlement funds, often in coordination with state or federal policy-makers.”²⁶² The communities of Buffalo, Rochester, and Syracuse, in New York State, as well as the state of Rhode Island were able to use Attorneys General settlements to address health and safety concerns in energy efficiency projects (including lead hazard remediation).²⁶³ Similarly, states may also authorize victim compensation funds for individuals who have developed lead poisoning. These funds may be established pursuant to legislation to collect fees from lead manufacturers and other industries responsible for introducing the neurotoxin into children’s environments. Streamlined enforcement provisions, coupled with significant penalties, can enable states to attain compliance from property owners while generating sufficient revenue to maintain its programs.

6. Tax Credits

Alternatively, states can incentivize property owners to engage in primary prevention. Tax credits provide an opportunity for individual property owners to receive funding to offset the cost of lead mitigation. In Massachusetts, owners who pay for the “deleading” of their property can claim a credit up to \$1,500 per dwelling unit for full compliance with the laws, or up to \$500 per dwelling unit for having interim control pending full compliance.²⁶⁴ Property owners seem to be taking advantage of this program; the Massachusetts Department of Revenue estimates that this tax break costs about \$2.5 million annually in forgone tax revenue.²⁶⁵ Rhode Island’s Residential Lead Abatement Income Tax Credit also allows a refundable credit against the state personal income taxes due for residential lead paint removal or reduction.²⁶⁶ This program provides a maximum of \$1,500 per dwelling unit for mitigation and a maximum of \$5,000 for abatement,²⁶⁷ with a limit of three separate dwelling units for which property

261. City of Buffalo Code § 264-13.

262. GREEN & HEALTHY HOMES INITIATIVE, LEAD FUNDING TOOLKIT, *supra* note 201, at 31.

263. *Id.* at 32.

264. 830 MASS. CODE REGS. 62.6.3(6).

265. *Tax Break for Removal of Lead Paint*, MASS. BUDGET & POL’Y CTR. (Aug. 2016), <http://children.massbudget.org/tax-break-removal-lead-paint>.

266. STATE OF RHODE ISLAND — DIVISION OF TAXATION, PERSONAL INCOME TAX, TAX CREDITS/DEDUCTIONS — RESIDENTIAL LEAD ABATEMENT INCOME TAX CREDIT 1, 1, <http://www.tax.ri.gov/regulations/other/CR%2013-08%20Lead%20Abatement.pdf> (last visited March 12, 2020).

267. *Id.* at 4.

owners can claim credits each year.²⁶⁸ Finally, Ohio recently adopted a new program that will allow CHIP funding to be used in more ways to abate lead hazards.²⁶⁹ Beginning with the 2020 taxable year, \$5 million per year will be available for property owners to claim for the next two years in the form of non-refundable credits, with a maximum of \$10,000 per taxpayer.²⁷⁰ Tax credits provide homeowners with an incentive to comply with the laws in place for lead poisoning prevention and conduct lead remediation or repairs that will make their homes safe.

7. Federal Grant and Loan Programs

The U.S. Department of Housing and Urban Development (HUD) provides funding for lead poisoning prevention at the state level. The Lead-Based Paint Hazard Control, open to urban, rural, and suburban jurisdictions, and the Lead Hazard Reduction Program (LHRD), targeted at urban jurisdictions, help cities and states identify and control lead-based paint hazards in eligible rental or owner-occupied properties.²⁷¹ Governments, local nonprofits, and individuals can apply for HUD grants. In 2019, HUD awarded a total amount of \$5,600,000 to Erie County, New York, in its effort to help protect children and families from lead-based paint and home health hazards.²⁷² As part of its LEADS SAFE Erie County LHRD Program, qualifying properties will receive free lead-based paint inspection and risk assessment, valued at \$800 per unit, and, if identified as a lead and/or healthy homes hazard, new windows, doors, siding, trim, exterior and interior painting, porch repair, and home safety measures.²⁷³ In order to qualify, the property must (1) be in Erie County, New York; (2) be built before 1978; (3) be a one, two, three, or four unit building; (4) have a child or children under the age of six living in the home or regularly visiting more than six hours per week, OR have a pregnant occupant; and (5) have an occupant that meets the minimum household

²⁶⁸ *Id.*

²⁶⁹ Jason Warner, *Ohio Prioritizes Lead Abatement Initiatives*, GREATER OHIO POL'Y CTR. (Aug. 22, 2019), <https://www.greaterohio.org/blog/2019/8/22/ohio-prioritizes-lead-abatement-initiatives>.

²⁷⁰ *Id.*

²⁷¹ *Lead-Based Paint & Lead Hazard Reduction Demonstration Grant Programs*, U.S. DEP'T OF HOUSING & URBAN DEV., https://www.hud.gov/program_offices/healthy_homes/lbp/lhc (last visited Mar. 12, 2020).

²⁷² *HUD Awards Record \$319 Million to Protect Families from Lead and Other Home Health Hazards*, U.S. DEP'T OF HOUS. & URBAN DEV. (Sep. 30, 2019), https://www.hud.gov/press/press_releases_media_advisories/HUD_No_19_145.

²⁷³ *Lead Hazard Reduction Demonstration Program (LHRD), Erie County*, N.Y. DEP'T OF HEALTH, <http://www2.erie.gov/health/index.php?q=lead-hazard-reduction-demonstration-program-lhrd> (last visited Mar. 12, 2020).

income eligibility.²⁷⁴ Recently, in 2019, Lancaster was awarded a \$9.1 million LHRD grant that will be used to make 710 housing units safe in the city.²⁷⁵

Moreover, HUD 203(k) loans can help property owners refinance their mortgage to pay for the removal of lead hazards.²⁷⁶ This program allows owners to “finance the purchase of a home — or refinance the current mortgage — and include the cost of its repairs through a single mortgage.”²⁷⁷ These loans can be especially beneficial for low- and moderate-income individuals or families since the loan down payment can be as little as 3%.²⁷⁸

B. Accountability

In order for lead poisoning prevention initiatives and requirements to be successful, the law must be strictly enforced to ensure compliance. These actions can take multiple forms, including compliance monitoring, legal action against violators, remedies involving the affected property, and monitoring lead-safe practices. These measures are critical to preventing lead poisoning and providing swift recourse when a lead hazard is identified.

1. Robust Enforcement

Robust enforcement and monitoring of compliance with primary prevention laws is critical to safeguarding the health of citizens. For example, after the state of Rhode Island passed an aggressive lead hazard mitigation law in 2005, it encountered difficulty achieving compliance and reducing blood lead levels among children. The law requires regular inspections and abatement of certain rental units, even when a child does not currently reside in the unit. When property owners complied, children had significantly lower blood lead levels.²⁷⁹ However, when the law was not enforced, it had no effect on blood lead levels in children. In Rhode Island’s four largest cities, only one in five properties covered by the law was in compliance four years after the law’s passage.²⁸⁰

²⁷⁴. *Id.*

²⁷⁵. *City of Lancaster Awarded HUD Grant to Combat Lead Hazards*, City of Lancaster (Sept. 26, 2019) <https://cityoflanasterpa.com/blog/city-of-lancaster-awarded-hud-grant-to-combat-lead-hazards/>.

²⁷⁶. *The Section 203(k) Loan Program: Turning “Fixer-Uppers” into Dream Homes*, U.S. DEP’T OF HOUSING & URBAN DEV. 1, 1 (Feb. 2005), <https://www.hud.gov/sites/documents/2005-09FHA.PDF>.

²⁷⁷. *Id.*

²⁷⁸. *Id.*

²⁷⁹. “The law works when it is followed,” said Michelle Rogers, a senior project analyst in the Brown University School of Public Health. *R.I. Lead Law Effective, Often Ignored*, BROWN UNIV. (July 7, 2014), <https://news.brown.edu/articles/2014/07/lead>.

²⁸⁰. *Id.*

Other states have created causes of action for agencies tasked with enforcement. In 2012, Maryland updated its lead laws to allow the Department of Environment to directly pursue civil injunctive relief rather than having to exhaust administrative avenues.²⁸¹ The law also allows the Department to impose direct monetary penalties for violations of the lead laws: \$20 a day for failure to register a property and \$500 a day for failure to carry out required risk reduction.²⁸² In 2012, the Department issued fifty-eight administrative complaints for a total of more than \$450,000 in penalties.²⁸³ A San Diego, California ordinance authorizes “administrative abatement” that allows the city to assess substantial fines and that has resulted in increased compliance.²⁸⁴ In San Diego, the law requires that owners under city-issued compliance orders obtain their own lead hazard clearances, thus reducing the implementation cost to the municipality.²⁸⁵ Finally, in New Jersey, owners who fail to appeal noncompliance notices are presumed by law to be in violation and, after a second reinspection, the state can impose penalties and request the courts to enter judgment on outstanding penalties, usually by imposing a lien on rental receipts.²⁸⁶

Property maintenance codes provide another method to address lead hazards. States, such as Rhode Island and New York, have adopted the International Property Maintenance Code (IPMC), a model code by the International Code Council, and amended it to add strong lead hazard provisions. For example, Rhode Island’s amendments specifically define lead-based hazards within the IPMC, tie lead requirements to existing Rhode Island laws and other local agency actions, and require owners to actively maintain lead-based surfaces.²⁸⁷ However, strong property maintenance codes are only effective if they are properly enforced. As ChangeLab Solutions notes, this requires (1) effective collaboration between community organizations and code enforcement agencies, (2) cross-agency coordination, and (3) a “cooperative compliance” model of interaction between

281. Amendments to Maryland’s Lead Laws Effective January 1, 2012, <http://mde.maryland.gov/programs/LAND/Documents/LeadNews/LeadNoticeAmendmentsMdLeadLawsEffective2012-01-01.pdf>.

282. James B. Witkin & Megan M. Roberts-Satinsky, *Get the Lead Out: Recent Developments in D.C. and Maryland Lead Paint Laws*, WASHINGTON LAWYER (Mar. 2015), <http://www.linowes-law.com/news-publications-50.html>.

283. *Department of Environment Issues Enforcement Actions Agency Seeks Penalties, Corrective Actions for Alleged Violations of Land, Air and Water Regulations*, MD. DEP’T OF ENV’T. (July 31, 2012), <http://mde.maryland.gov/programs/Pressroom/Pages/Enforcement073112.aspx>.

284. Korfmacher & Hanley, *supra* note 72, at 800.

285. *Id.*

286. TEN EFFECTIVE STRATEGIES, *supra* note 257, at 12.

287. R.I. STATE BLDG. CODE, SBC-6 State Property Maintenance Code (effective July 1, 2013), Provisions 111.3.3, 202, 305.3.1, 305.3.2, 305.3.3, 305.3.4 <http://sos.ri.gov/assets/downloads/documents/SBC6-state-property-maintenance-code.pdf>.

officials and property owners.²⁸⁸ In Rhode Island, LeadSafe Kids provides training for property owners and government officials on Rhode Island's Lead Hazard Mitigation Act.²⁸⁹ Lead regulations are upheld by the Lead Poisoning Prevention Act (under the Rhode Island Department of Health (DOH)) and the Lead Hazard Mitigation Act (under the Housing Resources Commission (HRC)). Rhode Island DOH regulates comprehensive environmental lead inspections while HRC regulates lead mitigation inspections and requires lead-safe certificates for certain rental properties. Together these entities have the ability to carry out comprehensive enforcement to ensure compliance with Rhode Island's updated property maintenance code.

Like property owners, governments, designated parties, agencies, and public-benefit organizations tasked with enforcing lead poisoning laws and regulations must also be held accountable where they fail to comply with legally mandated obligations. In November 2017, attorneys at New Haven Legal Assistance Association (NHLAA) and Connecticut Legal Services filed a lawsuit against the City of New Haven Health Department.²⁹⁰ The complaint alleged that the Department failed to conduct adequate epidemiological investigation, lead abatement supervision, reinspection, and post-abatement management of the home of three-year-old Jacob Guaman after his blood lead level reached 5 µg/dL, as required by local law. Jacob's blood lead level rose to 36 µg/dL and remained elevated for nearly two years without action.²⁹¹ After hearing testimony, the court ordered an independent inspector to identify lead hazards and conduct a post-abatement inspection. The court also ordered the Health Department to abate the property itself (placing a lien on the landlord's property).²⁹² Subsequent lawsuits in the city revealed that the City's Health Department had failed in its duty to protect numerous other families.²⁹³ The City of New Haven responded by attempting to unilaterally increase the blood lead action level that triggered lead hazard inspections from 5 µg/dL to 20 µg/dL or between 15 and 20 µg/dL in two

288. *Up to Code*, *supra* note 50, at 16.

289. *Childhood Lead Action Project*, RHODE ISLAND LEADS SAFE KIDS, TRAINING, <http://www.lead safekids.org/en/training>.

290. *Jacob v. City of New Haven*, NNH-CV17-5040434-S (Conn. Super. Ct. 2017), available at <http://civillinquiry.jud.ct.gov/CaseDetail/PublicCaseDetail.aspx?DocketNo=NNHCV175040434S>.

291. *Id.*

292. Mary E. O'Leary, *New Haven Ordered to Have House Cleared of Lead*, NEW HAVEN REGISTER (Dec. 6, 2017), <https://www.nhregister.com/news/article/New-Haven-ordered-to-have-house-cleared-of-lead-12411797.php>; Thomas Breen, *Weakened Lead Law Advances*, NEW HAVEN INDEPENDENT (Nov. 13, 2019), https://www.newhavenindependent.org/index.php/archives/entry/lead_vote/#cmt.

293. Order 435696, 1, *Soliman v. Muhammad et al.*, NHH-CV18-5002790-S, Docket No. 125, (Conn. Super. Ct. 2018) <http://civillinquiry.jud.ct.gov/DocumentInquiry/DocumentInquiry.aspx?DocumentNo=14932955>.

tests three months apart. After NHLAA filed a class action lawsuit against the City for this change, the court ruled that the administration could not modify its lead policy to a less strict standard without amending the underlying ordinance through the proper procedures.²⁹⁴

In November 2017, an investigation by New York City's Department of Investigation found that the New York City Housing Authority (NYCHA), a public-benefit corporation and federal grantee, had failed to conduct mandatory inspections in public housing apartments for four years,²⁹⁵ and had submitted false certifications of compliance to HUD.²⁹⁶ As a result, between 2012 and 2016, 820 children under the age of 6 who lived in NYC public housing had an elevated blood lead level greater than 5 µg/dL.²⁹⁷ Mayor Bill de Blasio announced the following July that the city would conduct lead inspections in every NYCHA unit "where lead paint may have been used."²⁹⁸

i. Tenant Rights and Remedies

In addition to robust enforcement of existing regulations, jurisdictions must enact a private right of action for affected tenants exposed to lead hazards as well as hold lead paint manufactures liable for the harms their products caused in the community. Tenants exposed to lead hazards have limited legal recourse. They often must wait on local health departments or attorneys general to order compliance or turn to common law negligence remedies²⁹⁹ and municipal housing

294. Memorandum of Decision, *Nyriel Smith v. City of New Haven*, NHH-CV19-5003875-S, Docket No. 122, (Conn. Super. Ct. 2019), <http://civlinquiry.jud.ct.gov/DocumentInquiry/DocumentInquiry.aspx?DocumentNo=17162514>.

295. J. David Goodman & William Neuman, *Lead Paint Failures Magnified by City Hall's Failure to Communicate*, N.Y. TIMES (Dec. 4, 2017), https://www.nytimes.com/2017/12/04/nyregion/lead-paint-nyc-de-blasio-olatoye-nycha.html?_r=0.

296. *DOI Investigation Reveals NYCHA Failed to Conduct Mandatory Lead Paint Safety Inspections for Four Years*, N.Y.C. Dep't of Investigation (Nov. 14, 2017), http://www1.nyc.gov/assets/doi/press-releases/2017/nov/27NYCHALeadPaint11-14-2017_UL.pdf.

297. Luis Ferré-Sadurní, *820 Children Under 6 in Public Housing Tested High for Lead*, N.Y. TIMES (July 1, 2018), <https://www.nytimes.com/2018/07/01/nyregion/nycha-lead-paint-children.html>; Emily A. Benfer, *New York's Public Housing is the Size of a City. It's Failing Children*, WASH. POST. (Feb. 11, 2019), https://www.washingtonpost.com/opinions/new-yorks-public-housing-system-is-the-size-of-a-city-its-failing-children/2019/02/11/458f63c2-2bb7-11e9-984d-9b8fba003e81_story.html.

298. J. David Goodman, *Mayor Says All Public Housing Units at Risk for Lead to Be Tested*, N.Y. TIMES (July 9, 2018), https://www.nytimes.com/2018/07/09/nyregion/de-blasio-lead-paint-nycha.html?emc=edit_th_180710&nl=todaysheadlines&nliid=853645860710.

299. In 1996, the Connecticut Supreme Court struck down a lower court's interpretation that Connecticut statutes allowed for strict liability in lead poisoning cases, instead finding that tenants alleging negligence per se needed to prove both that the landlord knew of the lead paint danger and was provided a "reasonable" opportunity to remedy the condition. *See Gore v. People's Sav. Bank*, 40 Conn. App. 219, 225 (1994). In addition, because children must first be injured in order to have a

code enforcement.³⁰⁰

Illinois law typifies this approach. We have previously observed that, “like *all lead laws*, the ILPPA [Illinois Lead Poisoning Prevention Act] does not create a private right of action or tenants’ rights. It relies on the [Illinois Department of Public Health] to identify a hazard and on the State’s Attorney or Attorney General to execute penalties and enforcement mechanisms at their discretion.”³⁰¹ This withholds power from those affected by lead poisoning and allows for discretion by local health departments and code enforcers. This is especially harmful because the majority of homeowners insurance policies exempt lead poisoning, dramatically reducing a tenant’s likelihood of recouping damages.

States should instead embed methods of enforcement in administrative and civil proceedings. For example, in Philadelphia, a specialized court gives tenants the ability to seek civil remedies for failure to remediate.³⁰² Judges who are familiar with lead poisoning effects and laws issue orders to remediate, rather than solely issuing monetary damages for harm caused by lead poisoning. This approach has resulted in increased compliance rates and the swift remediation of properties.³⁰³

At the same time, states and municipalities must ensure that robust lead laws do not result in negative consequences for the very people they were meant to protect. Adherence to lead poisoning prevention laws can result in additional maintenance; landlords may then be reluctant to rent to tenants who have young children.³⁰⁴ In addition to protections under the Fair Housing Act, state and local laws must include specific procedures to protect families and tenants with young children from familial discrimination.³⁰⁵ For example, in New York State, a law imposes a fine and a cause of action for civil liability against any landlord who discriminates solely on the ground that a person or family has a child.³⁰⁶ In addition, states and municipalities can adopt express language prohibiting retaliatory evictions that occur within a set timeframe of reporting a child with an EBLL or a suspected lead hazard. For example, several jurisdictions have put in place protections for the tenant from being evicted after a positive lead poisoning

cause of action, any case or action will not take on the primary goal of preventing the exposure in the first place.

300. An additional hurdle comes from the disparity in power between some tenants and landlords. Tenants, compared to the government, have a harder time initiating actions on their own. “Many tenants are reluctant to report a problem for fear of being labeled a ‘troublemaker’ or experiencing retaliation from the landlord.” Benfer & Gold, *supra* note 53, at S28.

301. Benfer, *supra* note 24, at 333 (emphasis added).

302. Carla Campbell et al., *Philadelphia’s Lead Court is Making a Difference*, 38 J. HEALTH POL’Y 709, 713 (2013). See also Benfer, *supra* note 24, at 341.

303. Benfer, *supra* note 24, at 341.

304. Korfmacher & Hanley, *supra* note 72, at 796.

305. *Id.* at 796.

306. N.Y. REAL PROP. LAW §237-a.

test.³⁰⁷

ii. Liability for the Lead Paint Industry Association and Paint Manufacturers

Organizations and companies responsible for manufacturing, marketing, and selling lead-based paint must be held accountable for the harms caused by their products.³⁰⁸ While lead paint in homes was banned in 1978,³⁰⁹ lead paint manufacturers knew of lead paint's dangers for decades prior.³¹⁰ Although the Lead Paint Industry Association, founded in 1928, was instrumental in minimizing health concerns associated with lead paint exposure “for fear that they might undermine business,”³¹¹ liability theories can be advanced to hold the paint and lead industries accountable.

Some states have adopted provisions that require a public nuisance action to be brought as product liability claims. For example, in Ohio, the adoption of the 2007 Amendment Substitute Senate Bill 117 amended Ohio's Product Liability Act (OPLA) to state that the term “[p]roduct liability claim” also includes *any public nuisance claim* or cause of action at common law in which it is alleged that the design, manufacture, supply, marketing, distribution, promotion, advertising, labeling, or sale of a product unreasonable interferes with a right common to the general public.³¹² This means that the law, by its language, now generally precludes common law public nuisance claims in Ohio by requiring that any such claim be brought as a product liability claim under OPLA.³¹³ It might be possible to bring a claim against lead paint manufacturers under OPLA, but to do so would require avoiding the procedural limitations imposed by OPLA that limit claims on the basis of time.³¹⁴ OPLA typifies the approach many states have taken to

307. See, e.g., MASS. GEN. LAWS, pt. II, tit. I, ch. 185, § 18: Reprisal for reporting violations of law . . . ; Milwaukee Ordinance 18759, (July 26, 2019), <https://milwaukee.legistar.com/LegislationDetail.aspx?ID=3872234&GUID=C17A86CE-7863-4F12-B977-0E15F26CC70F&Options=ID%7CText%7C&Search=181759>.

308. Benfer, *supra* note 24, at 340.

309. Other countries had banned the use of lead-based paints far earlier. In 1909, France, Belgium, and Austria banned white-lead interior paint. See Rebecca Kessler, *Lead-Based Decorative Paints: Where Are They Still Sold — and Why?*, 122 ENVTL. HEALTH PERSP. A96, A98 (2014).

310. Bob Egelko, *California Judge Says Companies Must Remove Pre-1951 Lead Paint in Homes*, SFGATE (Nov. 15, 2017), <http://www.sfgate.com/bayarea/article/California-judge-says-companies-must-remove-12357820.php>; see also *California Counties and Cities Announce Groundbreaking \$305 Million Settlement of Landmark Lead Paint Litigation*, CTY. OF SANTA CLARA, OFF. CTY. COUNSEL (July 17, 2019), <https://www.sccgov.org/sites/cco/leadpaint/Pages/home.aspx>.

311. MARKOWITZ & ROSNER, *supra* note 2, at 29.

312. OHIO REV. CODE ANN. § 2307.71(A)(13)(c) (emphasis added).

313. There do exist exceptions to this statutory rule which could be used in the case of lead paint. The viability of these exceptions will be explored in greater depth in subsequent sections.

314. OHIO REV. CODE ANN. § 2305.10(A) (stating that “an action based on a product liability

temporally limit liability for paint manufacturers, thereby compounding the difficulty of advancing a claim.

However, if state statutes may be abrogated, lead paint manufacturers may instead be liable under public nuisance doctrine. In the landmark case *People v. ConAgra Grocery Products Co.*, ten California cities and counties sued three lead paint manufacturers – ConAgra, Sherwin-Williams, and NL – for creating a public nuisance. This case marked the first time that a court held lead paint manufacturers liable for creating a public nuisance, ordering the manufacturers to pay \$1.15 billion to an abatement fund. As the court stated: “[t]he community has a collective social interest in the safety of children in residential housing. Interior residential lead paint interferes with the community’s ‘public right’ to housing that does not poison children. This interference seriously threatens to cause grave harm to the physical health of the community’s children.”³¹⁵

While an important case, part of the success of *People v. ConAgra* hinged on elements unique to California law. In recent years, municipalities in New Jersey,³¹⁶ Illinois,³¹⁷ Rhode Island,³¹⁸ and Missouri³¹⁹ have brought similar public nuisance claims against lead paint manufacturers. However, unlike California, each of these states has ruled in favor of the lead paint manufacturers, reasoning that lead safety is not a public right, causation cannot be proven without identification of a specific manufacturer in a specific home, or that legislation places the blame on landowners as the real tortfeasors. Nevertheless, paint and lead companies historically

claim and an action for bodily injury or injuring personal property shall be brought within two years after the cause of action accrues”). In states that have adopted similar statutes of limitation and repose, communities may be barred from advancing claims against paint manufacturers that ceased production of lead paint to be used in the home in the 1970s, as the latest such claims could be initiated is around 1990. This is based on the fact that the Lead-Based Paint Poisoning Prevention Act banned the use of lead paint in residential structures beginning in 1978. Pub. L. No. 91-695, 84 Stat. 2078.

315. *People v. ConAgra Grocery Prods. Co.*, 17 Cal. App. 5th 51, 112 (2017).

316. *In re Lead Paint Litigation*, 191 N.J. 405, 434 (2007) (“Even were we to conclude that the distribution of lead-based paint products constituted actionable conduct for purposes of permitting a tort-based recovery, we would nonetheless reject plaintiffs’ complaints. As our explanation of public nuisance has made plain, the remedies available traditionally vary as between public and private plaintiffs.”).

317. *See City of Chicago v. Am. Cyanamid Co.*, 355 Ill. App. 3d 209, 220 (2005) (stating that “plaintiff is attempting to . . . [make] each manufacturer the insurer for all harm attributable to the entire universe of all lead pigments”).

318. *See State v. Lead Indus. Ass’n*, 951 A.2d 428, 448 (R.I. 2008). (“[t]he manufacture and distribution of products rarely, if ever, causes a violation of a public right as that term has been understood in the law of public nuisance. Products generally are purchased and used by individual consumers, and any harm they cause—even if the use of the product is widespread and the manufacturer’s or distributor’s conduct is unreasonable—is not an actionable violation of a public right. The sheer number of violations does not transform the harm from individual injury to communal injury”).

319. *See City of St. Louis v. Benjamin Moore & Co.*, 226 S.W.3d 110, 116 (Miss. 2007).

responsible for the introduction of lead into children's environments should be held accountable for removing the neurotoxin and public nuisance doctrine may be a viable avenue depending on the jurisdiction.

2. Remedies Involving the Property

i. Rent Reduction and Escrow

Rent abatement and reduction provisions in local law protect tenants from having to pay rent when their homes have dangerous conditions. Moreover, by depriving landlords of their source of income, these policies encourage landlords to fix lead hazards in a timely manner. For example, Los Angeles' Rent Escrow Account Program (REAP) allows tenants to receive a rent reduction if the property has cited housing code violations. To incentivize the landlord, the city records a lien on REAP properties, which it will only remove once the owner brings the property in compliance.³²⁰ Similarly, in October 2017, Detroit, Michigan updated its rental regulations to include provisions allowing tenants to escrow rent if the landlord has not passed lead inspections.³²¹ However, escrow accounts should be approached cautiously, as many tenants have experienced difficulty recouping their funds, which are often urgently needed for a new security deposit.

ii. Liens

Some jurisdictions have implemented lien programs for certain code violations that may be replicated to address lead hazards. Waterbury, Connecticut's "Blight Initiative" includes a "Clean and Lien" program. When the Waterbury Development Corporation (WDC) or Police Department receives a complaint, they can mandate that the owner remove blight. If the owner cannot be found or does not appear in court, WDC cleans the property and places a lien on the property for all costs.³²²

Other jurisdictions have enacted lien programs specific to lead hazard abatement. For example, in Philadelphia, if the City Health Department issues an order to correct a code violation, and the owner does not comply, the "Department may, itself or by contract, correct the condition by eliminating the hazard, charge the costs thereof to the owner, and, with the approval of the Law Department,

320. Benfer, *supra* note 24, at 340.

321. Christine MacDonald, *Detroit Council Toughens Rules for Landlords*, DETROIT NEWS (Oct. 31, 2017), <http://www.detroitnews.com/story/news/local/detroit-city/2017/10/31/detroit-council-tightens-landlord-rental-inspection-regulations/107196580/>.

322. *Blight Initiative*, WATERBURY DEV. CORP., <http://www.wdconline.org/content/100/544/default.aspx> (last visited Mar. 13, 2020).

collect the costs by lien or otherwise.”³²³

Underscoring the importance of local will, including such a provision in city ordinances is only valuable if the city exercises the option to protect residents’ health. The City of New Haven has long had a municipal ordinance allowing the Health Department to carry out lead abatement and place a lien on the property.³²⁴ The City, however, did not exercise its powers until ordered to do so in *Guaman v. City of New Haven Health Department* described above, in which the court ordered the Health Department itself to abate the home of Jacob Guaman in lieu of the landlord and place a lien on the property.

3. Enforcement of Lead-Safe Practices

States and municipalities should ensure that additional hazards are not created as a result of improper renovation and demolition practices of properties that contain lead hazards. To prevent lead poisoning while remediating lead hazards, jurisdictions should adopt and enforce the Lead Renovation, Repair, and Painting (RRP) Rule, require lead-safe demolition practices, and mandate strict licensing standards for lead remediation professionals.

i. State Adoption and Enforcement of the Lead Renovation, Repair, and Painting Rule

The RRP Rule, administered by the EPA, mandates specific training, workplace, and recordkeeping requirements on firms and workers that perform projects that disturb lead-based paint in homes, childcare facilities, and preschools built before 1978. The rule applies to activities where more than six square feet per interior project or more than 21 square feet per exterior project are disturbed. RRP is a vital component of the primary prevention of lead poisoning in the house.³²⁵ However, because RRP is a federal rule, it can be challenging for local governments to enforce.³²⁶ Local adoption and enforcement of lead-safe work practices would result in greater compliance with RRP rule standards.³²⁷ States that adopt the RRP rule can better enforce, oversee, and improve upon RRP

323. PHILA. HEALTH CODE & CHARTER, tit. 6, 6-403(4)(b)(1)(a).

324. New Haven Municipal Ordinances Sec. 16-66(e).

325. N.Y. LAWYERS FOR THE PUB. INTEREST, LEAD LOOPHOLES: HOW LAX ENFORCEMENT OF NEW YORK CITY LEAD PAINT POISONING PREVENTION LAW LETS LANDLORDS OFF THE HOOK AND LEAVES CHILDREN AT RISK 1, 16 (2018), https://nylpi.org/wp-content/uploads/2018/09/LeadReport_WhitePaper_092718_LETTER.pdf.

326. Enforcement can be difficult due to the large number of jobs combined with the relatively small staff available to oversee work. James D. Blando, Nickita Antoine & Daniel Lefkowitz, *Lead-Based Paint Awareness, Work Practices, and Compliance During Residential Construction and Renovation*, 75 J. ENVTL. HEALTH 20, 21 (2013).

327. Korfmacher & Hanley, *supra* note 72, at 787.

requirements in order to decrease lead hazards and lead poisoning as a result of renovation and repair projects. Specifically, states can (1) replace the current cleaning verification method with a more effective and scientifically verified dust swipe method for clearance testing³²⁸ and (2) improve training requirements, work practices, and the system maintained for filing complaints, among other measures.³²⁹

In addition, states can include demolition in the activities covered by the RRP Rule. Lead dust and debris from the demolition of pre-1978 properties can cause harm to children who live near demolition sites and can continue to be a potential hazard for years.³³⁰ As RRP only applies to homes, child care facilities, and preschools built before 1978, very few jurisdictions currently have lead-safe demolition standards that apply specifically to pre-1978 properties.³³¹ States and local government adoption and enforcement of standards to prevent the spread of lead dust and other contaminants is a critical component of lead poisoning prevention.³³²

ii. Licensing Standards for Professionals

Professionals who perform lead hazard remediation and abatement must be required to adhere to specific licensing requirements. Licensing requirements typically include training, so that lead “hazard remediation itself does not inadvertently expose residents to harm.”³³³ Individuals who perform lead hazard remediation and abatement tasks without the proper training can aggravate the hazard. To be most effective, these licensing standards should be strictly enforced and revisited periodically “in light of advances in science and medicine.”³³⁴

328. The CDC Advisory Commission on Childhood Lead Poisoning Prevention determined that visual assessments and remediation “should now be considered unacceptable.” ADVISORY COMM. ON CHILDHOOD LEAD POISONING PREVENTION, *supra* note 20. HUD has acknowledged the importance of clearance testing and requires it for all projects done in federally owned housing. A 2018 GAO Report found that visual assessments are ineffective in identifying lead hazards and the 1994 GAO Report found that “[T]hese and other public housing authorities may be overlooking significant hazards in these inspections, which require only visual evidence and do not include testing for lead-based paint hazards.” U.S. GOV’T ACCOUNTABILITY OFFICE, LEAD-BASED PAINT POISONING: CHILDREN IN SECTION 8 TENANT-BASED HOUSING ARE NOT ADEQUATELY PROTECTED I, 5 (1994).

329. Rhode Island and Massachusetts have adopted requirements that only a licensed renovator may conduct RRP work. *See* 216 R.I. CODE R. § 050-15-3.2.3 and 454 MASS. CODE REGS. § 22.03.

330. GREEN & HEALTHY HOMES INITIATIVE, STRATEGIC PLAN, *supra* note 70, at 15; David E. Jacobs et al., *Lead and Other Heavy Metals in Dust Fall from Single-Family Housing Demolition*, 128 PUB. HEALTH REP. 454 (2013).

331. GREEN & HEALTHY HOMES INITIATIVE, STRATEGIC PLAN, *supra* note 70, at 15.

332. Jacobs et al., *supra* note 330.

333. Benfer & Gold, *supra* note 53, at S32.

334. *Id.* at S32–33.

CONCLUSION

There is no question that lead poisoning results in irreparable harm to children. At the same time, the risk of, and harms associated with, lead poisoning disproportionately affect children of color. For over a century, children have been victims of inadequate lead poisoning prevention laws that fail to address lead exposure pathways and eliminate the lead epidemic. Many more generations will follow unless and until federal, state and local governments systematically identify and remove lead from contaminated houses. This will require policy makers to implement both primary prevention strategies, including inspection of housing units prior to occupancy, comprehensive identification of lead hazards, and leveraging technology and data to identify and remove hazards before a child is injured, as well as secondary prevention strategies, such as universal blood lead level screening for all children and updating the definition of lead poisoning to conform to advances in science and medicine. Ultimately, these strategies must be deployed within a health justice framework that focuses on primary prevention and the health of the whole community. It will require prioritizing the health of low-income and traditionally marginalized communities in all policies and engaging those most affected by lead poisoning as leaders in problem solving. Only then can the United States secure a lead-free future for all children and preserve each child's ability to realize his or her fullest potential.

Defining “Regular Occupation” in Long-Term Disability Insurance Policies

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Abstract:

Millions of American workers purchase “regular occupation” disability insurance to protect against disability-related job loss. Unlike general disability insurance policies, which require workers be disabled from doing any job to receive benefit payments, “regular occupation” insurance pays benefits when workers become disabled from doing their specific job. Whether a disabled worker receives benefits under such a plan often turns on how insurers and courts define the worker’s “regular occupation.”

Some Circuits look to the duties, conditions, and experience required to do a worker’s job. But others define a worker’s “regular occupation” in generic terms—even if that description does not accurately capture the person’s work. When a worker’s occupation is defined generically, the worker is unlikely to qualify as disabled under their insurance plan and thus does not qualify for benefits. The divergent interpretations of “regular occupation” insurance plans across circuits run headlong into the goals of fair and uniform benefit administration set out in the Employee Retirement Income Security Act (ERISA).

This Note argues “regular occupation” must be defined with reference to a worker’s actual job requirements. We explore the shortcomings of defining “regular occupation” without reference to a worker’s actual job and propose several solutions to standardize the definition of “regular occupation.”

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TABLE OF CONTENTS

INTRODUCTION	213
I. WHAT IS LONG-TERM DISABILITY INSURANCE?	214
II. THE COURTS OF APPEALS DO NOT AGREE ON HOW TO DEFINE “REGULAR OCCUPATION.”	215
A. THE SECOND AND THIRD CIRCUITS DEFINE “REGULAR OCCUPATION” IN TERMS OF WORKERS’ ACTUAL JOB REQUIREMENTS.....	215
B. THE FIFTH, SIXTH, AND EIGHTH CIRCUITS DEFINE “REGULAR OCCUPATION” IN GENERAL TERMS.....	216
C. AS A RESULT OF THE SPLIT, OUTCOMES FOR WORKERS WITH IDENTICAL JOBS, DISABILITIES, AND INSURANCE POLICIES VARY	218
III. “REGULAR OCCUPATION” MUST BE DEFINED WITH REFERENCE TO A CLAIMANT’S ACTUAL JOB REQUIREMENTS.	219
A. THE DICTIONARY OF OCCUPATIONAL TITLES DISTORTS THE ADJUDICATION OF ERISA DISABILITY BENEFIT CASES.	219
1. THE DOT WAS NOT DESIGNED FOR DISABILITY DETERMINATIONS.....	220
2. THE DOT IS BASED ON FLAWED DATA.	221
3. THE DOT IS OBSOLETE.....	221
B. DEFINING OCCUPATIONS IN GENERAL TERMS UNFAIRLY JEOPARDIZES AMERICANS’ ACCESS TO DISABILITY INSURANCE BENEFITS.	222
1. MILLIONS OF AMERICANS ARE COVERED BY LONG-TERM DISABILITY INSURANCE POLICIES THAT CONTAIN THE “REGULAR OCCUPATION” LANGUAGE WHOSE MEANING UNDERLIES THE CIRCUIT SPLIT.	222
2. DEFINING OCCUPATIONS IN GENERAL TERMS IS CONTRARY TO ERISA’S GOALS AND FLOUTS THE PURPOSE OF LONG-TERM DISABILITY INSURANCE.....	224
C. ACCURATE BENEFIT DETERMINATIONS PREVENT HARM TO WORKERS AND BOLSTER LONG-TERM ECONOMIC STABILITY.	225
1. DISABLED WORKERS WHO ARE DENIED BENEFITS FACE DRASTIC FINANCIAL AND HEALTH CONSEQUENCES.....	225
2. DEFINING JOBS ACCURATELY MAKES IT EASIER FOR WORKERS TO SUCCESSFULLY RETRAIN AND GO BACK TO WORK.....	226
D. INSURERS HAVE LITTLE INCENTIVE TO MAKE ACCURATE BENEFIT	

DETERMINATIONS.....	227
E. THE BENEFITS OF DEFINING “REGULAR OCCUPATION” WITH SPECIFICITY OUTWEIGH THE POTENTIAL COSTS.....	230
IV. POSSIBLE SOLUTIONS.....	231
A. THE JUDICIARY SHOULD ADVANCE A UNIFORM LEGAL RULE.	231
B. CONGRESS SHOULD LEGISLATE A UNIFORM RULE.	231
CONCLUSION	233

INTRODUCTION

It is impossible for Juanita Nichols to do her job. Now sixty-two years old, Nichols spent her entire career working in a poultry factory.¹ Her job involved processing raw chicken, a task for which she received industry-specific training applicable only to inspecting and processing poultry. Because the work involved raw meat, Nichols' job required she work in near-freezing temperatures all day.² Prolonged exposure to this extreme cold caused Nichols to develop Raynaud's disease,³ a circulatory disorder that causes people to lose circulation in their extremities when exposed to cold temperatures. Nichols' diagnosis meant she could no longer work in the chicken-processing plant. She was now disabled from doing the only job she had ever had.

Before falling ill, Nichols purchased long-term disability insurance through her employer to protect against this exact scenario.⁴ Her policy provided benefits if, as a result of injury or illness, Nichols could not "perform the material duties of [] her Regular Occupation."⁵ But when Nichols filed a claim for benefits under the policy after developing Raynaud's, her claim was denied.⁶

When evaluating whether Nichols was disabled from doing "her Regular Occupation," Reliance Standard Life Insurance (Reliance) defined "regular occupation" in terms of how a food processing job was "normally performed in the national economy," not "the way it is performed for a specific employer or in a specific locale."⁷ In short, Reliance defined "regular occupation" in general terms; it did not define Nichols' "regular occupation" with reference to her specific job requirements.

Without considering any additional information, Reliance defined Nichols' job using a reference manual called the Dictionary of Occupational Titles (DOT). The book contained an entry titled "sanitarian, any industry," which Reliance asserted best fit Nichols' position. The company then used the list of associated job duties to assess whether Nichols' Raynaud's diagnosis disabled her from performing her job. Because the "sanitarian (any industry)" entry did not refer to working in the cold, Reliance found Nichols was not disabled and denied her benefits.⁸ Nichols asked Reliance to reconsider, but the insurance company concluded "[a]ny exposure to cold temperatures would be job-site specific, rather

1. Nichols v. Reliance Std. Life Ins. Co., 924 F.3d 802, 805 (5th Cir. 2019).

2. Nichols v. Reliance Std. Life Ins. Co., 2018 U.S. Dist. LEXIS 109526, *3 (S.D. Miss. June 29, 2018) (noting the factory was consistently kept at forty degrees Fahrenheit).

3. Nichols, 924 F.3d at 805; Nichols, 2018 U.S. Dist. LEXIS 109526 at *34.

4. Nichols, 924 F.3d at 805.

5. Id. at 806 n.1.

6. Id. at 806.

7. Id.

8. Id.

than a duty of her ‘regular occupation’ as ‘sanitarian.’”⁹

Nichols sued reliance under the Employee Retirement Income Security Act (ERISA), which creates a private right of action to recover insurance benefits.¹⁰ Though the district court sided with Nichols,¹¹ the Fifth Circuit ultimately held Reliance made a “fair and reasonable” determination.¹² Nichols appealed, but the Supreme Court denied certiorari this fall.¹³

This Note argues the terms “regular occupation” and “own occupation” in long-term disability insurance policies must be defined with reference to all of the material duties and conditions of a worker’s job. Part I explains the purpose and structure of long-term disability insurance. Part II details the circuit split over how to define “regular occupation” in cases like Nichols’. Part III presents the shortcomings of defining “regular occupation” in general terms and explains the importance of resolving the split in favor of a more specific definition. Finally, Part IV proposes several solutions to standardize the definition of “regular occupation” and bring administration of long-term disability insurance policies back into alignment with ERISA’s goals.

I. WHAT IS LONG-TERM DISABILITY INSURANCE?

Disability insurance protects future earnings.¹⁴ Many employers provide both short- and long-term disability insurance.¹⁵ Short-term disability insurance pays workers a portion of their salary when they are temporarily disabled from doing their job.¹⁶ Benefits are typically limited to three to six months and are used to compensate workers for income loss due to injuries like broken bones or other inherently temporary disabling conditions.¹⁷

Long-term disability insurance kicks in after short-term benefits run out.¹⁸ Despite its name, long-term disability insurance typically only provides benefits for two to five years.¹⁹ It is designed to be temporary: the policies are intended to provide much-needed financial support while a worker retrain and searches for a

9. *Nichols*, 2018 U.S. Dist. LEXIS 109526 at *5.

10. 29 U.S.C. § 1132(a)(1)(B).

11. *Nichols*, 2018 U.S. Dist. LEXIS 109526, at *11–12.

12. *Nichols*, 924 F.3d at 810.

13. *Nichols v. Reliance Std. Life Ins. Co.*, 140 S. Ct. 186 (2019).

14. TAMRA L. BARRACLOUGH ET AL., *THE ADVISORS GUIDE TO DISABILITY INSURANCE* 8 (2016).

15. *Id.* at 59.

16. James Passamano, Beth Sufian & Karey Sopchak, *Protecting Income and Health Coverage When a Worker Becomes Disabled*, 55 HOUSTON LAWYER 16, 18 (2018).

17. BARRACLOUGH ET AL., *supra* note 14 at 60.

18. *Id.*

19. *Id.* at 63.

new job.²⁰

Typically, insurers offer two types of long-term disability insurance: “any occupation” and “regular occupation.” “Any occupation” disability insurance provides protection when a worker is disabled from doing *any* job.²¹ “Regular occupation” or “own occupation” insurance, on the other hand, provides benefits when the worker can no longer perform their particular job.²²

II. THE COURTS OF APPEALS DO NOT AGREE ON HOW TO DEFINE “REGULAR OCCUPATION.”

Disagreement over how to define “regular occupation” has divided the courts of appeals for two decades.²³ The Second and Third Circuits have long held “regular occupation” must be defined with reference to the actual requirements of a worker’s job.²⁴ The Fifth, Sixth, and Eighth Circuits, however, accept more generic characterizations of jobs, even when those definitions do not capture all facets of a worker’s role.²⁵ The following sections illustrate the different approaches to defining “regular occupation” by summarizing emblematic cases on each side of the circuit split.

A. The Second and Third Circuits Define “Regular Occupation” in Terms of Workers’ Actual Job Requirements.

Martha Kinstler was the director of nursing services at a small healthcare facility.²⁶ Her role required her to stand approximately twenty-five percent of the work day and perform clinical duties for forty percent of the work day.²⁷ Kinstler purchased a long-term disability insurance policy through her employer that

20. *Id.* at 61.

21. 4 Law of Life and Health Insurance § 8.03[1] (“Any occupation” disability insurance is also called “general disability” insurance.).

22. *Id.* at § 8.02[1]. “Own occupation” and “regular occupation” are interchangeable in the context of disability insurance policies. *See Patterson v. Aetna Life Ins. Co.*, 763 Fed. Appx. 268, 271–72 (3d Cir. 2019) (“equat[ing] ‘own occupation’ with . . . ‘regular occupation.’”); *Osborne v. Hartford Life & Accident Ins. Co.*, 465 F.3d 296, 300 (6th Cir. 2006) (stating the “relatively minor difference in language” between “own occupation” and “regular occupation” “does not warrant a different result.”).

23. *See Kinstler v. First Reliance Std. Life Ins. Co.*, 181 F.3d 243, 249 (2d Cir. 1999); *see also Darvell v. Life Ins. Co. of N. Am.*, 597 F.3d 929, 935 (8th Cir. 2010) (acknowledging “[t]he circuits are split . . . on this issue”).

24. *See, e.g., Lasser v. Reliance Std. Life Ins. Co.*, 344 F.3d 381, 386 (3d Cir. 2003); *Kinstler*, 181 F.3d at 252–53.

25. *See Darvell*, 597 F.3d at 935; *House v. Am. United Life Ins. Co.*, 499 F.3d 443, 452 (5th Cir. 2007); *Osborne v. Hartford Life & Accident Ins. Co.*, 465 F.3d 296, 299 (6th Cir. 2006).

26. *Kinstler*, 181 F.3d at 245.

27. *Id.* at 246.

provided benefits when the “[i]nsured cannot perform the material duties of his/her regular occupation.”²⁸

After injuring her knee in a car accident, Kinstler sought disability benefits under the policy. Though Kinstler’s physician said she could “not work in any capacity where she [was] expected to walk distances more than 50 feet repeatedly[,] carry loads, lift or climb,”²⁹ Kinstler’s insurer relied on the opinion of a different doctor who determined Kinstler would be able to work so long as she was sedentary.³⁰

After determining the scope of Kinstler’s limitations, the insurance company turned to the DOT, which, as noted above, is a reference manual that catalogs jobs and their corresponding duties. The company categorized Kinstler’s occupation as “Director of Nursing.” Because the job duties associated with “Director of Nursing” in the DOT were largely sedentary and did not include direct patient care, Kinstler’s insurer refused to pay her benefits.³¹ The insurer argued that although Kinstler’s job required she perform direct patient care, those tasks were not an essential function of a “director of nursing” according to the DOT.³²

On appeal, the Second Circuit rejected the insurer’s argument and held Kinstler was improperly denied benefits.³³ The Second Circuit recognized that although Kinstler’s job title was nominally the same as the job identified in the DOT, her “regular occupation” “must be defined as a position of the ‘same general character’ as her job, *i.e.*, a director of nursing at a small health care agency.”³⁴ Thus, “even though at a large hospital, a director of nursing might have only . . . sedentary tasks,” Kinstler’s position required more activity.³⁵ Under this understanding of “regular occupation,” the court reinstated Kinstler’s benefits.³⁶

B. The Fifth, Sixth, and Eighth Circuits Define “Regular Occupation” in General Terms.

Decisions like *Kinstler* and others from the Second and Third Circuits are irreconcilable with decisions in the Fifth, Sixth, and Eighth Circuits. Take for example the case of Juanita Nichols, discussed in this Note’s introduction. As previously explained, Nichols’ insurer, Reliance, denied her benefits when Nichols was diagnosed with Raynaud’s disease. Nichols sued and the U.S. District Court

28. *Id.*

29. *Id.*

30. *Id.* at 246–47.

31. *Id.* at 247.

32. *Id.*

33. *Id.* at 252–53.

34. *Id.* at 253.

35. *Id.*

36. *Id.*

for the Southern District of Mississippi reversed Reliance's determination, noting the insurer ignored "both common sense and the record evidence" when it denied Nichols benefits. The court held it was unreasonable to define Nichols' occupation by relying solely on a single DOT entry that did not capture all of Nichols' job duties.³⁷

The Fifth Circuit reversed, finding Reliance's definition of Nichols' regular occupation was supported by substantial evidence: the DOT.³⁸ The court held that even though Nichols paid for "regular occupation" disability insurance, "Reliance did not need to account for every task Nichols performed," it "merely needed to make a 'fair and reasonable' determination of whether Nichols' disability precluded her from performing the material duties of her regular occupation."³⁹

Not everyone agrees with this approach. Judges on both the Fifth and Sixth Circuits have published dissents from cases like Nichols'.⁴⁰ These opinions echo the law in the Second and Third Circuits, explaining "regular occupation . . . in general[] means the individual insured's usual and customary means of earning a livelihood."⁴¹ Moreover, one judge explains, "regular occupation" "does not permit the insurer to define [disability] at an unreasonably high level of generality so as to offer the insured no real protection."⁴²

The issue is not simply one of contract interpretation. Though contract language may differ slightly across insurance companies and between policies,⁴³ the core question remains how an insurer (or court) should determine what, exactly, constitutes an applicant's "regular occupation." Juanita Nichols' policy states that her insurer, Reliance, would determine her "regular occupation" by referencing how "it is normally performed in the national economy, and not the unique duties performed for a specific employer or in a specific locale."⁴⁴ Requiring insurers define the demands of workers' occupations with reference to "the national economy" glosses over the central issue: Insurers can only identify how a job is performed in the national economy if it first identifies what the job is.

Put another way, when we talk about defining "regular occupation," we mean

37. *Nichols v. Reliance Std. Life Ins. Co.*, 2018 U.S. Dist. LEXIS 109526, at *11–12 (S.D. Miss. June 29, 2018).

38. *Nichols v. Reliance Std. Life Ins. Co.*, 924 F.3d 802, 810 (5th Cir. 2019).

39. *Id.* at 812.

40. *See, e.g., House v. Am. United Life Ins. Co.*, 499 F.3d 443, 456 (5th Cir. 2007) (Dennis, J., dissenting); *Osborne v. Hartford Life & Accident Ins. Co.*, 465 F.3d 296, 301 (6th Cir. 2006) (Cole, J., dissenting).

41. *House*, 499 F.3d at 462.

42. *Id.* at 462.

43. *Compare Nichols*, 924 F.3d at 806 n.2 (policy stated "regular occupation" determined in reference to how "it is normally performed in the national economy, and not the unique duties performed for a specific employer or in a specific locale") with *Kinsler*, 181 F.3d at 246 (policy did not state how "regular occupation" would be interpreted).

44. *Nichols*, 924 F.3d at 806 n.2.

both identifying the correct title and then, in turn, identifying the tasks and conditions necessary to do that job. For example, though Nichols' insurance policy allowed her insurer to define her "regular occupation" with reference to the national economy, Reliance defined the wrong occupation. It classified Nichols as a "sanitarian (*any industry*)."

Had Reliance looked at how *poultry* processors operate in the national economy, it would have determined cold exposure was, in fact, a necessary condition of Nichols' work.

C. As a Result of the Split, Outcomes for Workers with Identical Jobs, Disabilities, and Insurance Policies Vary.

Judicial disagreement about the meaning of "own occupation" and "regular occupation" has led to an intolerable difference in outcomes for disabled workers. Insurers routinely define claimants' regular occupations at a high level of generality, which allows them to deny benefits to people who are, in fact, disabled from doing their real-world jobs.⁴⁵ Though some courts reject insurers' interpretations of "regular occupation," others blindly accept them.

This practice can lead to disparate outcomes for workers with identical cases. Consider two large-animal veterinarians, each of whom has "regular occupation" disability insurance. Both suffer an injury that prevents them from the heavy lifting necessary to care for large animals. Insurers deny both veterinarians' disability claims because, though they can no longer work with large animals, they can do the work of a general veterinarian.⁴⁶ On appeals to the Second and Fifth Circuits, for example, the Fifth would uphold the insurer's determination denying benefits, but the Second would find the veterinarian must be classified as a *large-animal* vet and reverse. The circuit split means workers with identical jobs, identical disabilities, and identical policies do not experience identical protections nationwide. This disparity is especially problematic under ERISA, which is meant to standardize the provision of employment benefits to U.S. workers.

The veterinarian hypothetical closely resembles two actual cases involving lawyers. A trial lawyer and an environmental lawyer were disabled from working in their respective specialties.⁴⁷ The Fifth Circuit denied the trial attorney benefits,

45. See, e.g., *Darvell v. Life Ins. Co. of N. Am.*, 597 F.3d 929, 934 (8th Cir. 2010) (insurer defined a door-to-door salesman as a sedentary "account executive" and denied benefits); *Lasser v. Reliance Std. Life Ins. Co.*, 344 F.3d 381, 386 (3d Cir. 2003) (insurer defined an orthopedic surgeon responsible for emergency surgery as a general surgeon and denied benefits); *Kinstler*, 181 F.3d at 247 (insurer defined a nurse as "director, nursing service" even though she had direct patient care duties and denied benefits).

46. See *DICTIONARY OF OCCUPATIONAL TITLES* § 073.061-010 (4th ed. 1991) (defining veterinarian without reference to animal size).

47. Compare *House*, 499 F.3d at 447, with *Doe v. Std. Ins. Co.*, 852 F.3d 118, 121 (1st Cir. 2017).

holding the “distinction between ‘trial lawyer’ and ‘lawyer’ [is] too fine under a common sense interpretation of ‘regular occupation.’”⁴⁸ The First Circuit, however, found it unreasonable to use the generic description of “lawyer,” “rather than a job description that fully . . . encompassed the material duties of [the lawyer’s] specialized area of legal practice”⁴⁹ and awarded the environmental lawyer benefits. This judicial inconsistency results in different outcomes for similarly situated workers.

III. “REGULAR OCCUPATION” MUST BE DEFINED WITH REFERENCE TO A CLAIMANT’S ACTUAL JOB REQUIREMENTS.

There are two main problems with defining “regular occupation” without reference to the specific requirements of a person’s job. First, the main text on which insurers and courts rely when defining a worker’s “regular occupation” is deeply flawed. The DOT should not be used in benefit determinations. Its shortcomings are (at least) threefold: the DOT was not designed for use in disability determinations, it is based on flawed data, and it is obsolete. Blind reliance on the DOT distorts benefit determinations and makes it more likely a worker will be erroneously denied benefits.

Second, these inaccurate determinations jeopardize the welfare of millions of Americans and make it harder to recover after disability-related job loss. Conversely, accurate determinations—those based on job definitions that capture all of a worker’s duties—provide workers with much-needed financial support and, in turn, encourage long-term economic stability.

Legal intervention is necessary to remedy these problems. The insurers who draft and administer the policies at issue have an inherent conflict of interest: they have a fiduciary duty both to the beneficiaries of their plans and to their shareholders. Yet insurers consistently prioritize shareholders over workers by defining “regular occupation” broadly and denying otherwise viable claims. When courts allow insurers to define “regular occupation” generically, they tacitly endorse insurers’ refusal to balance these competing interests in good faith.

A. The Dictionary of Occupational Titles Distorts the Adjudication of ERISA Disability Benefit Cases.

As noted, some circuits rely on a single definition in the DOT to define a worker’s occupation.⁵⁰ But the definitions do not accurately describe workers’ jobs, so use of the book unfairly distorts benefits determinations. As we now

48. *House*, 499 F.3d at 453.

49. *Doe*, 852 F.3d at 123–24.

50. *Nichols v. Reliance Std. Life Ins., Co.*, 924 F.3d 802, 811–12 (5th Cir. 2019).

explain, insurers' use and lower courts' acceptance of the DOT is misplaced for three reasons: The DOT was never intended for use in disability determinations, it is based on bad data, and it is outdated.

1. The DOT was Not Designed for Disability Determinations.

The DOT was designed to help place people in jobs, not for use in deciding whether someone is disabled. The DOT catalogs information about more than 12,000 occupations.⁵¹ Each entry includes a job title and a non-comprehensive list of duties performed by individuals in that type of job.⁵²

Until 1991, the DOT was used by employment counselors at the U.S. Department of Labor to match applicants with job openings.⁵³ Other government agencies, like the Veteran's Administration, also used the DOT to place workers in jobs.⁵⁴

The DOT itself recognizes it is not designed for use in benefit determinations. Its introduction directs users to "supplement [the] data with local information detailing jobs within their community."⁵⁵ The DOT acknowledges that its definitions "reflect[] jobs as they have been found to occur, but they may not coincide in every respect with the content of jobs as performed in particular establishments or at certain localities."⁵⁶

The Social Security Administration (SSA), which adjudicates thousands of disability benefit claims each year, has come to realize that the DOT is not appropriate for use in disability determinations. Though the SSA uses the DOT as an aid in its determinations, the agency cautions that a "job title is never sufficient to identify [a person's] occupation."⁵⁷ Instead, jobs are classified by "the title of the job as given by the claimant; possible alternative wording for the title; *major tasks in the job; and the industry of the job.*"⁵⁸

Although the SSA and some courts⁵⁹ recognize that "occupation" must be defined in terms of a worker's actual job duties (not with single-minded obedience to the DOT), private insurers continue to use the DOT to define "occupation" in

51. WORK, JOBS, AND OCCUPATIONS: A CRITICAL REVIEW OF THE DICTIONARY OF OCCUPATIONAL TITLES I, 4 (Ann R. Miller et al. eds., 1980) [hereinafter WORK, JOBS, AND OCCUPATIONS].

52. *Id.* at 4–5.

53. *Id.* at 5.

54. *Id.* at 45, 258.

55. DICTIONARY OF OCCUPATIONAL TITLES vii (4th ed. 1991).

56. *Id.*

57. Soc. Sec. Admin., Past Relevant Work – The Particular Job or the Occupation as Generally Performed, SSR 82-61 (2017), <https://secure.ssa.gov/poms.nsf/lnx/0425005025> [<https://perma.cc/F3LW-9FZM>].

58. *Id.* (emphasis added).

59. *See, e.g., Lasser v. Reliance Std. Life Ins. Co.*, 344 F.3d 381, 387 n.5 (3d Cir. 2003).

general terms, harming disabled workers.

2. *The DOT is Based on Flawed Data.*

The data underlying the DOT's job definitions are flawed, so many of its job descriptions are inaccurate.⁶⁰ The data used to compile the DOT's job descriptions was primarily collected by field branches of the Department of Labor, which were staffed with employees from local state agencies.⁶¹ This decentralized staffing caused data collection problems because the national office lacked effective control over the field offices and could not standardize the process.⁶² For example, individual instructions from the national office on how to observe jobs "appear to have been insufficient and inadequate" as "[m]ajor steps in the job analysis process did not have sufficient guidance."⁶³

Though insurers use the DOT as evidence of how jobs are performed nationwide, jobs were frequently observed in only one market, raising questions about whether industries or jobs were adequately researched.⁶⁴ Some states limited researchers' ability to travel outside of the state to observe jobs.⁶⁵ Definitions based on limited observations do not represent the universal conditions of doing a job (to the extent universal conditions exist in any job). All of these problems suggest the DOT's job descriptions do not reflect actual job duties and conditions in the real world.

Problems with the DOT's data go beyond its collection. When drafting the DOT, "definitions were written especially hurriedly, with the likely result that source data [was] not fully explored."⁶⁶ When updating the DOT for its fourth printing, significant time "was spent trying to verify or update third edition occupations." As a result, data collection may not have "adequate[ly] cover[ed] . . . newly emerging industries and occupations."⁶⁷ These problems, too, undermine the DOT's accuracy.

3. *The DOT is Obsolete.*

The DOT is badly out of date, yet insurers continue to rely on it, and some courts blindly accept its use. The DOT has not been updated since 1991 and is no

60. WORK, JOBS, AND OCCUPATIONS, *supra* note 51, at 316.

61. *Id.* at 100–01.

62. *Id.* at 101.

63. *Id.* at 145.

64. *Id.* at 116, 147.

65. *Id.* at 113, 119.

66. *Id.* at 146.

67. *Id.*

longer published.⁶⁸ To make matters worse, more than a tenth of the job descriptions in the 1991 edition were not based on new data.⁶⁹ Instead, the definitions were carried over from the previous edition, for which data was collected in 1965.⁷⁰ These carry-over job descriptions are now fifty-five years old.

As noted, the SSA takes into account a claimant's actual job duties when using the DOT in disability determinations. The SSA recognizes the DOT is outdated because "[a] gradual change occurs in most jobs so that after 15 years it is no longer realistic to expect that skills and abilities acquired in a job . . . continue to apply."⁷¹ The SSA has thus recognized the need to replace the DOT with a new system "to make accurate [benefit] decisions."⁷²

Because the DOT is a snapshot in time—from 1991 at best—it will only become less and less relevant and cannot evolve alongside industry. Though jobs may not disappear completely, the tasks required to perform them may become automated. Thus, though "working with robots, rather than being replaced by them, is likely to become the norm," the DOT's manufacturing titles will never be updated to reflect the need to supervise automated manufacturing.⁷³

The DOT's obsolescence is particularly evident in jobs that have changed in light of the internet. For example, the DOT definition of news editor refers only to print duties, though many news sites are now exclusively online.⁷⁴

B. Defining Occupations in General Terms Unfairly Jeopardizes Americans' Access to Disability Insurance Benefits.

1. Millions of Americans are Covered by Long-Term Disability Insurance Policies that Contain the "Regular Occupation" Language whose Meaning Underlies the Circuit Split.

One in four Americans become disabled from doing their job before age sixty-five.⁷⁵ To protect against disability-related job loss, about ninety million

68. *Browning v. Colvin*, 766 F.3d 702, 709 (7th Cir. 2014).

69. WORK, JOBS, AND OCCUPATIONS, *supra* note 51, at 156.

70. *Id.*

71. 20 C.F.R. § 404.1565 (2012).

72. *The Need for Occupational Information*, Soc. Sec. Admin., https://www.ssa.gov/disabilityresearch/occupational_info_systems.html [https://perma.cc/F3LW-9FZM] (last visited Sept. 12, 2019).

73. See Jamie Condliffe, *The Week in Tech: Some Workers Hate Robots. Retraining May Change That*, N.Y. TIMES (July 19, 2019), <https://www.nytimes.com/2019/07/19/technology/amazon-automation-labor.html> [https://perma.cc/R6MW-RUST].

74. See *Popovich v. Met Life Ins. Co.*, 281 F. Supp. 3d 993, 1007–08 (C.D. Cal. 2017); DICTIONARY OF OCCUPATIONAL TITLES, § 132.067-026 (4th ed. 1991).

75. COUNCIL FOR DISABILITY AWARENESS, THE CRISIS OF DISABILITY COVERAGE IN AMERICA 3 (2018), http://disabilitycanhappen.org/public_html/wp-content/uploads/2018/04/The-CDA-RealityCheckup-Media-Kit.pdf [https://perma.cc/G4B8-XU8M].

Americans pay for long-term disability insurance.⁷⁶ These policies are typically purchased by workers through their employers' benefit plans and are governed by ERISA.⁷⁷ Overall, forty-one percent of employers offer long-term disability insurance as part of their employee benefits packages; the proportion of large employers that offer it is much higher.⁷⁸

Many of these policies contain the "own occupation" or "regular occupation" language at issue in the circuit split. For example, the nation's largest private-sector employer, Walmart, offers long-term "own occupation" disability insurance to its 2.2 million employees.⁷⁹

Workers cannot avoid unfair benefit determinations under a "regular occupation" policy by shopping for a different policy with different language. Insurance markets are typically controlled by just a few providers; consumers generally have little choice and are subject to whatever policies those insurers offer. For example, employers purchase insurance plans for their employees through large-group insurance markets. In forty-three states, at least eighty percent of the large-group insurance market is controlled by just three insurers.⁸⁰ In at least twenty-six states, three insurers control ninety percent of the large-group insurance market.⁸¹ Options for people seeking disability insurance in the individual market—that is, not through their employers—are similarly limited. In thirty-four states, a maximum of three insurers offer individual long-term disability policies.⁸² In ten states, only one insurer offers individual coverage.⁸³

As a practical matter, then, a consumer cannot choose to purchase insurance from an insurer that is willing to pay disability benefits for a "regular occupation" disability claim in light of the worker's actual job duties and conditions. Such a provider may not exist. Instead, a worker is likely stuck with insurers who define "regular occupation" in general terms, which leads to unjust benefit denials. If a

76. See Fred Schott, *How Many Working Americans Have Adequate Disability Coverage?*, COUNCIL FOR DISABILITY AWARENESS (Apr. 26, 2018), <https://blog.disabilitycanhappen.org/how-many-americans-have-disability-coverage/> [<https://perma.cc/6ZSF-KEK5>].

77. *Id.*

78. See Michelle Andrews, *Why a Long-Term Disability Policy is More Important than Pet Insurance*, NPR (Oct. 11, 2017), <https://www.npr.org/sections/health-shots/2017/10/11/556946744/why-a-long-term-disability-policy-is-more-important-than-pet-insurance> [<https://perma.cc/8V2T-KB5X>].

79. *Fortune* 500, FORTUNE.COM, <https://fortune.com/fortune500/2019/search/?employees=desc> (last visited Sept. 20, 2019); Long-Term Disability, https://one.walmart.com/content/usone/en_us/me/time/disability/long-term-disability.html [<https://perma.cc/Q4T7-QTTL>] (last visited Sept. 20, 2019).

80. U.S. GOV'T ACCOUNTABILITY OFFICE, PRIVATE HEALTH INSURANCE, ENROLLMENT REMAINS CONCENTRATED AMONG FEW ISSUERS, INCLUDING IN EXCHANGES 67–68 (2019), <https://www.gao.gov/assets/700/697746.pdf> [<https://perma.cc/NS68-NAPD>].

81. *Id.*

82. *Id.* at 54–55.

83. *Id.* at 54–55.

worker is one of the relatively few who has the resources and wherewithal to appeal an unjust benefit determination, the worker must live in a circuit that defines “regular occupation” in terms of workers’ actual job requirements to have any hope of obtaining benefits.

2. Defining Occupations in General Terms is Contrary to ERISA’s Goals and Flouts the purpose of Long-term Disability Insurance.

Defining workers’ jobs at a high level of generality, regardless of actual job duties and conditions, runs afoul of two of ERISA’s main goals: protecting workers and establishing uniformity.

Congress enacted ERISA “to promote the interests of employees and their beneficiaries in employee benefit plans.”⁸⁴ Defining occupations at their highest level of generality does not protect workers’ interests. Just the opposite: The practice makes it easier to deny claims and robs workers of needed benefits for which they pay a premium.

ERISA also seeks to establish a uniform administrative scheme “to guide processing of claims and disbursement of benefits.”⁸⁵ The circuit split undermines uniformity. For example, as already explained, the Fifth Circuit allows insurers to interpret “regular occupation” generically and categorize workers according to DOT entries, but in the Second and Third Circuits, that approach is considered unreasonable. There, insurers must define “regular occupation” in terms more closely tied to a worker’s actual job responsibilities and conditions. This variation is a far cry from the “uniform administrative scheme” ERISA envisions.⁸⁶

When courts define “regular occupation” and “own occupation” in general terms, they undercut the role of long-term disability insurance in rehabilitation and retraining. Despite its name, “long-term” disability insurance is designed to be temporary; it provides financial support between job loss and new work. Many policies provide benefits for only two to five years.⁸⁷ Workers rarely need longer. The average claim lasts just over two and a half years.⁸⁸

The expectation is that while receiving benefit payments “the insured will

84. *Shaw v. Delta Air Lines*, 463 U.S. 85, 90 (1983).

85. *See Egelhoff v. Egelhoff*, 523 U.S. 141, 148 (2001).

86. *See id.*

87. *See, e.g., Long Term Disability Insurance*, METLIFE, <https://www.metlife.com/insurance/disability-insurance/long-term/> [<https://perma.cc/3AVX-6PHR>] (last visited Oct. 17, 2019). For example, the nation’s second-largest private-sector employer, Amazon, caps long-term disability coverage at two years. *See, e.g., Bigham v. Liberty Life Assurance Co.*, 148 F. Supp. 3d 1159, 1163 (W.D. Wash. 2015).

88. COUNCIL FOR DISABILITY AWARENESS, *The Average Duration of Long-Term Disability is 31.2 Months. Are You Prepared?* (Jan. 18, 2016), <https://blog.disabilitycanhappen.org/the-average-duration-of-long-term-disability-is-31-2-months/> [<https://perma.cc/F5FJ-BKXY>].

[make] the necessary adjustment to another line of work” or will qualify for continuing benefits under a general disability policy due to the severity of their impairment.⁸⁹ When courts generalize claimants’ job descriptions, they rob workers of much-needed financial assistance, making it harder to pursue training and pivot to a new line of work.

C. Accurate Benefit Determinations Prevent Harm to Workers and Bolster Long-Term Economic Stability.

1. Disabled Workers who are Denied Benefits Face Drastic Financial and Health Consequences.

When courts allow insurers to deny benefits arbitrarily, they sow chaos instead of providing financial stability. More than half of Americans struggle to make ends meet in the wake of economic shocks like job loss.⁹⁰ This is unsurprising given that almost half of Americans do not have enough savings to cover three months of living expenses.⁹¹ A 2014 study of consumer bankruptcy filings found job loss and medical bills are the two most common reasons consumer debtors file for bankruptcy.⁹² Disabled workers who are denied benefits face both.

The stakes associated with benefit denials are higher than financial instability alone. A 2015 survey conducted by the American Psychological Association (APA) found money to be the country’s number one stressor, with nearly a quarter of adults rating their money-related stress as “extreme.”⁹³ Financial uncertainty is correlated with depression, anxiety, and myriad other health concerns.⁹⁴

Individuals low on funds are also less likely to go to the doctor, which exacerbates or prolongs workers’ disabling conditions. Twenty-one percent of APA survey respondents said their budgets were so tight they considered foregoing

89. See *McFarland v. Gen. Am. Life Ins. Co.*, 149 F.3d 583, 587 (7th Cir. 1993).

90. PEW CHARITABLE TRUST, *THE ROLE OF EMERGENCY SAVINGS IN FAMILY FINANCIAL SECURITY: HOW DO FAMILIES COPE WITH FINANCIAL SHOCKS?* 2 (2015), https://www.pewtrusts.org/~media/assets/2015/10/emergency-savings-report-1_artfinal.pdf [<https://perma.cc/9YPC-X2XT>].

91. *Chances of Disability: Me, Disabled?*, COUNCIL FOR DISABILITY AWARENESS, <https://disabilitycanhappen.org/disability-statistic/> [<https://perma.cc/M7N2-DX7X>] (last visited Nov. 21, 2019).

92. Daniel A. Austin, *Medical Debt as a Cause of Consumer Bankruptcy*, 67 ME. L. REV. 1, 21 (2014).

93. AM. PSYCHOLOGICAL ASS’N, *STRESS IN AMERICA: PAYING WITH OUR HEALTH* 2 (Feb. 4, 2015), <https://www.apa.org/news/press/releases/stress/2014/stress-report.pdf> [<https://perma.cc/FEH7-8RBX>].

94. See Neal Gabler, *The Secret Shame of Middle-Class Americans*, THE ATLANTIC (May 2016), <https://www.theatlantic.com/magazine/archive/2016/05/my-secret-shame/476415/> [<https://perma.cc/BZ2X-TPSU>].

or did forego a doctor's visit in the last year.⁹⁵ For unemployed people with disabilities, the choice between saving money and seeing a doctor may be especially fraught.

Without access to benefits, disabled workers must find alternative sources of income. Ideally, they will retrain and reenter the workforce in jobs that provide pay comparable to their prior positions. Without the financial stability provided by long-term disability benefits, workers may be forced to seek new jobs—lower-paying, less-skilled jobs—because they need immediate income.⁹⁶ These lower-paying jobs consume time and energy a worker might otherwise devote to retraining. When workers are forced to take a job just to make ends meet, it becomes even less likely they will successfully recover from disability-related job loss.⁹⁷

Unfairly denying benefits negatively affects the broader economy, too. When workers lose their jobs and lack sufficient savings, they suddenly need to cut back on spending, which removes money from the economy.⁹⁸

2. Defining Jobs Accurately Makes it Easier for Workers to Successfully Retrain and Go Back to Work.

Workers are more likely to qualify for disability benefits when courts define their occupation consistently with the job's actual requirements. Disability insurance benefits typically provide approximately sixty percent of a worker's salary.⁹⁹ Though not sufficient to completely replace one's regular pay, the limited financial stability provided by disability benefits allows workers to pursue retraining.¹⁰⁰ Retraining is critical to successfully bridging the gap between former and new employment. Data show early interventions, like the awarding of benefits

95. AM. PSYCHOLOGICAL ASS'N, *supra* note 93, at 3.

96. See Jack Kelly, *The Frightening Rise in Low-Quality, Low-Paying Jobs: Is This Really a Strong Market*, FORBES (Nov. 25, 2019), <https://www.forbes.com/sites/jackkelly/2019/11/25/the-frightening-rise-in-low-quality-low-paying-jobs-is-this-really-a-strong-job-market/#3784e8cd4fd1> [<https://perma.cc/G5MQ-9G29>] (noting job seekers spend “an exceedingly long period of time searching for a suitable job [and receive] lackluster salary offers”).

97. See GOSTA ESPING-ANDERSEN ET AL., WHY WE NEED A NEW WELFARE STATE 111–12 (2002) (“Once people have entered low-skilled jobs they find far fewer opportunities for upgrading their skills than are available to people in more skilled work. As a result, over time, they are likely to suffer an accumulating skill deficit.”).

98. See Allison Schrager & Quartz, *The Growing Ranks of America's High-Earning Poor*, THE ATLANTIC (Nov. 3, 2015), <https://www.theatlantic.com/business/archive/2015/11/income-rich-asset-poor/413977/> [<https://perma.cc/CV4Q-W9ZP>].

99. Kristen Monaco, *Disability insurance plans: trends in employee access and employer costs*, U.S. BUREAU OF LABOR STATISTICS (Feb. 2015), <https://www.bls.gov/opub/btn/volume-4/disability-insurance-plans.htm> [<https://perma.cc/QX6X-CM76>].

100. See *McFarland v. Gen. Am. Life Ins. Co.*, 149 F.3d 583, 587 (7th Cir. 1993) (“[T]he insured will [make] the necessary adjustment to another line of work” while receiving benefit payments).

shortly after job loss, “may reduce the rate at which work limitations become career ending-disabilities.”¹⁰¹

The earlier a worker starts retraining, the better. As a practical matter, this usually means starting to retrain just after job loss, though workers benefit most when they begin retraining even before they have left their prior positions.¹⁰² Even if overlap is impossible, quickly transitioning to a new job still matters. When people enroll in retraining programs within nine days of applying for unemployment benefits, they “end[] up working significantly more weeks, and earn[] more than workers who entered training a year or more after the job loss.”¹⁰³ Conversely, when there is delay in retraining of even one year, workers’ chances of finding new careers are often permanently hindered and their lifelong earnings limited.¹⁰⁴

Long-term disability insurance thus plays a critical role in helping workers transition to new work after job loss. When courts construe the terms “regular occupation” and “own occupation” generally, workers who are disabled from doing the only jobs their training and experience enable them to perform are denied benefits. These unjust denials stymie workers’ ability to pursue retraining and get back to work. Defining a worker’s “regular occupation” in terms of their actual job requirements and conditions, on the other hand, ensures that deserving workers are able to pursue new work without crushing financial stress.

D. Insurers Have Little Incentive to Make Accurate Benefit Determinations.

Insurers have little incentive to accurately define “regular occupation.” As discussed above, they have conflicting fiduciary duties: under ERISA, insurers owe a fiduciary duty to beneficiaries when administering plans,¹⁰⁵ but, as a

101. David Autor, Mark Duggan & Jonathan Gruber, *Moral Hazard and Claims Deterrence in Private Disability Insurance*, 6 AM. ECON. J.: APPLIED ECON. 110, 111 n.1 (2014).

102. Jeffrey Selingo, *The False Promise of Worker Retraining*, THE ATLANTIC (Jan. 8, 2018), <https://www.theatlantic.com/education/archive/2018/01/the-false-promises-of-worker-retraining/549398/> [<https://perma.cc/4KZF-AXPZ>]. There are a variety of factors other than timeliness of benefits that affect access to retraining and can temper its efficacy. *See generally id.* (explaining barriers to retraining). Addressing those challenges is beyond the scope of this Note (though the authors want to emphasize it is critically important to address the shortcomings of job retraining programs, particularly given that more than 120 million workers in the world’s twelve largest economies may need retraining in the next three years alone as a result of automation. *See* ANNETTE LAPRADE ET AL., THE ENTERPRISE GUIDE TO CLOSING THE SKILLS GAP 2 (2019)). Though early retraining does not guarantee a successful career pivot, the fact remains the earlier workers receive benefits, the earlier they are likely to retrain and, thus, the likelier that retraining is to be successful.

103. Selingo, *supra* note 102.

104. *Id.*; *see also* Autor, Duggan & Gruber, *supra* note 101, at 111 n.1.

105. 29 U.S.C. § 1102(a)(1) (giving a fiduciary “authority to control and manage the operation and administration of [a] plan.”); 29 U.S.C. § 1133(2) (requiring a fiduciary to provide a “full and

corporation, they also owe a fiduciary duty to their shareholders to maximize profits.¹⁰⁶ An insurer is simultaneously “responsible for administering [benefit] plan[s] so that those who deserve benefits receive them” and has a duty “to pay as little in benefits as possible to plan participants because the less money the insurer pays out, the more money it retains in its own coffers.”¹⁰⁷

Many insurance companies, including some of the largest in the world, have engaged in discriminatory denial of disability benefits.¹⁰⁸ Unum, the largest American insurer specializing in disability insurance, recently engaged in a deliberate program to deny meritorious benefit claims in bad faith.¹⁰⁹ At the end of each quarter, Unum required its claims managers to deny enough claims to meet financial goals, regardless of the merits of the claim.¹¹⁰ Fraudulent denials disproportionately affected benefit determinations of “so-called subjective illnesses,” the type typically hardest to prove, such as “chronic pain, migraines, or even Parkinson’s.”¹¹¹ Numerous “scathing” opinions have similarly decried the practices of Reliance, a common litigant in these types of cases.¹¹² One court went so far as to catalog all the opinions in which courts rejected Reliance’s benefit determinations,¹¹³ noting, “[t]hese opinions reveal that Reliance takes a range of extraordinary steps to deny claims for disability benefits.”¹¹⁴

This comes as no surprise. Insurers benefit when “regular occupation” is defined in general terms. ERISA provides a private right of action to recover benefits due under a worker’s plan and a mechanism to enforce rights under the terms of a plan.¹¹⁵ ERISA does not, however, set out the standard of review for

fair review” of the denial of benefits claimed under a plan); *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 109 (1989) (“ERISA . . . imposes a duty of loyalty on fiduciaries and plan administrators”).

106. *See, e.g., Abatie v. Alta Health Ins.*, 458 F.3d 955, 966 (9th Cir. 2006).

107. *Id.*

108. *See, e.g., John H. Langbein, Trust Law as Regulatory law: The Unum/Provident Scandal and Judicial Review of Benefit Denials Under ERISA*, 101 NW. U. L. REV. 1315, 1316–18 (detailing the systematic denial of ERISA administered disability benefits by Unum, one of the largest insurers).

109. *Id.*

110. *Id.* at 1318–19.

111. *Id.* at 1319.

112. *See Hoff v. Reliance Std. Life Ins. Co.*, 160 F. App’x 652, 654 (9th Cir. 2005) (holding that Reliance had “an illogical interpretation of [the claimant’s] policy and a corresponding failure to investigate the facts.”); *see also Lasser v. Reliance Std. Life Ins. Co.*, 146 F. Supp. 2d 619, 641 (admonishing Reliance for “a level of care which . . . cannot be squared with the sensitive inquiry these important [] cases require.”); *McDevitt v. Reliance Std. Life Ins. Co.*, 663 F. Supp. 2d 419, 423 (D. Md. 2009) (calling Reliance “blind or indifferent” to “the ultimate purpose of insurance . . . [which] is not to erect administrative barriers, increase transaction costs, or delay the payment of legitimate claims.”).

113. *Nichols v. Reliance Std. Life Ins. Co.*, 2018 U.S. Dist. LEXIS 109526 at *15 n.79 (S.D. Miss. June 29, 2018).

114. *Id.* at *18.

115. 28 U.S.C. § 1132(a)(1)(B); *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 108

these actions.¹¹⁶ The Supreme Court has held “a denial of benefits challenged under [ERISA] is to be reviewed under a *de novo* standard unless the benefit plan gives the administrator . . . discretionary authority to determine eligibility for benefits or to construe the terms of the plan.”¹¹⁷ Where the administrator retains authority to construe terms of the plan or determine benefits, as insurer-administrators often do, determinations are subject to an arbitrary and capricious standard of review.¹¹⁸ Thus, insurers who make eligibility determinations likely receive a highly deferential standard of review in court. As a result, workers are unlikely to receive benefits because many courts blindly accept the DOT as reasonable evidence of a claimant’s job simply because insurers assert it is.¹¹⁹ Indeed, plan administrator’s ability to “impose self-serving terms that severely restrict the ability of a reviewing court to correct a wrongful benefit denial” was part of the reason *Unum* was able to deny meritorious claims.¹²⁰

Moreover, traditional contract interpretation principles do not help workers in these cases. The contract may not be construed against the drafter-insurer where the insurer retains the ability to interpret “ambiguous” terms of the plan.¹²¹ When

(1989).

116. *Firestone Tire & Rubber Co.*, 489 U.S. at 109.

117. *Id.* at 115.

118. *Id.* at 109–10.

119. *See, e.g., Darvell v. Life Ins. Co. of N. Am.*, 597 F.3d 929, 934 (8th Cir. 2010) (insurer defined a door-to-door salesman as a sedentary “account executive” and denied benefits); *Lasser v. Reliance Std. Life Ins. Co.*, 344 F.3d 381, 386 (3d Cir. 2003) (insurer defined an orthopedic surgeon responsible for emergency surgery as a general surgeon and denied benefits); *Kinstler v. First Reliance Std. Life Ins. Co.*, 181 F.3d 243, 247 (2d Cir. 1999) (insurer defined a nurse as “director, nursing service” even though she had direct patient care duties and denied benefits).

120. *See Langbein, supra* note 108, at 1316.

121. *Fleisher v. Standard Ins. Co.*, 679 F.3d 116, 124 (3d Cir. 2012) (“Notably, every Court of Appeals to have addressed the issue has concluded that a court reviewing a benefits decision for abuse of discretion cannot apply the principle that ambiguous plan terms are construed against the party that drafted the plan.”); *Marrs v. Motorola, Inc.*, 577 F.3d 783, 787 (7th Cir. 2009) (“[A]lthough, generally, ambiguities in an insurance policy are construed in favor of an insured, in the ERISA context in which a plan administrator has been empowered to interpret the terms of the plan, this rule does not obtain.”) (internal citation and quotation marks omitted); *D & H Therapy Assocs., LLC v. Boston Mut. Life Ins. Co.*, 640 F.3d 27, 35 (1st Cir. 2011) (“We have also noted that the doctrine of *contra proferentem* does not apply to review of an ERISA plan construction advanced by an administrator given authority to construe the plan.”) (internal citations omitted); *Carden v. Aetna Life Ins. Co.*, 559 F.3d 256, 260 (4th Cir. 2009) (holding that under circuit case law the court may not “curb the discretion given an administrator by a plan[.]”); *White v. Coca-Cola Co.*, 542 F.3d 848, 857 (11th Cir. 2008) (stating that “[w]e have rejected *contra proferentem* in ERISA appeals” because “arbitrary and capricious standard of review would have little meaning if ambiguous language in an ERISA plan were construed against the plan administrator.”) (internal citations and quotations omitted); *Lennon v. Metro. Life Ins. Co.*, 504 F.3d 617, 627 n.2 (6th Cir. 2007) (“Were this Court tasked with interpreting the language *de novo*, in view of the word’s apparent ambiguity, the rule of *contra proferentem* would apply.”); *Kimber v. Thiokol Corp.*, 196 F.3d 1092, 1100 (10th Cir. 1999) (“We now hold that when a plan administrator has discretion to interpret the plan and the

courts allow “regular occupation” to be defined generically, insurers can manipulate benefit determinations in whichever way they see fit. In short, when courts allow insurers to define “regular occupation” with reference to a single DOT title, they become complicit in insurance companies’ manipulation of the system and abdicate their role as a check on company power in consumer relationships.

E. The Benefits of Defining “Regular Occupation” with Specificity Outweigh the Potential Costs.

Though defining “regular occupation” narrowly will afford more workers better insurance coverage when they most need it, expanding benefits in this way has costs. For example, increasing the specificity with which insurers define “regular occupation” may lead to more frequent payouts under the policies at issue. This increase in payouts may, in turn, result in increased premiums. Defining “regular occupation” narrowly may render these policies too expensive for lower-income workers.

One possible solution: employers could subsidize any increase in rates. The benefits of shouldering this financial burden outweigh the costs. Companies often use strong(er) disability protection as an attractive benefit to entice employees, and insurers often market it as such.¹²² Moreover, high-quality “regular occupation” insurance facilitates early intervention when tragedy strikes.¹²³ This early intervention in turn facilitates employees’ returns to the workforce and decreases dependence on other benefit programs like social security disability insurance.¹²⁴

This cost-benefit analysis plays out the same way when conducted at the individual, corporate, and societal levels. The good that flows from defining

standard of review is arbitrary and capricious, the doctrine of *contra proferentem* is inapplicable.”); *Winters v. Costco Wholesale Corp.*, 49 F.3d 550, 554 (9th Cir. 1995) (“[T]he Plan here states that the Plan Administrator [has the authority to construe provisions] . . . and the general rule of *contra proferentem* does not apply.”); *Pagan v. NYNEX Pension Plan*, 52 F.3d 438, 443 (2nd Cir. 1995) (“[A]pplication of the rule of *contra proferentem* is limited to those occasions in which this Court reviews an ERISA plan *de novo*.”).

122. *Voluntary Benefits*, RELIANCE STANDARD, <https://www.reliancestandard.com/home/products/voluntary-benefits/> [https://perma.cc/KF3W-8PVQ] (last visited Apr. 28, 2020) (describing voluntary benefits, like long-term disability insurance, as “high quality employee benefits programs [that] help attract and keep valuable employees.”); *Should You Offer Group Disability Insurance to Your Employees?*, THE HARTFORD, <https://www.thehartford.com/business-insurance/strategy/disability-insurance/offer-group-disability-insurance> [https://perma.cc/3GBT-7KKQ] (last visited Apr. 28, 2020) (describing disability benefits as a “valuable addition to [] employee benefits package[s].”).

123. See Priyanka Anand & David Wittenburg, *An Analysis of Private Long-Term Disability Insurance Access, Cost, and Trends*, MONTHLY LAB. REV. (March 2017), <https://www.bls.gov/opub/mlr/2017/article/an-analysis-of-long-term-disability-insurance-access-cost-and-trends.htm> [https://perma.cc/GC5K-5FGF].

124. *Id.*

“regular occupation” with specific reference to a claimant’s actual job duties outweighs any second-order effects such an interpretation may have on the insurance markets.

IV. POSSIBLE SOLUTIONS

A. The Judiciary Should Advance a Uniform Legal Rule.

Distortion in the market precludes the possibility of effective consumer advocacy and disincentivizes insurers from self-regulating. Outside intervention is required to bring administration of long-term disability policies back into alignment with the goals of ERISA. The Second and Third Circuits have already recognized this and implemented legal rules mandating insurers look beyond the DOT and take a claimant’s actual job duties and conditions into account when making benefit determinations.¹²⁵ When the Supreme Court denied certiorari in *Nichols v. Reliance*,¹²⁶ it foreclosed (for now) the possibility of such a judicially-created rule on a national scale.

The onus is now on other circuit courts to recognize the fundamental mismatch between the goals of ERISA and purposes of long-term disability insurance on the one hand, and the way in which insurers currently manipulate disability benefits on the other. Absent intervention from the legal system, workers will continue experiencing unequal levels of protection under identical insurance policies. Courts should require insurers look beyond a single DOT definition when defining workers’ “regular occupation” in disability benefit determinations. Mandating insurers account for workers’ actual job requirements—by looking to an individual’s job description, multiple DOT definitions, or other sources of information outlining the worker’s responsibilities—will ensure workers get the benefit of their bargain, *i.e.*, insurance against loss of *their own, regular occupation*.

Unless and until the circuits align themselves with the approach articulated in the Third and Second Circuits, intolerable differences will remain in how workers are treated state to state. That said, given the intractable nature of debate in the circuits to date, judicial intervention seems to hinge on the Supreme Court granting cert in a future case.

B. Congress Should Legislate a Uniform Rule.

Because the Supreme Court recently denied certiorari in a case presenting the

125. *See, e.g., Kinstler v. First Reliance Std. Life Ins. Co.*, 181 F.3d 243, 253 (2d Cir. 1999).

126. *Nichols v. Reliance Std. Life Ins. Co.*, 140 S. Ct. 186 (2019).

“regular occupation” question,¹²⁷ the legislature now appears best-positioned to take action. Congress should mandate insurers account for actual job responsibilities when administering “regular occupation” disability insurance.

ERISA has been amended a number of times since it was first enacted in 1974.¹²⁸ These amendments seek to control the actions of employers and plan administrators. For example, the Omnibus Budget Reconciliation Act of 1986 prohibited employers from limiting the participation of new employees close to retirement in retirement plans.¹²⁹ The same amendment also prohibited employers from freezing benefits for plan participants over sixty-five years old.¹³⁰ The Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) extended healthcare coverage for employees who had their benefits reduced.¹³¹ The Health Insurance Portability and Accountability Act added additional responsibilities with respect to private health plans, including language dictating how insurers must treat mothers and newborn children.¹³² Amending ERISA to define “regular occupation” fits neatly into this legislative history.

In fact, legislators have recently proposed major changes to ERISA.¹³³ ERISA reform could explicitly endorse the legal rule from the Second and Third Circuits: “regular occupation” must be defined by the work a claimant was doing prior to disability, with reference to the conditions of that work.¹³⁴ There is no doubt that such a rule would be administrable: it has worked for the past three decades in multiple circuits.¹³⁵ Federal legislation controlling “regular occupation” disability insurance would ensure uniformity and fairness in benefit determinations.

To ensure compliance and maximize effect, an ideal legislative solution would address the best practices for making benefit determinations, not just dictate what “regular occupation” means. Insurers should not be able to sidestep their duty to pay benefits owed under “regular occupation” plans simply by using language

127. *Id.*

128. *See, e.g.,* Schmidt v. AK Steel Corp. Pension Agreement Plan, U.S. Dist. LEXIS 144792, at *6 (S.D. Ohio Jan. 14, 2010) (explaining that “[w]hile ERISA has been amended several times since 1974, the cause of action and the right to recover has been an essential part of ERISA from the beginning.”).

129. *History of EBSA and ERISA*, EMPLOYEE BENEFITS SECURITY ADMINISTRATION, <https://www.dol.gov/agencies/ebsa/about-ebsa/about-us/history-of-ebsa-and-erisa> [https://perma.cc/35PT-4WPL] (last visited Nov. 21, 2020).

130. *Id.*

131. *Id.*; *see generally* 29 U.S.C. § 1161 (2012).

132. 29 U.S.C. § 1185 (2012).

133. *See, e.g., Empowering American Workers and Raising Wages*, <https://elizabethwarren.com/plans/empowering-american-workers?source=soc-WB-cw-tw> [https://perma.cc/CMY4-8Y65]. (last visited Nov. 21, 2019).

134. *Lasser v. Reliance Std. Life Ins. Co.*, 344 F.3d 381, 386 (3d Cir. 2003) (citing *Kinstler v. First Reliance Std. Life Ins. Co.*, 181 F.3d 243, 253 (2d Cir. 1999)).

135. *See Kinstler*, 181 F.3d at 243.

other than “regular occupation” in their policies. That is, if the phrase “regular occupation” must be defined with reference to a claimant’s job responsibilities, an insurer should not be permitted to revise its policies and insert different language to escape accountability. A legislative amendment must consider the possibility that insurers will choose to write their contracts without reference to “own” or “regular occupation.” The best amendment to ERISA, then, would require insurers to look at the entirety of a worker’s job responsibilities, with reference to multiple sources, when determining whether a claimant is disabled from doing his or her job under long-term disability insurance policies.

CONCLUSION

There is an intractable circuit split over how to define the terms “regular occupation” and “own occupation” in long-term disability insurance policies. When courts allow insurers to define the terms generically, without reference to a worker’s actual job requirements, they flout the purposes of ERISA and jeopardize the welfare of millions of Americans. The DOT—the book on which courts and insurers rely when making these determinations—is ill-suited to the task. It was not designed for use in disability determinations, is “supported” by bad data, and is obsolete. In short, the current method of defining “regular occupation” in the Fifth, Sixth, and Eighth Circuits results in inconsistent and unjust benefit determinations.

Power imbalance in the insurance market prevents consumers from negotiating contracts that better reflect their needs. Relatedly, market conditions disincentivize insurers from defining “regular occupation” with any level of specificity. As a result, the market does not allow participants to correct the problem themselves. Outside intervention is required to bring administration of long-term disability policies back into alignment with ERISA.

Millions of Americans rely on long-term disability insurance to protect their income in the wake of unimaginable hardship. When insurers and courts refuse to deliver workers the benefit of their bargain, individuals, their families, and the larger economy suffer.

While the Supreme Court recently declined to correct the intolerable difference in law among the circuits, the legislature now has an opportunity to amend ERISA and mandate insurers define “regular occupation” with specificity.