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Health Care Sanctuaries

Medha D. Makhlouf[*]

Abstract:

It is increasingly common for noncitizens living in the United States to avoid seeing a doctor or enrolling in publicly funded health programs because they fear surveillance by immigration authorities. This is the consequence of a decades-long shift in the locus of immigration enforcement activities from the border to the interior, as well as a recent period of heightened immigration enforcement. These fears persist because the law incompletely constrains immigration surveillance in health care.

This Article argues that immigration surveillance in health care is a poor choice of resource allocation for immigration enforcement because it has severe consequences for health and the health care system; additionally, it compromises the legitimacy of the state vis-à-vis its noncitizen residents. The consequences include public health threats, health care system inefficiency, ethical dilemmas, and increased vulnerability in immigrant communities. Laws permitting immigration surveillance in health care also create legitimacy harms by obstructing noncitizens' access to health care and undermining their privacy and rights to public benefits. The COVID-19 pandemic starkly illustrates these dangers, but they exist even in the absence of a novel disease outbreak.

Health care access for noncitizens has largely been left to the vagaries of immigration policy. Immigration surveillance in health care should prompt us to consider the scope and limits of health law and the role of discretion in immigration law. Health care sanctuaries—durable legal protections against immigration surveillance in health care—recover some of the lost equilibrium between immigration enforcement and other goals and values of public policy.

[*] Assistant Professor and Director, Medical-Legal Partnership Clinic, Penn State Dickinson Law; Assistant Professor, Department of Public Health Sciences, Penn State College of Medicine. I am grateful for helpful feedback from Eisha Jain, Ji Seon Song, Sidney Watson, and participants in the Privacy Law Scholars Conference, the AALS Virtual Health Law Workshop, and the *New York University Clinical Law Review* Writers' Workshop. Thank you to Christian Sweger for excellent research assistance. Thank you to my colleagues in the Penn State Dickinson Law Katz Workshop and to my family for their support and encouragement.

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INTRODUCTION

> *Low-income immigrants with a serious medical condition are in an impossible situation. How much do you risk for medical care? Deportation would devastate your family but so would your illness and death.*[1]

A grandfather who visits a hospital emergency room for severe abdominal pain refuses to follow up with a gastroenterologist because he is worried that enrolling in Medicaid will affect his pending immigration application. A mother decides to skip prenatal care for her third pregnancy because she has seen Immigration and Customs Enforcement (ICE) officers in the parking lot of the health clinic. A fast-food worker with COVID-19 symptoms seeks relief from a *curandero* (traditional healer) instead of accessing publicly funded testing and treatment because he believes that the information will be tracked and reported to immigration authorities. These are examples of how fears of immigration surveillance serve as barriers to health care.

This Article focuses on concerns that arise from two modes of immigration surveillance in health care: (1) interrogation, arrest, search, or detention by immigration enforcement officers at health care sites; and (2) use of personal information disclosed for the purpose of obtaining health care to deny immigration benefits or for immigration enforcement purposes. Reluctance to seek health care or coverage because of fear of immigration consequences is a barrier to health care access for noncitizens.[2] Fear discourages noncitizens from seeking care even when they are legally entitled to do so.[3] It influences the care-seeking behaviors both of noncitizens with an array of legal statuses and of their U.S.-citizen family members.

This Article applies the sociological concept of "system avoidance" to avoidance of engagement with the health care system because of immigration-related concerns. System avoidance occurs when "individuals avoid[] institutions that keep formal records . . . and therefore heighten the risk of surveillance and apprehension by authorities."[4] The migration research literature refers to

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1 LISA SUN-HEE PARK, ENTITLED TO NOTHING: THE STRUGGLE FOR IMMIGRANT HEALTH CARE IN THE AGE OF WELFARE REFORM 135 (2011).

2 Karen Hacker et al., *Barriers to Health Care for Undocumented Immigrants: A Literature Review*, 8 RISK MGMT. & HEALTHCARE POL'Y 175, 178 (2015).

3 *Id*. at 180.

4 Sarah Brayne, *Surveillance and System Avoidance: Criminal Justice Contact and Institutional Attachment*, 79 AM. SOCIO. REV. 367, 368 (2014). Brayne first used the term "system avoidance" to describe a behavioral response of individuals who had criminal justice contact and who thereafter limited their interactions with recordkeeping institutions such as schools, banks, and hospitals. *Id*. at 372. This research indicates that people who have had criminal justice contact avoid recordkeeping institutions in order to evade heightened surveillance and, implicitly, further involvement with the

avoidance of surveilling institutions by noncitizens with vulnerable legal statuses as "chilling effects."[5] As immigration enforcement in homes, workplaces, schools, government offices, and the streets has become more commonplace, noncitizens have grown increasingly fearful that routine interactions at everyday places can lead to arrest and deportation. Health care sites are one such place. Health care system avoidance based on fear of immigration surveillance is an example of how the expansion of immigration enforcement in the interior of the United States has discouraged noncitizens from engaging in socially beneficial behavior.

The concept of health care system avoidance has spawned a rich literature about "legally vulnerable populations" that applies in broad contexts,[6] which raises

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criminal justice system. Brayne notes that although it has been suggested that system avoidance may be observed among other disadvantaged groups, such as undocumented immigrants, studies of the phenomenon in noncitizens are few. *Id*. at 387. Since publication of this landmark article, researchers have gathered evidence of system avoidance among noncitizens. *See, e.g.*, Caitlin Patler & Gabriela Gonzalez, *Compounded Vulnerability: The Consequences of Immigration Detention for Institutional Attachment and System Avoidance in Mixed-Immigration-Status Families*, SOC. PROBS., Dec. 2020, at 14 (noting that members of mixed-status families "express concerns that involvement in formal records-keeping institutions will damage the family's uncertain legal future").

5 Patler & Gonzalez, *supra* note 4, at 14 (noting the similarity between the concepts of system avoidance and chilling effects). Studies examining "chilling effects" or similar phenomena among noncitizens span numerous disciplines. Patler and Gonzalez note that in the sociological literature, "[i]t is well known that immigrants with vulnerable legal statuses—especially undocumented immigrants—are wary of surveilling institutions." *Id.* at 2. Asad Asad builds on the sociological literature on system avoidance to introduce the concept of "system embeddedness," observing that some undocumented immigrants avoid opportunities to legalize their immigration status because they believe that remaining illegible to the immigration system is less risky than engaging with it. Asad L. Asad, *On the Radar: System Embeddedness and Latin American Immigrants' Perceived Risk of Deportation*, 54 L. & SOC'Y REV. 133, 161 (2020). Kathleen Page and Sarah Polk offer the medical clinician's perspective, describing the experience of attempting to care for a pregnant noncitizen patient who was diagnosed with syphilis, but who did not pursue treatment because of fear of immigration surveillance at the clinic. Kathleen R. Page & Sarah Polk, *Chilling Effect? Post-Election Health Care Use by Undocumented and Mixed-Status Families*, 376 NEW ENG. J. MED. e20(1), e20(1) (2017). From a health policy perspective, Dhruv Khullar and Dave Chokshi observe that "aggressive immigration law enforcement" can cause chilling effects for noncitizens and their family members that persist even when a less aggressive enforcement regime is implemented. Dhruv Khullar & Dave A. Chokshi, *Challenges for Immigrant Health in the USA—The Road to Crisis*, 393 LANCET 2168, 2170 (2019). They also note the uptick in reports of ICE arrests at hospitals since 2017. *Id*. The link between immigration policies and chilling effects on public benefits access have been considered in the legal literature as well. *See, e.g.*, David A. Super, *The Future of U.S. Immigration Law*, 53 U.C. DAVIS L. REV. 509, 555-57 (2019). Asad highlights the need for further research on whether noncitizens' involvement with the health care system and public benefits agencies influences their perceptions of risk of deportability. Asad, *supra*, at 161.

6 Patler & Gonzalez, *supra* note 4, at 14. *See, e.g*., ALICE GOFFMAN, ON THE RUN: FUGITIVE LIFE IN AN AMERICAN CITY 34 (2014) (describing how policing in certain hospital emergency rooms effectively allocates access to health care based on social perceptions of criminality); Brooke A. Cunningham, *This, Too, Is What Racism Feels Like*, 39 HEALTH AFF. 2029 (2020) (describing health care system avoidance as a strategy to avoid exposure to racism in the health care system itself); Erin M. Kerrison & Alyasah A. Sewell*, Negative Illness Feedbacks: High-Frisk Policing Reduces*

the question: Why examine health care system avoidance as it applies to noncitizens? While it is true that awareness of health care system avoidance has motivated efforts to expand access to health care and address health care disparities, these efforts are inadequate if they do not address the unique and disproportionate risks of accessing health care as a noncitizen. Despite this, health care access for noncitizens has largely been left to the vagaries of immigration law and policy. Furthermore, an examination of system avoidance as a confluence of health and immigration policies can help to explain more generally how legally imposed categories stratify groups within the U.S. health care system.

This Article presents a rough framework for balancing health-related policy goals with immigration policy goals, each of which are vitally important and often contested. It bridges legal scholarship on health care access and immigration surveillance—two bodies of literature that have developed independently and that have consequential interactions. It contributes to the literature on health care access and marginalized communities by synthesizing insights from health law, immigration law, and sociology to examine law's role in generating health care system avoidance behaviors. It contributes to the interdisciplinary literature on immigration as a social determinant of health by providing a case study of how legal status stratification shapes the health of noncitizens and their family members.[7]

This is also the first Article to comprehensively describe the laws and policies pertaining to the government's conduct of immigration surveillance activities at health care sites. Even though some of these laws and policies treat health care sites as sanctuaries from immigration enforcement, fear of engaging with the health care system is widespread in immigrant communities. The failure of law to persuade in this context reflects beliefs among noncitizens and their family members that the government will not constrain interior immigration enforcement even when there are serious health-related tradeoffs. Correcting this misperception and reforming the law to create health care sanctuaries is in the government's immediate and long-term interests. Most urgently, the government will benefit from renewed trust during its quest to make the coronavirus into a manageable

Civilian Reliance on ED Services, 55 HEALTH SERVS. RSCH. 787, 788 (2020) (exploring the phenomenon of health care system avoidance in the context of racialized policing practices and police violence); Ji Seon Song, *Policing the Emergency Room*, 134 Harv. L. Rev. 2646 (2021) (analyzing the law's role in facilitating racialized policing practices at health care sites).

7 *See, e.g.*, NAT'L ACADS. OF SCIS., ENG'G, & MED., IMMIGRATION AS A SOCIAL DETERMINANT OF HEALTH: PROCEEDINGS OF A WORKSHOP (2018); Heide Castañeda et al., *Immigration as a Social Determinant of Health*, 36 ANN. REV. PUB. HEALTH 375 (2015); Wendy E. Parmet, *Immigration Law as a Social Determinant of Health*, 92 TEMP. L. REV. 931 (2020); Meredith Van Natta, *Stratified Citizenship, Stratified Health: Examining Latinx Legal Status in the U.S. Healthcare Safety Net*, 220 SOC. SCI. & MED. 49 (2019).

threat through mass inoculation.[8] Transparency and inclusion in the distribution of COVID-19 vaccines, including to noncitizens, will protect the lives and livelihoods of all people living in the United States.

This Article argues that immigration surveillance in health care is a poor choice of resource allocation for immigration enforcement because it has severe collateral consequences for the U.S. health care system and compromises the legitimacy of the state vis-à-vis its noncitizen residents. Immigration surveillance resources should be concentrated on efforts that produce the greatest benefits and the fewest drawbacks. Although immigration surveillance in health care may be justified, even sensible in certain narrow circumstances,[9] it is a poor tradeoff in the general case.

This Article proceeds in five parts. Part I introduces the phenomenon of immigration-related health care system avoidance. It presents data showing that noncitizens and their family members avoid health clinics, hospitals, and enrollment in publicly funded health coverage because of immigration-related fears. It draws on sociological theories to demonstrate that these beliefs are grounded in legitimate concerns about the expanding web of immigration surveillance.

Part II describes the legal framework of immigration surveillance in health care. Although existing laws and policies partially protect noncitizens from immigration surveillance in health care, the gradual expansion and normalization of interior immigration enforcement motivates system avoidance behaviors among noncitizens and their family members. Immigration surveillance involves the mass collection and analysis of personal data and the delegation of immigration control activities to public and private actors who are not affiliated with immigration enforcement agencies.[10] It is related to a decades-long shift in the locus of

8 Advocates, health care providers, and public health experts have long expressed concerns that immigration-related fears are a barrier to persuading undocumented noncitizens—many of whom live in areas hard-hit by COVID-19 and who are at high risk of exposure due to their work—to get the vaccine once it becomes available to them. *See, e.g.*, Catherine E. Shoichet, *Fear Could Stop the Coronavirus Vaccine from Reaching Some of the People Who Need It Most*, CNN (Dec. 22, 2020, 11:40 AM), https://www.cnn.com/2020/12/22/health/undocumented-immigrants-coronavirus-vaccine/index.html.

9 Justifications for criminal policing in health care settings may include providing security for health care personnel; responding to calls from hospitals based on certain types of injuries, for example, non-self-inflicted gunshot wounds; collecting evidence such as patient belongings and statements where crime is suspected; and remaining with an injured patient if they are already under arrest. *See* Song, *supra* note 6, at 13-15. These justifications are far less convincing as applied to immigration policing when no crime is suspected. However, disentangling policing in the criminal justice system from immigration enforcement has become more complicated as ties between the two systems have deepened. *See Developments in the Law: Policing*, 128 HARV. L. REV. 1707, 1773 (2015).

10 *See* Anil Kalhan, *Immigration Surveillance*, 74 MD. L. REV. 1, 27 (2014).

immigration enforcement activities from the border to the interior.[11]

Delegating immigration surveillance to public and private actors who are not affiliated with immigration enforcement agencies is an increasingly important part of immigration enforcement.[12] It casts a wider net for identifying noncitizens of interest to immigration enforcement agencies; at the same time, it discourages noncitizens from engaging in socially valuable behaviors, such as seeking COVID-19 testing from a publicly funded health clinic or enrolling in Medicaid in order to afford the costs of treatment.[13] Immigration enforcement officers routinely surveil noncitizens while they go about the ordinary tasks of life in their homes, places of employment, schools, courthouses, and hospitals. As a result, noncitizens perceive the prospect of interrogation or arrest by immigration enforcement officers at or near health care sites as a realistic risk.[14] Likewise, they avoid participating in publicly funded health programs if there is a possibility that the information they disclose will be shared with immigration agencies.

Laws and policies limiting immigration enforcement activity at health care provider sites and generally protecting the confidentiality of personal information submitted to public benefit agencies have not allayed noncitizens' fears of accessing health care or publicly funded health coverage.[15] This is, in part, due to gaps, uncertainties, and exceptions in the law. Noncitizens' skepticism about the law's protections may also be considered a rational response to the overt and covert expansion of immigration surveillance over time. For example, a regulation promulgated in 2019,[16] and since rescinded,[17] increased the risk that certain noncitizens who enrolled in Medicaid would be denied lawful permanent resident

11 *See, e.g.*, Eisha Jain, *The Interior Structure of Immigration Enforcement*, 167 U. PA. L. REV. 1463, 1466 (2019) (arguing that "immigration enforcement should not be conceptualized as synonymous with deportation; rather, deportation is merely the tip of a much larger enforcement pyramid").

12 *Id.* at 1466-67 (describing interior immigration enforcement as "a low-cost way to achieve enforcement objectives"); *see also* Dennis Broeders & Godfried Engbersen, *The Fight Against Illegal Migration: Identification Policies and Immigrants' Counterstrategies*, 50 AM. BEHAV. SCIENTIST 1592, 1593 (2007) (describing this phenomenon in the European context).

13 Broeders & Engbersen, *supra* note 12, at 1595.

14 By "health care sites," I mean the full spectrum of places where people go to access health care, including hospitals, outpatient clinics (whether they are private, public, volunteer-run, mobile, school-based, or inside retail stores), urgent care centers, state and local health departments, community-based organizations offering health services, pharmacies, and health fairs.

15 *See, e.g.*, July Lee et al., *Opportunities for Supporting Latino Immigrants in Emergency and Ambulatory Care Settings*, 46 J. CMTY. HEALTH 494, 498 (2020) (describing noncitizen parents' "fear that health care settings will send their personal information to the government, allowing ICE to find their addresses and look for them in their homes").

16 Inadmissibility on Public Charge Grounds, 84 Fed. Reg. 41,292, 41,295 (Aug. 14, 2019) (to be codified at 8 C.F.R. pts. 103, 212, 213, 245, 248).

17 Inadmissibility on Public Charge Grounds; Implementation of Vacatur, 86 Fed. Reg. 14,221 (Mar. 15, 2021) (to be codified at 8 C.F.R. pts. 103, 106, 212, 213, 214, 245, 248).

(LPR) status. As part of the immigration application process, noncitizens were required to provide details about their use of Medicaid and other public benefits.[18] They were also compelled to authorize U.S. Citizenship and Immigration Services to verify this information with other government agencies, including the Department of Health and Human Services.[19] This policy and others have exacerbated noncitizens' fears of accessing publicly funded health care because of the perception that any use of public benefits will increase the risk that a future immigration application will be denied.

Part III draws out the ways in which permitting surveillance in health care (or affirming conceptions that it occurs) creates tradeoffs between immigration and health policy. Laws that permit immigration surveillance in health care, and therefore generate fears of accessing health care among noncitizens and their family members, have serious collateral consequences for the health care system that should be considered in weighing their utility. First, when people delay or avoid seeking vaccines or treatment for infectious disease like COVID-19, they increase their risk of transmitting the infection to others, thereby contributing to disease burden. Second, it is harder for providers to generate good outcomes and practice cost-effective care when patients delay or avoid routine care—the risk of becoming seriously ill or dying from all kinds of medical conditions increases.[20] Third, permitting immigration surveillance in health care creates ethical dilemmas for health care providers. When health care providers become or are perceived as being complicit with immigration enforcement, it may contradict their professional duties to patients. Providers cannot act with single-minded devotion to the well-being of patients when patients' engagement with the health care system may have negative immigration consequences. As a result, providers are sometimes forced to alter clinical risk calculations and clinical recommendations for reasons relating to immigration enforcement.[21] Fourth, policies that increase the risks of people dying or suffering from treatable and preventable conditions may violate health equity norms, including commitments to reduce racial health disparities.

The state also compromises its legitimacy in several ways by permitting immigration surveillance in health care. This is the subject of Part IV. First, the laws regulating immigration surveillance in health care impose nearly insurmountable barriers for noncitizens to understand how and when they may

18 *See* Inadmissibility on Public Charge Grounds, 84 Fed. Reg. at 41,419.

19 *See* U.S. CITIZENSHIP & IMMIGR. SERVS., DEP'T OF HOMELAND SEC., FORM I-944, DECLARATION OF SELF-SUFFICIENCY (2019).

20 *See, e.g.*, Mark É. Czeisler et al., *Delay or Avoidance of Medical Care Because of COVID-19-Related Concerns – United States, June 2020*, 69 MORBIDITY & MORTALITY WKLY. REP. 1250 (2020) (describing how delay or avoidance of medical care during the COVID-19 pandemic increased morbidity and mortality risk from treatable and preventable conditions).

21 Meredith Van Natta, *First Do No Harm: Medical Legal Violence and Immigrant Health in Coral County, USA*, SOC. SCI. & MED., Aug. 2019, at 1.

access health care without triggering immigration-related consequences. This is a severe and burdensome constraint on noncitizens. Second, they encourage or require noncitizens to relinquish their privacy rights in their public benefits records. Third, they undermine noncitizens' property rights in public benefits by threatening a deprivation of liberty based on exercise of those rights.

Part V explains how creating durable legal protections against immigration surveillance in health care—"health care sanctuaries"—and making them well known can allay fears of accessing health care in immigrant communities. Such legal changes will recover some of the lost equilibrium between immigration enforcement and other goals and values of public policy.[22] If legal health care sanctuaries are a political impossibility, health care institutions can still take steps to limit information sharing with immigration agencies, provide physical refuge from immigration enforcement, link noncitizens with legal services, and promote norms of justice and empathy in immigration policy. Institution-level policy changes designed to protect noncitizen access to health care may catalyze legal reform.

I. NONCITIZENS AND HEALTH CARE SYSTEM AVOIDANCE

This Part introduces the phenomenon of immigration-related health care system avoidance by describing who is affected and summarizing the sociological literature explaining how and why it occurs. While noncitizens face barriers to accessing health care that are common to many other socioeconomically marginalized groups,[23] immigration-related health care system avoidance is driven by fears of immigration surveillance while accessing health care.[24] When they perceive this risk, noncitizens and their family members avoid engaging with the

22 Amanda Frost, *Can the Government Deport Immigrants Using Information it Encouraged Them to Provide?*, 2 ADMIN. L. REV. ACCORD 97, 98 (2017) (stating that "[t]he federal government has always balanced immigration enforcement against other goals and values" in the context of analyzing whether the Trump Administration should use information submitted by Deferred Action for Childhood Arrivals (DACA) applicants to deport them).

23 *See, e.g.*, Timothy Callaghan et al., *Immigrant Health Access in Texas: Policy, Rhetoric, and Fear in the Trump Era*, 19 BMC HEALTH SERVS. RSCH. 342, 343 (2019) (summarizing prior research indicating that access barriers for Hispanic immigrants include "lack of insurance . . . the cost of care, transportation, the inability to take time away from work, child care, limited knowledge, language, gender, ethnicity, documentation status, and fear"); Scott D. Rhodes et al., *The Impact of Local Immigration Enforcement Policies on the Health of Immigrant Hispanics/Latinos in the United States*, 105 AM. J. PUB. HEALTH 329, 329 (2015) (noting barriers of "a lack of bilingual and bicultural services, low health literacy, insufficient public transportation, and limited knowledge of available health services").

24 *See* Rhodes et al., *supra* note 23, at 329 (highlighting "fear of deportation, a lack of required forms of documentation, interaction with law enforcement personnel, and racial profiling" as "factors . . . associated with reduced utilization of health services and worse health" among noncitizens identifying as Hispanic or Latino).

health care system. In practice, this involves delaying or canceling doctors' visits and declining to participate in health care programs in order to guard against negative immigration consequences.

A broad range of noncitizens as well as U.S. citizens may engage in health care system avoidance.[25] Undocumented noncitizens are the most obvious targets of immigration surveillance because they are not legally authorized to be in the country. This group comprises not only people who enter the country without inspection at the border, but also those who entered with legal status but who have violated the terms of their status. Typical ways of violating the terms of one's status are to stay in the country beyond the date of one's authorized period of stay or to perform work that is not authorized by one's status.[26] For example, a noncitizen may enter the country with a tourist visa that authorizes them to stay in the United States for three months. If that noncitizen stays in the country beyond three months, they are considered undocumented.

It is common for noncitizens to move across the documentation status continuum throughout their lives, with periods of authorized and unauthorized status.[27] Because of the backlog in processing for most immigration applications, applicants can wait months or years to receive a decision on an immigration application, all the while living in a kind of "twilight" status.[28] Long-term residence in the United States is a characteristic of most undocumented noncitizens' lives.[29] Despite this fact, undocumented noncitizens live with the knowledge that even routine interactions—such as going to the doctor—can result in arrest, detention, and deportation.[30]

Foreign-born people *with* legal status are not immune to the negative consequences of immigration surveillance. An environment of heightened immigration enforcement can affect health care-related behaviors of noncitizens

25 As will be explained, U.S. citizens may fear that their interactions with health care institutions could put their noncitizen family members at risk of negative immigration consequences, such as denial of a pending or future immigration application or deportation. *See infra* text accompanying notes 36-38, 40-41. Jennifer Chacón proposes using the concept of "liminal legality" to describe the condition of a broad range of people whose lives are impacted by heightened monitoring of noncitizens by government agencies (among other trends in immigration policy). Jennifer M. Chacón, *Producing Liminal Legality*, 92 DENV. U.L. REV. 709, 712, 730 (2015).

26 Broeders & Engbersen, *supra* note 12, at 1594 ("Most typologies of irregular migration are . . . set up around three main criteria. There is legal and illegal *entry*, legal and illegal *residence*, and legal or illegal *employment*.").

27 *See, e.g.*, Jain, *supra* note 11, at 1473 (explaining that the distinction between "legal" and "illegal" noncitizens is not always clear because some who currently lack a valid status may acquire one in the future and some with a valid status may lose it).

28 DAVID A. MARTIN, MIGRATION POL'Y INST., TWILIGHT STATUSES: A CLOSER EXAMINATION OF THE UNAUTHORIZED POPULATION 1 (2005).

29 Jain, *supra* note 11, at 1464-65 (noting "the median length of residence being about fourteen years").

30 *Id*. at 1473-74.

who are not the "intended target[s]" of immigration enforcement.[31] One reason for this is that it can be confusing—both for noncitizens and for those to whom immigration surveillance duties have been delegated—to determine whether a particular status or quasi-status subjects a person to immigration enforcement.[32] Naturalized U.S. citizens may feel that their status is insecure, especially in light of the significant escalation of denaturalization proceedings from 2017 to 2020.[33] Even natural-born U.S. citizens, particularly those who are related to noncitizens or who are simply nonwhite, have reason to feel that their status is precarious.[34] In recent years, the media has reported on several cases of natural-born U.S. citizens who were deported to other countries or denied the rights of citizenship, such as obtaining a U.S. passport.[35]

Finally, members of "mixed-status" households—which may include U.S. citizens and noncitizens with various statuses or no status—may alter their care-seeking behaviors in response to immigration surveillance in order to avoid scrutiny of the noncitizen family members.[36] Heide Castañeda's research has highlighted the analytical significance of mixed-status families in studying access to health care, noting that each family member may have a different relationship to the state and therefore different rights and opportunities with respect to health care access.[37] If there was any chance that enrollment would affect a family

31 Lisa J. Hardy et al, *A Call for Further Research on the Impact of State-Level Immigration Policies on Public Health*, 102 AM. J. PUB. HEALTH 1250, 1250 (2012) (describing the effects of S.B. 1070 on noncitizens with legal status in Arizona); *see also* Van Natta, *supra* note 21, at 3 (describing how a person in asylum proceedings feared "becoming legible to federal bureaucracies" by applying for publicly funded health insurance).

32 Huyen Pham, *The Private Enforcement of Immigration Laws*, 96 GEO. L.J. 777, 782 (2008) (noting "[t]here is no one definitive document that establishes legal presence. . . . [T]o private parties who have no immigration law training, making that determination can be fraught with error.").

33 Irina D. Manta & Cassandra Burke Robertson, *Inalienable Citizenship*, N.C. L. REV. (forthcoming) (manuscript at 4-5), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3691695& (describing the politically driven increase, since 2017, in the number of denaturalization cases referred to the Department of Justice for prosecution).

34 Chacón describes how, over the last two decades, a shift in immigration policy has enhanced the sense of legal precarity among lawful permanent residents and U.S. citizens. Chacón, *supra* note 25, at 731, 734. She also describes how "many individuals experience overlapping forms of liminality because of their race, their geographic location and their immigration status." *Id*. at 731.

35 Manta & Robertson, *supra* note 33, at 3 (describing the cases of five natural-born U.S. citizens who were denied rights of U.S. citizenship, including a Black teenager who was deported to Colombia even though she had no ties or familial connection to the country).

36 Patler & Gonzalez, *supra* note 4, at 4 (reporting "reductions in qualified Medicaid enrollment, healthcare-seeking, and accessing service-providing institutions among U.S. citizens who may share households with noncitizens").

37 Heide Castañeda, *Stratification by Immigration Status: Contradictory Exclusion and Inclusion After Health Care Reform*, *in* UNEQUAL COVERAGE: THE EXPERIENCE OF HEALTH CARE REFORM IN THE UNITED STATES 37, 44-45 (Jessica M. Mulligan & Heide Castañeda eds., 2018) (noting that the complexity of immigration status-related eligibility rules governing subsidized health coverage is a barrier to enrollment for mixed-status families).

member's ability to remain in the United States or become a U.S. citizen, families would err on the side of caution, declining to enroll in or even withdrawing from programs.[38] Even members of mixed-status families who knew they were eligible for subsidized health coverage declined to enroll to avoid "being on the list" or owing any "debts" to the government, lest such actions impact their or their family members' ability to obtain immigration benefits.[39] Parents in mixed-status families face especially difficult choices between accessing public benefits that will support their children's health and development and risking either long-term family separation or having to raise their children—often U.S. citizens—in an unfamiliar country with fewer opportunities and, sometimes, dangerous conditions.[40]

This indicates that the chilling effects of immigration surveillance in health care extend to U.S. citizen family members of noncitizens.[41] For these reasons, references to noncitizen behavior in this Article may apply to their U.S. citizen household members. When family members decline to enroll in public benefits for which they are eligible, all family members suffer from the foregone support.[42]

Fear of deportation and other immigration consequences is a well-documented, longstanding, and widespread barrier to health care for noncitizens.[43]

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38 *Id*. at 45; Patler & Gonzalez, *supra* note 4, at 9-10 (observing that spouses of noncitizens in immigration detention or who had been deported "avoided accessing much-needed public benefits" based on a fear of negatively impacting their spouses' immigration case or future case). Applications for publicly funded health insurance typically require applicants to submit personal information about all members of the household, even if they are not applying for benefits.

39 Castañeda, *supra* note 37, at 44.

40 Super, *supra* note 5, at 559; *see also* Castañeda, *supra* note 37, at 47 (noting that such decisions were made "with an eye toward the greater good of the family"); Lee et al., *supra* note 15, at 6 ("Since the most recent public charge ruling was proposed, many [Latino immigrant] parents have disenrolled themselves from medical insurance but the overwhelming majority continue to keep their children enrolled."); Rhodes et al., *supra* note 23, at 334 (finding that parents' fear of being identified as undocumented led them to delay necessary diagnoses, care, and treatment for their children).

41 Patler & Gonzalez, *supra* note 4, at 14. *See generally* Rhodes et al., *supra* note 23, at 336 (finding that immigration-related health care system avoidance led some study participants to "sacrific[e] their own health and the health of members of their families"); Catherine J. Taylor, *Health Consequences of Laws and Public Policies That Target, or Protect, Marginalized Populations*, 14 SOCIO. COMPASS 1, 6 (2020) (describing how health-related consequences of laws and policies targeting undocumented noncitizens can spill over to lawfully present noncitizens and co-ethnic U.S. citizens who live in the same communities).

42 Super, *supra* note 5, at 548-49, 559.

43 *See, e.g.*, LEIGHTON KU & MARIELLEN JEWERS, MIGRATION POL'Y INST., HEALTH CARE FOR IMMIGRANT FAMILIES: CURRENT POLICIES AND ISSUES 11 (2013); PARK, *supra* note 1, at 46-47 (describing "possible negative ramifications for the individual and his or her family's immigration status" as one among several barriers to health care for noncitizens); Asad, *supra* note 5, at 150 (describing one noncitizen's deportation fears of returning to the hospital, where he also owes $20,000 for an emergency gallstone surgery); Callaghan et al., *supra* note 23, at 346 ("[F]ear remains a pervasive and problematic barrier for undocumented immigrants and their families attempting to access care."); Shari B. Fallek, *Health Care for Illegal Aliens: Why It Is a Necessity*, 19 HOUS. J.

Numerous studies show that fear of immigration consequences can motivate noncitizens' decisions to delay seeking health care.[44] Family members of people having medical emergencies hesitate to dial 911 over concern about whether an unpaid ambulance bill will invite scrutiny under the public charge law.[45] Burn victims arrive at the hospital too late to survive infection.[46] Women in labor show up at emergency rooms without having had any prenatal care;[47] some who suffer from untreated gestational diabetes during their pregnancies must have limbs amputated afterward.[48] Fears of immigration-related consequences are so intense that some noncitizens *decline care altogether*,[49] even in life-threatening situations.[50]

INT'L L. 951, 973 (1997) (describing how "thousands of fearful immigrants have refrained from seeking medical aid and attending their appointments at California clinics" after the passage of Proposition 187, even though enforcement was enjoined); Hacker et al., *supra* note 2, at 178 (finding that 65% of articles in a medical literature review of barriers to health care for noncitizens without legal status identified fear of deportation as a barrier and noting that the phenomenon was observed in France and Denmark, as well as in the United States); Karen Hacker et al., *Providers' Perspectives on the Impact of Immigration and Customs Enforcement (ICE) Activity on Immigrant Health*, 23 J. HEALTH CARE FOR THE POOR & UNDERSERVED 651, 660-61 (2012); Lee et al., *supra* note 15, at 4-6 (describing immigrant parents' "fear of being discovered and deported by [ICE] en route to the health care setting or once already there," which leads them to delay seeking care); *id*. at 1-2 (describing Latino immigrants' fears of seeking testing or care for COVID-19); Sana Loue, *Immigrants, Immigration Law, and Tuberculosis*, 71 WASH. L. REV. 969, 985 (1996) (describing fear among undocumented immigrants that health care providers would report them to immigration); Helen B. Marrow & Tiffany D. Joseph, *Excluded and Frozen Out: Unauthorised Immigrants' (Non)Access to Care After U.S. Health Care Reform*, 41 J. ETHNIC & MIGRATION STUD. 2253, 2265 (2015) (describing patients' fear of using health care services due to possible surveillance by immigration and local law enforcement in Massachusetts and San Francisco); K-Sue Park, *Self-Deportation Nation*, 132 HARV. L. REV. 1878, 1486 (2019); Rhodes et al., *supra* note 23, at 329, 336 (finding that noncitizen study participants feared deportation and therefore avoided health services).

44 *See, e.g.*, NOLAN KLINE, PATHOGENIC POLICING: IMMIGRATION ENFORCEMENT AND HEALTH IN THE U.S. SOUTH 151 (2019) (noting that the threat of immigration surveillance at health care sites in the Atlanta area "ultimately resulted in Grady [Memorial Hospital] becoming a place that some immigrants felt was safe only in case of an emergency"); Rhodes et al., *supra* note 23, at 332, 336 (finding that noncitizen study participants reported delaying preventive care, including prenatal care, and enduring illness rather than seeking diagnostic care); PARK, *supra* note 1, at 47.

45 PARK, *supra* note 1, at 46, 92 (describing cases involving choking and a heart attack).

46 *Id*. at 92

47 *See id*. at 93; Caitlin Dickerson, *Undocumented and Pregnant: Why Women Are Afraid to Get Prenatal Care*, N.Y. TIMES (Nov. 22, 2020), https://www.nytimes.com/2020/11/22/us/undocumented-immigrants-pregnant-prenatal.html.

48 PARK, *supra* note 1, at 93.

49 Callaghan et al., *supra* note 23, at 346 (noting that undocumented immigrants and their family members in Texas routinely forego necessary health care); Rhodes et al., *supra* note 23, at 332 (finding that noncitizens "did not access or utilize health services for which they were eligible, including preventive services" such as reproductive health services based on fears of immigration surveillance).

50 *See, e.g.*, PARK, *supra* note 1, at 93 (describing how a patient diagnosed with uterine cancer declined to proceed with the recommended treatment, a hysterectomy, because she was afraid that

Having health insurance is critical for obtaining timely and adequate health care, and decades of research demonstrate that noncitizens and their family members will hesitate to enroll in publicly funded health insurance if there is a risk of negative immigration consequences.[51] Even a request for immigration documents, Social Security numbers (SSNs), or valid driver's licenses from a public benefit agency may be sufficient to provoke concerns about immigration surveillance and deter noncitizens from seeking coverage.[52] Immigration-related concerns are partially responsible for the twenty percent decline in Medicaid enrollment among noncitizen families with children between 1994 and 1997, when punitive immigration and welfare laws were enacted.[53] Similarly, during the Trump Administration, which vowed to increase immigration enforcement from day one and promulgated new public charge regulations that would penalize certain noncitizens for enrolling in Medicaid, enrollment among Latinx immigrant families decreased.[54]

Sometimes, immigration-related health care system avoidance is based on

she or her family would be deported); Kathleen R. Page & Alejandra Flores-Miller, *Lessons We've Learned—Covid-19 and the Undocumented Latinx Community*, 384 NEW ENG. J. MED 5, 5-6 (describing noncitizen fears of seeking testing and treatment for COVID-19, despite their higher risk of exposure to the virus).

51 *See, e.g.*, Marcella Alsan & Crystal S. Yang, *Fear and the Safety Net: Evidence from Secure Communities* 27 (Nat'l Bureau of Econ. Rsch., Working Paper No. 24731, 2019) (finding decreased safety net participation by noncitizens and their family members based on deportation fear); Hacker et al., *supra* note 43, at 660 ("Patients feared that providing any documentation for insurance enrollment purposes would risk exposure."); Kimberly A. Johns & Christos Varkoutas, *The Tuberculosis Crisis: The Deadly Consequence of Immigration Policies and Welfare Reform*, 15 J. CONTEMP. HEALTH L. & POL'Y 101, 121 (1998); KU & JEWERS, *supra* note 43, at 11 ("Unauthorized immigrants often worry that seeking care, particularly at a public facility, may lead to exposure of their unauthorized status and increase the risk of sanctions such as deportation. Even legal immigrants may worry that using benefits could jeopardize their legal status and perhaps make it harder to gain citizenship or permanent residency."); Jeffrey T. Kullgren, *Restrictions on Undocumented Immigrants' Access to Health Services: The Public Health Implications of Welfare Reform*, 93 AM. J. PUB. HEALTH, 1630, 1632 (2003).

52 *See, e.g.*, KLINE, *supra* note 44, at 59 (describing the impact of a Georgia law excluding passports as an acceptable form of identification when applying for public benefits); Castañeda, *supra* note 37, at 46 (describing the impact of new identification requirements in the ACA on members of mixed-status families who are eligible for publicly funded health insurance); Lee et al., *supra* note 15, at 5; Rhodes et al., *supra* note 23, at 332, 334.

53 Super, *supra* note 5, at 556.

54 Lee et al., *supra* note 15, at 6.

incorrect information,[55] but the fear is often warranted.[56] Researchers have gathered evidence of health care providers threatening to call immigration authorities for the purpose of discouraging noncitizens from seeking care.[57] In one case that received national media attention, staff at the medical clinic where Blanca Borrego arrived for a routine gynecological appointment called law enforcement when they suspected that she had provided a fake driver's license as identification, leading to her arrest in an exam room and putting her at risk of deportation.[58]

Such egregious behavior has the effect of reducing the number of places where noncitizens feel safe obtaining health care.[59] Just as studies of system avoidance have revealed that people who have had criminal justice contact will continue to engage with institutions perceived as "non-surveilling,"[60] many noncitizens feel that they are limited to underfunded, alternative, or nonmedical sources of care.[61] This indicates that it is the surveillance that discourages engagement, not "an

55 *See, e.g.*, Callaghan et al., *supra* note 23, at 346 (reporting a community health worker's observation that noncitizens may have erroneously connected decisions to seek health care with subsequent immigration decisions, "creating a cycle of misinformation"); Philip Kretsedemas, *Avoiding the State: Haitian Immigrants and Welfare Services in Miami-Dade County*, *in* IMMIGRANTS, WELFARE REFORM, AND THE POVERTY OF POLICY 107, 115 (Philip Kretsedemas & Ana Aparicio eds., 2004) (finding that nearly half of immigrants surveyed believed, erroneously, that obtaining services from a community health center would implicate public charge inadmissibility); Lee et al., *supra* note 15, at 6 (noting that some noncitizens declined to renew Medicaid coverage based on "mixed messages regarding the impact of public charge").

56 Ella Wesson, *Interviewing William Lopez: The Health Impacts of United States Immigration Policy in the Context of the Trump Administration and COVID-19*, HARV. HEALTH POL'Y REV. (Nov. 10, 2020), http://www.hhpronline.org/articles/2020/11/8/interviewing-william-lopez-the-health-impacts-of-united-states-immigration-policy-in-the-context-of-the-trump-administration-and-covid-19 (noting that undocumented noncitizens worry that accessing health care can lead to deportation because of a general fear of the government's ability to surveil).

57 *See, e.g.*, KLINE, *supra* note 44, at 149.

58 *See, e.g.*, Dan Solomon, *Undocumented Harris County Woman Faced Deportation After Being Arrested at Her OB-GYN*, TEX. MONTHLY (Sept. 16, 2015), https://www.texasmonthly.com/the-daily-post/an-undocumented-harris-county-woman-faced-deportation-after-being-arrested-at-her-ob-gyn/. It is unclear whether Ms. Borrego was ultimately deported.

59 KLINE, *supra* note 44, at 151; Rhodes et al., *supra* note 23, at 334 (finding that noncitizen study participants were "reoccupied [sic] with avoiding interactions with systems, suspicious of those in positions of power (including health care providers), and fearful of being detained and deported"); Harris Meyer, *Tougher Immigration Enforcement is Taking a Toll on Healthcare*, MODERN HEALTHCARE (Apr. 21, 2017), https://www.modernhealthcare.com/article/20170421/NEWS/170429967/tougher-immigration-enforcement-is-taking-a-toll-on-healthcare (quoting the chief medical officer of a community health center in Philadelphia who described the need to dispel rumors that the organization had shared information about patients with ICE agents).

60 Brayne, *supra* note 4, at 385.

61 *See* Rhodes et al., *supra* note 23, at 334 (reporting that noncitizen study participants "often rely on . . . self-diagnosing and self-treating and using medications purchased from Latino stores, brought from their home country, or left over from others' prescriptions").

aversion to institutions in general."[62]

Anecdotal evidence of immigration enforcement at health care sites abounds. Border Patrol agents monitor the corridors of hospital emergency departments, enter exam rooms, and discuss medical care with physicians.[63] Immigration enforcement agents and their local police delegates conduct surveillance from the parking lots of health care sites and detain noncitizen patients as they leave appointments.[64] One health care provider at a prenatal clinic in San Diego noted an increase in the number of patient "no-shows" on days when Border Patrol vans were parked in its lot.[65]

Undocumented noncitizens have been arrested while traveling to or from the hospital to obtain treatment for themselves or their ill family members, even in emergency situations.[66] Upon discharge, they may be transferred directly to detention facilities rather than being permitted to recuperate at home.[67] Near U.S.

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62 Brayne, *supra* note 4, at 385.

63 *See* Jaime La Charite et al., *Healthcare Professionals' Experience, Training, and Knowledge Regarding Immigration-Related Law Enforcement in Healthcare Facilities: An Online Survey*, 49 J.L., MED. & ETHICS 50, 52 (2021) ("Nearly 1 in 5 [providers surveyed] reported that they were aware of immigration enforcement activities in or near their workplace . . . ."); Adriana Gomez Licon, *Border Patrol's Growing Presence at Hospitals Creates Fear*, AP (Oct. 17, 2019), https://apnews.com/article/52a38ce1d4b84e289b807 3b47674514e ("The presence of immigration authorities is becoming increasingly common at health care facilities around the country, and hospitals are struggling with where to draw the line to protect patients' rights . . . .").

64 *See, e.g.*, KLINE, *supra* note 44, at 150-51 (describing observations of a Grady Memorial Hospital staff member about immigration policing); Altaf Saadi & Martin McKee, *Hospitals as Places of Sanctuary*, BMJ, May 17, 2018, at 1 (noting the occurrence of immigration enforcement at or near health facilities).

65 PARK, *supra* note 1, at 122-23.

66 *See, e.g.*, Camilo Montoya-Galvez, *15-year-old Girl Who Spent Her Life in the U.S. Facing Deportation After Hospital Arrest*, CBS NEWS (Sept. 25, 2020), https://www.cbsnews.com/news/15-year-old-girl-who-spent-her-life-in-the-u-s-facing-deportation-after-hospital-arrest/ (describing how an undocumented teenager and her aunt were arrested by CBP after the child was required to travel through an internal Border Patrol checkpoint in Texas to obtain emergency gallbladder surgery); Claudia Flores et al., *DHS Must Suspend Certain Immigration Enforcement Practices During the Coronavirus Outbreak*, CTR. FOR AM. PROGRESS (Mar. 10, 2020, 9:00 AM), https://www.americanprogress.org/issues/immigration/news/2020/03/10/481471/dhs-must-suspend-certain-immigration-enforcement-practices-coronavirus-outbreak/ (describing the arrest of "35-year-old Joel Arrona-Lara at a gas station as he was driving his pregnant wife to the hospital for a scheduled cesarean section"); Licon, *supra* note 63; Barbara Campbell, *Girl Detained by Border Patrol After Emergency Surgery Released to Parents*, NPR (Nov. 3, 2017), https://www.npr.org /sections/thetwo-way/2017/11/03/562003841/girl-detained-by-border-patrol-after-emergency-surgery-is-released-to-parents (describing how ten-year-old Rosa Maria Hernandez was detained after attempting to pass through an internal Border Patrol checkpoint in Texas in order to obtain emergency gallbladder surgery).

67 Campbell, *supra* note 66 (describing how Hernandez, who has cerebral palsy, was detained at a facility for children after receiving lifesaving surgery before eventually being released to her parents).

borders, immigration checkpoints prevent or complicate access to health care for family members of undocumented noncitizens, including U.S. citizen children with disabilities and premature babies.[68]

Since 9/11, federal agencies have increasingly cooperated to share information for the purpose of detecting and preventing all matter of threats.[69] These datasets, accessible to immigration enforcement agencies, include public health data gathered from public hospitals. It is not unreasonable to worry that the collection and analysis of such data could affect future immigration options.[70] When the cost of medical treatment is, potentially, deportation or denial of immigration benefits, health care system avoidance among noncitizens should be expected.

II. IMMIGRATION SURVEILLANCE IN HEALTH CARE

This Part describes the legal framework of immigration surveillance in health care. In this Article, I use the term "immigration surveillance in health care" to refer to specific modes of immigration surveillance at specific types of sites. The first of two modes of immigration surveillance on which I focus is interrogation, arrest, search, or detention by immigration enforcement officers at health care sites. The second is use of personal information disclosed for the purpose of obtaining health care to deny immigration benefits or for immigration enforcement purposes. This Part begins with an overview of the policy context of immigration surveillance in health care. It then describes the laws and policies governing physical and informational surveillance of noncitizens by immigration agencies at

68 Tom Jawetz & Ed Chung, *Federal Immigration Officials Can Help Protect Public Health During the Coronavirus Pandemic*, CTR. FOR AM. PROGRESS (Mar. 18, 2020, 9:03 AM), https://www.americanprogress.org/issues/immigration/news/2020/03/18/481865/federal-immigration-officials-can-help-protect-public-health-coronavirus-pandemic/; Elena Mejia Lutz, *At Border Patrol Checkpoints, an Impossible Choice Between Health Care and Deportation*, TEX. OBSERVER (Feb. 13, 2018), https://www.texasobserver.org/border-patrol-checkpoints-impossible-choice-health-care-deportation/ (describing a child with scoliosis whose necessary surgery was delayed for eleven years and a physician's recollection of "cases in which premature babies born to undocumented parents near the border must travel alone by helicopter or ambulance" to the hospital, despite a longstanding CBP policy requiring "expedited transit" for families in such circumstances); Campbell, *supra* note 66.

69 *See, e.g.*, Danielle Keats Citron & Frank Pasquale, *Network Accountability for the Domestic Intelligence Apparatus*, 62 HASTINGS L.J. 1441, 1450-51 (2011). This type of information-sharing likely preceded 9/11 on a smaller scale. As David Super notes, "[i]n some southwestern towns, public benefits eligibility workers are married to border patrol officers and have reported suspected undocumented immigrants over the breakfast table." Super, *supra* note 5, at 561-62.

70 *See* Danielle Keats Citron, *A Poor Mother's Right to Privacy: A Review*, 98 B.U. L. REV. 1139, 1147 (2018) ("Risk profiles [generated by the government] can be shared with a host of federal and state agencies, impacting poor mothers' opportunities, from government employment to immigration.").

health care sites. Although some legal protections against immigration surveillance in health care exist, gaps and uncertainties in the law explain why health care system avoidance persists among noncitizens and their family members.

A. Policy Context

In general, as a prerequisite for seeking out health care or health coverage, people must have some sense that they will be safe in doing so.[71] Law sometimes provides assurances to patients that their pursuit of health care will not result in negative consequences—for example, law that broadly protects the confidentiality of information that patients share with their health care providers.[72] In general, and with limited exceptions, patients should feel comfortable coming to health care sites without fear of arrest or interrogation and sharing personal information with their providers without fear of disclosure to law enforcement. However, as Part I illustrates, law does not always ensure conditions that will overcome potential patients' fears of the negative consequences of seeking out health care.

Immigration surveillance in health care is one form of interior immigration enforcement.[73] Like other forms, it "draws the migration border inward," occurring at sites of routine interaction that exist to support the health and wellbeing of

71 There are many examples of this. Pregnant women with opioid use disorder will not seek out prenatal care if they face a risk of criminal prosecution related to their drug use. Lynn Falletta et al., *Perceptions of Child Protective Services Among Pregnant or Recently Pregnant, Opioid-Using Women in Substance Abuse Treatment*, 79 CHILD ABUSE & NEGLECT 125, 126 (2018) (reporting that "several studies have found feared loss of custody to CPS as a potential barrier to prenatal care among women with substance use disorders"). Travelers suspected of having an infectious disease like COVID-19, Ebola, or multi-drug resistant tuberculosis will not submit to public health authorities for treatment unless they are assured of the limits and conditions of quarantine. *See* Valerie A. Earnshaw et al., *Medical Mistrust in the Context of Ebola: Implications for Intended Care-Seeking and Quarantine Policy Support in the United States*, 24 J. HEALTH PSYCH. 219, 225 (2016) ("[I]ndividuals who endorse medical conspiracy beliefs may oppose quarantine policies due to the control over individual autonomy that such policies grant authorities . . . ."). People with psychiatric disorders will not request an adjustment to their medication if doing so would put them in danger of involuntary commitment. *See* Marvin S. Swartz, Jeffrey W. Swanson & Michael J. Hannon, *Does Fear of Coercion Keep People Away from Mental Health Treatment? Evidence from a Survey of Persons with Schizophrenia and Mental Health Professionals*, 21 BEHAV. SCIS. & L. 459, 467 (2003) (reporting that "fear of involuntary hospitalization was the most frequently cited barrier to treatment" among subjects with schizophrenia). Patients who have experienced health care-induced trauma as children may avoid all preventive care as adults. *See* Chrystal L. Lewis et al., *Once BITTEN, Twice Shy: An Applied Trauma-Informed Healthcare Model*, 32 NURSING SCI. Q. 291, 293-94 (2019) (discussing the phenomenon of "medical trauma" and noting that "a patient with a history of trauma who is actively experiencing a PTS reaction might find it difficult to form a trusting relationship with his or her HCP during the medical encounter").

72 *See* Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, 110 Stat. 1938 (1996); 45 C.F.R. §§ 160, 164 (2021).

73 *See* Jain, *supra* note 11, at 1490 (describing how interior immigration enforcement may occur in various settings).

members of society.[74] Laws and policies that increase immigration surveillance in the country's interior are designed not only to apprehend and eventually remove deportable noncitizens, but also to deter all kinds of noncitizens from settling in or even coming to the United States by imposing harsh living conditions.[75] This theory of deterrence has come to be known as "self-deportation," and it operates by making ordinary—and even socially desirable—behaviors risky.[76] For a variety of reasons, heightened interior immigration enforcement is unlikely to persuade long-term undocumented noncitizens to leave.[77] It does, however, constrain their choices in everyday matters (such as whether to seek health care) that can have significant consequences.[78]

Uncertainty about the law complicates noncitizens' ability to calculate the risks of engaging in ordinary activities. One source of uncertainty among noncitizens is the discretion that is a hallmark of the U.S. immigration system.[79] Because immigration agencies have broad authority to decide, among other things, how to conduct immigration surveillance,[80] there is significant uncertainty among noncitizens about how the law will apply to them.[81] A second source of uncertainty

74 Kalhan, *supra* note 10, at 60-61; *see also* PARK, *supra* note 1, at 116 ("Welfare and health policies . . . inconspicuously extend the power of the border far beyond the literal, physical fence."). Put another way, "[t]he Border is everywhere." Robert S. Chang, *A Meditation on Borders*, *in* IMMIGRANTS OUT!: THE NEW NATIVISM AND THE ANTI-IMMIGRANT IMPULSE IN THE UNITED STATES 244, 246 (Juan F. Perea ed., 1997).

75 *See* Jain, *supra* note 11, at 1467 (noting that "simple deterrence" is one rationale behind heightened immigration enforcement efforts in the Trump Administration); *see also* Broeders & Engbersen, *supra* note 12, at 1593 (describing, in the European context, how this strategy "is meant to complicate and frustrate living and working conditions to such a degree that [irregular migrants] will turn around and try their luck elsewhere").

76 *See* Jain, *supra* note 11, at 1490; Park, *supra* note 43, at 1880-82.

77 Jain, *supra* note 11, at 1493 (describing factors such as having U.S.-citizen children, attenuated connections to their countries of origin, the financial costs of leaving, and the perceived low risk of detection if they continue to lay low).

78 *See* Broeders & Engbersen, *supra* note 12, at 1596 ("Panopticon Europe is designed as a '*factory of exclusion* and of people habituated to their status of the *excluded*'" (quoting Godfried Engbersen, *The Unanticipated Consequences of Panopticon Europe. Residence Strategies of Illegal Immigrants*, *in* CONTROLLING A NEW MIGRATION WORLD 222, 242 (Virginie Guiraudon & Christian Joppke eds., 2001))); Kalhan *supra* note 10, at 60-61 (describing the expansion of interior immigration enforcement as "a kind of immigration panopticism, which eliminates zones in society where immigration status is invisible and irrelevant").

79 Shoba Sivaprasad Wadhia, *The Role of Prosecutorial Discretion in Immigration Law*, 9 CONN. PUB. INT. L.J. 243, 244-45 (2010) (describing the economic and humanitarian rationales for prosecutorial discretion in the immigration system).

80 *Id.* at 244 ("Prosecutorial discretion extends to decisions about which offenses or populations to target; whom to stop, interrogate, and arrest; whether to detain or to release a noncitizen; whether to initiate removal proceedings; whether to execute a removal order; and various other decisions.").

81 Jain, *supra* note 11, at 1503 ("The vast majority of undocumented migrants do not experience removal; what they instead experience is uncertainty about how and when immigration enforcement may unfold.").

relates to unenforced[82] or proposed[83] immigration laws or policies. Noncitizens anticipating increased surveillance may reduce their interactions outside the home.[84] A third source of uncertainty is mixed messaging about immigration policies from official and unofficial sources.[85] For example, policymakers need not even propose new immigration laws or policies to encourage health care system avoidance; public rhetoric, media reports, and rumors can have the same effect.[86] Finally, immigration law is complex and can be difficult for laypeople to interpret without legal assistance.[87] The overall effect of uncertainty about the law is to make noncitizens more cautious, including when deciding whether to seek health care or coverage, even when serious injuries or illnesses are involved.[88]

The Trump Administration heightened immigration enforcement in numerous ways, contributing to the climate of fear for noncitizens and motivating them to disenroll from or forgo health care and coverage, as described in Part I.[89] Such

82 *See* KLINE, *supra* note 44, at 60 (describing how the Georgia legislature's passage of the Illegal Immigration Reform and Enforcement Act of 2011 ("H.B. 87"), which expanded immigration policing, promoted fear in immigrant communities even when provisions were unenforced).

83 Taylor, *supra* note 41, at 8 ("Political climates created by the social climate during the time of the attempt to pass a law, regardless of whether the law is ever actually passed, can also affect health outcomes.").

84 *Id*. at 8 (describing how laws that are never passed or policies that are never finalized can negatively affect noncitizens' health outcomes, making access to timely and quality health care even more important).

85 *See* Meyer, *supra* note 59 (stating that "official policy pronouncements [assuring noncitizens that immigration enforcement will not occur at health care sites] likely will do little to quell word-of-mouth alarms spread in frightened immigrant communities").

86 Jain, *supra* note 11, at 1489; *see also* KLINE, *supra* note 44, at 45, 60 (noting, in the context of H.B. 87 in Georgia, that the latter methods may be considered socially acceptable expressions of nativism that are also politically expedient and symbolically powerful).

87 Hacker et al., *supra* note 2, at 176, 178.

88 Callaghan et al., *supra* note 23, at 345 (describing a "hyper-vigilance" that occurs in undocumented immigrant communities); Hailey Cleek, *Sanctuary Clinics: Using the Patient-Physician Relationship to Discuss Immigration Policy as a Public Health Concern*, 53 WAKE FOREST L. REV. 979, 989-90 (2018) (describing how uncertainty is warranted based on officer-level and state-level inconsistencies in enforcing immigration laws); Van Natta, *supra* note 21, at 112411. Khiara Bridges examines this phenomenon in a parallel context: the illusion of privacy rights for poor, pregnant women. KHIARA M. BRIDGES, THE POVERTY OF PRIVACY RIGHTS 11 (2017) (arguing that they have "no effective privacy rights" in health settings that are perceived as threatening, hostile, and unsafe).

89 *See, e.g.*, SAMANTHA ARTIGA & PETRY UBRI, KAISER FAM. FOUND., LIVING IN AN IMMIGRANT FAMILY IN AMERICA: HOW FEAR AND TOXIC STRESS ARE AFFECTING DAILY LIFE, WELL-BEING, & HEALTH 1, 5 (2017); Lee et al., *supra* note 15, at 1-2 (describing noncitizens' fears of seeking testing and treatment for COVID-19 as "an unfortunate consequence of the anti-immigrant rhetoric propagated in the past few years"); Lutz, *supra* note 68 (quoting a physician in Brownsville, Texas, who said that "[u]nder Trump, the climate for undocumented immigrants who need health care is 'probably the worst' in the last decade"); Meyer, *supra* note 59 ("Providers and others who work in immigrant communities say anxieties have spiked in the wake of President Donald Trump's election."); Super, *supra* note 5, at 548 (describing how the Trump Administration's public charge

behavior by noncitizens was not irrational, as these policy changes increased the likelihood that leaving the house for any reason, including to seek health care, would risk immigration surveillance.[90] For example, physicians have observed that immigration enforcement operations at or near health care institutions increased in the year after Trump's inauguration.[91] During this period, a reporter documented how immigration agents along the U.S.-Mexico border were less likely to exercise discretion to not deport parents of ill or injured children who were travelling through internal Border Patrol checkpoints to access health care.[92]

As the next Section describes, the framework of immigration surveillance that enabled the Trump Administration's enforcement crackdown developed over decades.[93] Specifically, laws and policies governing publicly funded health and welfare services have historically enhanced immigration agencies' ability to identify "undeserving" or threatening noncitizens.[94] Political support for nativism is cyclical, which predictably results in anti-immigrant sentiments expressed through restrictions on health and welfare benefits.[95] The problems associated with immigration surveillance in health care long preceded the Trump Administration

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rule "would powerfully coerce families not to seek needed subsistence benefits if any of their members is not a citizen"); Van Natta, *supra* note 21, at 112415 (documenting health care providers' observations that, after the 2016 election, it became more difficult to put noncitizen patients at ease because of the difficulty of obtaining timely information about policy changes). Researchers have documented how heightened immigration enforcement in other contexts can create a climate of fear and motivate health care system avoidance. *See, e.g.*, Hardy et al., *supra* note 31, at 1251-52 ("Broad application of enforcement practices has been shown to negatively affect health care seeking behaviors and access to health care in the U.S.-Mexico border communities and throughout the United States.").

90 *See* Jason A. Cade, *Sanctuaries as Equitable Delegation in an Era of Mass Immigration Enforcement*, 113 NW. U. L. REV. 433, 435 (2018) ("Across the United States, immigration enforcement in 2017 took a sharp turn in a less nuanced and more draconian direction."); Lutz, *supra* note 68 (quoting a Texas immigration attorney in 2018 on the "alarming increase in the number of undocumented people . . . detained and deported at checkpoints while traveling to receive medical treatment for themselves or family members").

91 Saadi & McKee, *supra* note 64, at k2178.

92 Lutz, *supra* note 68.

93 *See, e.g.*, Kalhan, *supra* note 10 (describing the gradual expansion of immigration surveillance activities).

94 PARK, *supra* note 1, at 116; Castañeda, *supra* note 37, at 42 ("Efforts to limit health care have remained a standard and predictable tool for enforcing immigration control in the United States."); Pham, *supra* note 32, at 798-99 (describing federal legislation and a regulation proposed in 2004 that, together, would have required hospitals requesting federal reimbursement for uncompensated care to ask patients about immigration status and share information with ICE).

95 KLINE, *supra* note 44, at 43, 129 (noting that "immigration enforcement laws represented smaller, rationalized ways of reducing health care to certain populations," and explaining how Georgia's passage of HB87 was linked to the state's economic decline and "immigrant scapegoating"); Castañeda, *supra* note 37, at 42 (describing how even progressive laws such as the Affordable Care Act "classify and stereotype undocumented immigrants as illegal, immoral, and undeserving outsiders" by excluding them from its benefits).

and will outlast it as well, as indicated by continuing reports of noncitizens refusing the COVID-19 vaccine based on fears that receiving it could lead to deportation.[96]

B. Legal Framework

This Section provides an overview of the laws and policies governing immigration surveillance in health care. It begins by analyzing the circumstances in which surveillance of noncitizens seeking health care at provider sites is permitted and when it is discouraged. Next, it describes the laws and policies that require or permit information about noncitizens' use of publicly funded health programs to be shared with the Department of Homeland Security (DHS). Although there are some confidentiality protections for noncitizens who disclose information in order to obtain health care, the gaps and exceptions that permit information-sharing motivate immigration-related health care system avoidance. These analyses reveal the inevitability of widespread fears of immigration surveillance in health care among noncitizens. Throughout the Section, explanations are proposed for why these fears, rather than the letter of the law alone, primarily guide noncitizens' decisions about accessing health care.

1. Surveillance at Health Care Provider Sites

This subsection describes the laws and policies that govern immigration surveillance of noncitizens at, near, or en route to health care provider sites. First, it analyzes protections and exceptions in DHS's "sensitive locations" policies, concluding that immigration authorities have wide discretion to interpret and apply the policies as they see fit. In addition, the policies lack adequate accountability measures for violations and are merely executive directives that can be rescinded if the President prefers a different approach. Therefore, it is unsurprising that noncitizens do not trust the sensitive locations policies to protect them from immigration enforcement at health care provider sites. Next, it turns to an examination of health care information privacy laws and the extent to which they

96 *See, e.g.*, Juan Alfonso Nunez, *Undocumented Texans Are Eligible for the Vaccine. That Doesn't Mean They're Accessing It.*, TEX. MONTHLY (Apr. 28, 2021), https://www.texasmonthly.com/news-politics/many-undocumented-texans-eligible-for-covid-vaccine-but-not-accessing-it/; *see also* PARK, *supra* note 1, at 82 (warning, in the context of revised public charge regulations in 2011, of "[t]he need for constant vigilance of state practices, particularly with respect to immigrant populations, regardless of which political party [holds] state office"); Pham, *supra* note 32, at 779 (observing, in 2008, "a growing trend to shift some enforcement responsibilities onto private parties," such as public benefit agencies); Super, *supra* note 5, at 562 (describing a San Diego County policy in the late 1990s that would "report to immigration authorities every family receiving TANF-funded cash assistance or SNAP in which there was a member not receiving benefits whose immigration status was unknown or was thought to be unlawful unless the entire family . . . disenrolled by a certain date").

protect disclosure of information contained in noncitizens' medical records. It reveals why, notwithstanding the laws protecting patients' information from disclosure, noncitizens may be concerned about creating health care records that could potentially be disclosed to immigration authorities.

a. "Sensitive Locations" Policies

This subsection analyzes the effectiveness of DHS's sensitive locations policies at assuring noncitizens that they can go to health care sites without fear of surveillance. These policies, which limit enforcement activities at "sensitive locations," only partially shield noncitizens from immigration surveillance when they are physically at or near health care sites. Because the policies fail to define key terms with precision, contain numerous exceptions, can be rescinded quickly and easily by federal administrators, and lack adequate accountability measures, they do not completely assuage noncitizens' fears of being arrested while seeking health care.

It may be inferred from a review of DHS materials that discouraging system avoidance by noncitizens is one of the goals of the sensitive locations policies. DHS's subagencies responsible for immigration enforcement, ICE and U.S. Customs and Border Protection (CBP), have similar—but not identical—policies limiting the conduct of immigration enforcement activities at "sensitive locations."[97] Precedent for a policy that limits immigration enforcement at certain sites in order to avoid potential harm to the community dates to no later than 1993.[98] A 2008 version of the ICE policy describes it as "strik[ing] a balance between our law enforcement responsibilities and the public's confidence in the way ICE executes its mission" and "ensur[ing] that our personnel conduct enforcement operations in a manner that is safe and respectful of all persons."[99] The ICE policy currently in effect was established in 2011, and states that it is intended to "make substantial efforts to avoid unnecessarily alarming local communities."[100] An ICE website addressing frequently asked questions about the

97 Memorandum from David V. Aguilar, Deputy Comm'r, U.S. Customs & Border Prot., on U.S. Customs and Border Protection Enforcement Actions at or Near Certain Community Locations 1-2 (Jan. 18, 2013), http://file.lacounty.gov/SDSInter/bos/supdocs/US_Border.pdf [hereinafter CBP Sensitive Locations Policy]; Memorandum from John Morton, Dir., Dep't of Homeland Sec., on Enforcement Actions at or Focused on Sensitive Locations 1-2 (Oct. 24, 2011), https://www.ice.gov/doclib/ero-outreach/pdf/10029.2-policy.pdf [hereinafter ICE Sensitive Locations Policy].

98 *See* Memorandum from Julie L. Myers, Assistant Sec'y, U.S. Immigr. & Customs Enf't, on Field Guidance on Enforcement Actions or Investigative Activities At or Near Sensitive Community Locations 1 (July 3, 2008) (citing a 1993 INS policy directing officers to "avoid apprehension of persons . . . on the premises of schools, places of worship, funerals and other religious ceremonies").

99 *Id*. at 1.

100 ICE Sensitive Locations Policy, *supra* note 97, at 2.

policy provides the clearest statement of purpose: "[T]o enhance public understanding and trust, and to ensure that people seeking to participate in activities or utilize services provided at any sensitive location are free to do so, without fear or hesitation."[101] Preventing harm to community members who would avoid using services at a sensitive location based on a fear of deportation is a clear goal of the policy.

The ICE and CBP policies each list examples of sensitive locations, including "hospitals,"[102] but it is unclear whether the agencies would consider other sites where people obtain health care to be sensitive locations.[103] The ICE FAQ website provides some guidance, stating that, in addition to hospitals, the following health care sites are treated as sensitive locations: "doctors' offices, accredited health clinics, and emergent or urgent care facilities."[104] In March 2020—after receiving inquiries from advocacy groups, members of Congress, and the press about changes to enforcement practices due to the COVID-19 pandemic[105]—ICE issued a statement citing its sensitive locations policy and noting that "[i]ndividuals should not avoid seeking medical care because they fear civil immigration enforcement."[106] However, there was no indication that other sites where noncitizens may access health care or related services—such as "unaccredited" health clinics, pharmacies, health fairs, or COVID-19 testing sites—are considered sensitive locations.[107] This lack of clarity undermines noncitizens' confidence that

101 *FAQs: Sensitive Locations and Courthouse Arrests*, U.S. IMMIGR. & CUSTOMS ENF'T, https://www.ice.gov/about-ice/ero/sensitive-loc (last updated May 19, 2021).

102 ICE Sensitive Locations Policy *supra* note 97, at 2; CBP Sensitive Locations Policy, *supra* note 97, at 1.

103 Both policies assure personnel that they have discretion to treat additional sites as sensitive locations. CBP Sensitive Locations Policy, *supra* note 97, at 1 (urging personnel consider whether a location not listed is "similar in nature, description, or function"); ICE Sensitive Locations Policy, *supra* note 97, at 2 ("This is not an exclusive list . . . .").

104 U.S. IMMIGR. & CUSTOMS ENF'T, *supra* note 101. Some advocacy organizations note that CBP also considers such sites to be sensitive locations, citing to a CBP website addressing frequently asked questions. *See, e.g.*, REBECCA ULLRICH & NAT'L IMMIGR. L. CTR., THE DEPARTMENT OF HOMELAND SECURITY'S "SENSITIVE LOCATIONS" POLICIES 1 (2018), https://www.clasp.org/sites/default/files/publications/2018/06/2018_sensitive locationsdetailed.pdf. However, at the time of this writing, no such website existed.

105 *See* Jawetz & Chung, *supra* note 68.

106 *Updated ICE Statement on COVID-19*, U.S. IMMIGR. & CUSTOMS ENF'T, https://www.ice.gov/news/releases/updated-ice-statement-covid-19 (Jan. 13, 2021) (confirming that the sensitive locations policy applied to the health care sites listed on the FAQ website).

107 *See* Flores et al., *supra* note 66 (discussing dismissive tweets from a DHS spokesperson in response to concerns about immigration enforcement at health care and testing sites). In February 2021, DHS issued a statement "encourag[ing] all individuals, regardless of immigration status, to receive the COVID-19 vaccine once eligible under local distribution guidelines" and noting that neither ICE nor CBP would "conduct enforcement operations at or near vaccine distribution sites or clinics." *DHS Statement on Equal Access to COVID-19 Vaccines and Vaccine Distribution Sites*, DEP'T OF HOMELAND SEC. (Feb. 8, 2021), https://www.dhs.gov/publication/dhs-statement-equal-

they can avoid immigration surveillance by ICE while seeking health care at sites not listed in the ICE FAQ or by CBP at any non-hospital health care sites.

The policies also fail to describe with precision whether immigration enforcement actions are permitted within the vicinity of a health care site. This leaves noncitizens vulnerable to arrest immediately before or after receiving services at a health care site.[108] The ICE policy applies to enforcement actions "at or focused on" sensitive locations,[109] and notes that personnel should seek guidance from their supervisors if an enforcement operation "could reasonably be viewed as being at or *near* a sensitive location."[110] Similarly, the CBP policy applies to enforcement activities "at or near" sensitive locations.[111] Confusion about how the policies apply is justified,[112] especially given media coverage of arrests occurring "near" unquestionably sensitive locations like hospitals.[113] In response to outcry over the arrest of a teenager at a bus stop just outside of a hospital in Portland, Oregon, an ICE spokesperson defended the action by arguing that the bus stop was not technically on hospital property.[114] Such public justifications of enforcement actions that plainly violate the intent of the sensitive locations policies sow distrust and generate more fear in immigrant communities.

Another source of potential confusion in DHS's sensitive location policies is that ICE and CBP regulate enforcement activities at sensitive locations differently. The ICE policy applies to arrests, interviews, searches, and surveillance conducted for purposes of immigration enforcement.[115] It permits ICE officers to conduct a range of investigatory activities that may ultimately lead to immigration enforcement actions, including requesting records, providing notice to employees, serving subpoenas, or attending functions or meetings.[116] ICE officer presence at health care sites for any reason, such as to request information about noncitizens or to attend events, is likely sufficient to chill noncitizens from accessing services

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access-covid-19-vaccines-and-vaccine-distribution-sites.

108 *See* Licon, *supra* note 63 (noting that ICE and CBP sometimes bring noncitizens to the hospital for treatment and then detain them after they are discharged).

109 ICE Sensitive Locations Policy, *supra* note 97, at 2.

110 *Id.* at 2 (emphasis added). The policy also provides guidance to personnel if, during an enforcement action, they are "led to or *near* a sensitive location." *Id*. at 3 (emphasis added).

111 CBP Sensitive Locations Policy, *supra* note 97, at 1.

112 Meyer, *supra* note 59 (noting that the policy "appears to offer the agency some flexibility in where it can conduct raids").

113 ULLRICH & NAT'L IMMIGR. L. CTR., *supra* note 104, at 3-4; La Charite et al., *supra* note 63, at 55 (noting that their "alarming" finding that nearly 20% of providers surveyed were aware of immigration enforcement occurring at their health care institution "corroborate[s] reporting of such events in the media").

114 Katie Shepherd, *ICE Arrested an Undocumented Immigrant Just Outside a Portland Hospital*, WILLAMETTE WK. (Oct. 31, 2017), https://www.wweek.com/news/courts/2017/10/31/ice-arrested-an-undocumented-immigrant-just-outside-a-portland-hospital/.

115 ICE Sensitive Locations Policy, *supra* note 97, at 1.

116 *Id.* at 1.

at that site. CBP's policy does not specify the meaning of enforcement actions, but it appears to limit officers' conduct of investigatory activities more than the ICE policy.[117] Since noncitizens do not know which agency may be surveilling them, they must assume that the less protective policy always applies.

Further undermining their goal of assuring noncitizens that it is safe to access health care, the ICE and CBP sensitive locations policies permit enforcement activities at sensitive locations in a wide range of circumstances.[118] First, ICE and CBP officers may request to carry out an enforcement action at or near a sensitive location and a senior DHS official may approve such action at their discretion.[119] There are no limitations on a DHS official's ability to approve such actions, merely exhortations to "take extra care" to assess potential disruptions to a sensitive location's operations.[120] The ICE policy provides an example of when an enforcement action at a sensitive location may be approved: "if the only known address of a target is at or near a sensitive location."[121] A second exception to the sensitive locations policies applies when "exigent circumstances" exist; in such cases, officers need not obtain prior approval to conduct enforcement activities at sensitive locations.[122] Exigent circumstances include situations involving national security, terrorism, imminent risks to public safety, and the "imminent risk of destruction of evidence material to an ongoing criminal case."[123] Even if one agrees that enforcement action at health care sites should be permitted in exigent circumstances, the chilling effects of such actions will reverberate unless details of the circumstances are shared with the community. Third, CBP may conduct enforcement actions in hospitals when noncitizens who are already in their custody must be hospitalized.[124] Fourth, both CBP and ICE may conduct enforcement actions at or near international borders, including the "functional equivalent" of a border.[125] The CBP policy specifies, additionally, that enforcement activities "that

117 CBP Sensitive Locations Policy, *supra* note 97, at 1 (describing how "investigative activities" at or near sensitive locations must receive written approval from senior CBP officials).

118 *See* Lee et al., *supra* note 15, at 6 (noting that the policy "is not applied evenly in the U.S.").

119 ICE Sensitive Locations Policy, *supra* note 97, at 2 (listing the officials from whom ICE officers must obtain prior approval); CBP Sensitive Locations Policy, *supra* note 97, at 1 (same).

120 ICE Sensitive Locations Policy, *supra* note 97, at 2. *See* CBP Sensitive Locations Policy, *supra* note 97, at 1 (directing officers to "consider alternative measures that could achieve the enforcement objective without causing significant disruption to the normal activities or operations" of the sensitive location).

121 ICE Sensitive Locations Policy, *supra* note 97, at 2.

122 *Id.* at 2; CBP Sensitive Locations Policy, *supra* note 97, at 2.

123 ICE Sensitive Locations Policy, *supra* note 97, at 2-3. *See* CBP Sensitive Locations Policy, *supra* note 97, at 2.

124 CBP Sensitive Locations Policy, *supra* note 97, at 2. *See* Licon, *supra* note 63 (describing the policy as "discretionary and ambiguous when an enforcement action begins before a trip to a hospital or when an immigrant is already in custody").

125 CBP Sensitive Locations Policy, *supra* note 97, at 2; U.S. IMMIGR. & CUSTOMS ENF'T, *supra* note 101 (stating that the policy does not apply to operations "within the immediate vicinity of the

bear nexus to the border" may occur at sensitive locations.[126] The border exception to the sensitive locations policy is too vague for noncitizens to determine when it can be invoked. However, it explains how CBP agents in Texas were able to follow ten-year-old Rosa Maria Hernandez, who was in an ambulance, from a border checkpoint to the hospital, surveil her from within the hospital, and arrest her in her hospital bed immediately upon discharge without violating its sensitive locations policy.[127] Communities along the U.S.-Mexico border have been hit hard by the COVID-19 pandemic, and as of this writing, there is still no assurance from DHS that people passing through interior U.S. Border Patrol checkpoints to seek health care during the pandemic will be spared from immigration enforcement.[128] Fifth, the sensitive locations policies do not apply to local law enforcement officers who cooperate with ICE to perform immigration enforcement activities under the 287(g) program.[129] This exception explains how Blanca Borrego was arrested in an exam room at her gynecologist's office.[130]

The DHS sensitive locations policies are best characterized as agency guidance—not enforceable law—without strong accountability measures. Both policies state that they do not create a private right of action or any rights enforceable by law.[131] On its website, ICE describes a process by which people

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international border"). The functional equivalent of a border is "the first practical detention point after a border crossing or the final port of entry." YULE KIM, CONG. RSCH. SERV., PROTECTING THE U.S. PERIMETER: BORDER SEARCHES UNDER THE FOURTH AMENDMENT 7 (2009).

126 CBP Sensitive Locations Policy, *supra* note 97, at 2.

127 *See Government Releases 10-Year-Old Rosa Maria Hernandez After ACLU Files Lawsuit*, ACLU (Nov. 3, 2017), https://www.aclu.org/press-releases/government-releases-10-year-old-rosa-maria-hernandez-after-aclu-files-lawsuit; *see also* Licon, *supra* note 63 (describing a case in which a person fainted after her family was pulled over by CBP agents in Florida and was subsequently surveilled at the hospital). In September 2020, an undocumented teenager was detained in the hospital under similar circumstances, before being transferred to a detention facility and placed in removal proceedings. Her aunt, also undocumented, who accompanied her to the hospital was also arrested and detained separately by ICE. Montoya-Galvez, *supra* note 66.

128 *See* Memorandum from Carla L. Provost, Acting Chief, U.S. Border Patrol, U.S. Customs & Border Prot., on Medical Conveyances Transiting Through Checkpoints 1 (Jan. 5, 2018) (noting that only "[m]edical conveyances engaged in immediate emergency operations should always receive expedited transit through or around a checkpoint"); Jawetz & Chung, *supra* note 68 (urging DHS to issue such a statement). *See also* Maya Srikrishnan, *Border Patrol Activity in Rural North County Alarms Farmworkers, Advocates*, VOICE OF SAN DIEGO (May 26, 2020), https://www.voiceofsandiego.org/topics/government/immigration-enforcement-efforts-in-rural-north-county-alarm-farmworkers-advocates/ (suggesting that enforcement activity at interior checkpoints has increased since the COVID-19 pandemic began, including at checkpoints that some communities must traverse to access hospitals).

129 The 287(g) program deputizes state and local law enforcement agencies to perform certain immigration law enforcement actions. *See Delegation of Immigration Authority Section 287(g) Immigration and Nationality Act*, U.S. IMMIGR. & CUSTOMS ENF'T, (last updated May 20, 2021), https://www.ice.gov/identify-and-arrest/287g.

130 *See supra* text accompanying note 58.

131 CBP Sensitive Locations Policy, *supra* note 97, at 2; ICE Sensitive Locations Policy, *supra*

may report ICE actions that they believe are inconsistent with its sensitive locations policy.[132] However, neither the policies nor the agencies' websites describe the steps they will take after receiving a complaint. Also, because the policies do not describe any recourse for noncitizens who were arrested during an enforcement operation that violated any of the policies, there is no guarantee that individual officers or the agencies will be held accountable for violations in any way.[133]

Finally, even though the sensitive locations policies are relatively longstanding, they are not codified in law. The CBP policy reminds the reader that it "may be modified, superseded, or rescinded by CBP at any time without notice."[134] Both policies may be immediately modified or rescinded by senior DHS officials through issuance of a memorandum.

Overall, these features of the sensitive locations policies undermine their purpose of assuaging noncitizens' fears of accessing community services. Because so many important decisions are left to the individual discretion of immigration agency personnel—from what is considered a sensitive location, to how far from the site enforcement may occur, to whether exigent circumstances exist—the guarantee that the sensitive locations policies intend to provide is no guarantee at all. Considering the lack of clarity in the sensitive locations policies, the inadequate accountability for violations, and the absence of meaningful recourse for victims of policy violations, it should not be surprising to find that noncitizens take pains to avoid going to the doctor.

b. Health Information Privacy

Health information privacy laws protect citizens and noncitizens alike; however, noncitizens may have unique concerns that lead them to doubt the confidentiality of the information they share with health care providers. Fears that information disclosed or inadvertently revealed to health care providers may be shared with immigration authorities can discourage some noncitizens from seeking health care.

Health care providers are generally prohibited from disclosing personal information about their patients, which should be interpreted to include

note 97, at 3.

132 U.S. IMMIGR. & CUSTOMS ENF'T, *supra* note 101 (describing how to report violations to ICE Enforcement and Removal Operations or the Civil Liberties Division of the ICE Office of Diversity and Civil Rights). Advocacy groups recommend reporting violations by CBP to the CBP Information Center. *See* ULLRICH & NAT'L IMMIGR. L. CTR., *supra* note 104, at 6 (providing a phone number and website).

133 *See* ULLRICH & NAT'L IMMIGR. L. CTR., *supra* note 104, at 5 ("Without adequate accountability measures, ICE and CBP are effectively responsible for policing themselves.").

134 CBP Sensitive Locations Policy, *supra* note 97, at 2.

information about immigration-related matters so long as there is some relationship between the information and the provision of health care. The federal Health Insurance Portability and Accountability Act (HIPAA) Privacy Rules outline the protection of patient-specific information defined as "protected health information" (PHI).[135] The definition of PHI is broad and includes most but not all patient information that is within a health care provider's possession.[136] Health care providers may not typically have reason to inquire about patients' citizenship or immigration status, but such information can be clinically relevant.[137] Although there is very little case law analyzing whether certain categories of information constitute PHI and no case law addressing the question of whether immigration status should be considered PHI,[138] it is reasonable to argue that immigration status information should be considered PHI under the HIPAA Privacy Rules as long as a connection could be made to the patient's health condition, the provision of health care to the patient, or the payment for health care provided to the patient.[139] However, because immigration status information is not explicitly protected under the law, it is a source of uncertainty, and some immigrant advocacy groups advise health care providers to avoid documenting immigration-related information in medical and billing records.[140]

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135 45 C.F.R. § 160.103 (2021).

136 PHI is most "individually identifiable health information" that is "transmitted or maintained in any . . . form or medium," with limited exceptions. *Id*. Individually identifiable health information is defined as "a subset of health information, including demographic information collected from an individual, and: (1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (2) Relates to the past, present, or future physical or mental health condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provisions of health care to an individual; and (i) That identifies the individual; or (ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual." *Id*. *See* OFF. FOR CIV. RTS., U.S. DEP'T OF HEALTH & HUM. SERVS., GUIDANCE REGARDING METHODS FOR DE-IDENTIFICATION OF PROTECTED HEALTH INFORMATION IN ACCORDANCE WITH THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) PRIVACY RULE 5-6 (Nov. 26, 2012), https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/coveredentities/Deidentification/hhs_deid_guidance.pdf (indicating that, to assess whether information constitutes PHI, "[t]he relationship with health information is fundamental," and "[i]dentifying information alone, such as personal names, residential addresses, or phone numbers, would not necessarily be designated as PHI").

137 Scott J. Schweikart, *Should Immigration Status Information Be Considered Protected Health Information?*, 21 AMA J. ETHICS 32, 35 (2019). For example, it could come up during the medical history, in a screening for social determinants of health, when a patient requests medical evidence to support an immigration application, or to assist the patient with obtaining publicly funded health insurance.

138 *Id*. at 34.

139 *Id*. at 34; Cleek, *supra* note 88, at 1002 (concluding that disclosure of a patient's personal health information to DHS by a health care provider would likely violate HIPAA).

140 *See, e.g.*, NAT'L IMMIGR. L. CTR., HEALTH CARE PROVIDERS AND IMMIGRATION ENFORCEMENT: KNOW YOUR RIGHTS, KNOW YOUR PATIENTS' RIGHTS 3-4 (2017), https://www.nilc.org/wp-content/uploads/2017/04/Protecting-Access-to-Health-Care-2017-04-

One exception to the HIPAA Privacy Rules that could implicate immigration enforcement activities is for disclosures required by law.[141] Under HIPAA, health care providers are permitted to provide information to law enforcement officials when a request is pursuant to a warrant or other court order.[142] This might come in the form of an administrative subpoena in an immigration matter, issued by an Administrative Law Judge of the Executive Office for Immigration Review. ICE officers may serve subpoenas or otherwise request records from health care providers without violating the ICE sensitive locations policy.[143] However, health care providers are not obligated to respond to such requests for information under HIPAA; disclosure in such cases is merely permitted.[144] Providers must read their state laws in conjunction with HIPAA in order to understand whether they are required to disclose patient information in certain circumstances.[145]

Another exception to the HIPAA Privacy Rules that permits health care providers to disclose PHI without patient authorization—and that may be a source of concern and confusion among undocumented noncitizens in particular—relates to the reporting of criminal activity.[146] In such cases, "a covered entity may disclose to a law enforcement official [PHI] that the covered entity believes in good faith constitutes evidence of criminal conduct that occurred on the premises of the covered entity."[147] This exception would not apply in the case of an undocumented person who comes to a covered entity for the purpose of seeking health care or health coverage, because failing to have a valid legal status is not a violation of criminal law.[148] However, it explains why the health care providers who called the police on Blanca Borrego when they suspected that she had provided a fake driver's license as identification were within their rights to do so.[149] Importantly, even if a patient who a provider knows to be undocumented committed a crime on

17.pdf.

141 45 C.F.R. § 164.512(f)(1)(ii)(C) (2021) (describing the requirements for an administrative request).

142 § 164.512(f)(1).

143 *See* ICE Sensitive Locations Policy, *supra* note 97, at 1.

144 § 164.512(f)(1); *see* NAT'L IMMIGR. L. CTR., *supra* note 140, at 2.

145 NAT'L IMMIGR. L. CTR., *supra* note 140, at 2.

146 § 164.512(f)(5).

147 *Id*.

148 Schweikart, *supra* note 137, at 35.

149 *See* Solomon, *supra* note 58. Federal regulators determined that the disclosure to law enforcement was allowed under HIPAA. However, they fined the health system $2.4 million for subsequent disclosures of Borrego's name to the media after the incident provoked outrage. Mike Hixenbaugh, *Memorial Hermann to Pay $2.4M after Sharing Patient Name in Press Release*, CHRON.COM (May 10, 2017), https://www.chron.com/local/prognosis/article/Memorial-Hermann-to-pay-feds-2-4-million-after-11136432.php. The health system also agreed to implement policy changes to avoid breaches of patient privacy in the future. *Id*.; *see also* Michele Goodwin & Erwin Chemerinsky, *Pregnancy, Poverty, and the State*, 127 YALE L.J. 1270, 1285 (2018) (commenting that Borrego's case illustrates the impotency of the medical privacy rights she supposedly possessed).

the premises of a health clinic, the clinic staff would not be obligated to disclose the PHI relating to the patient's lack of immigration status.[150] The exception would permit, but not require, disclosure of PHI in that scenario.[151]

Finally, HIPAA permits health care providers to disclose PHI when a patient authorizes such disclosure, and some noncitizen patients may be required to do so as part of an immigration application process. Immigration officers may order a medical examination of an applicant for immigration benefits at any time.[152] Some immigration applicants, such as most LPR applicants, are required to undergo a medical examination in order to prove that they are not barred from admissibility to the United States for health-related reasons.[153] They do this by submitting a form that reports the results of a medical examination and that is completed by a doctor who is designated as a civil surgeon by U.S. Citizenship and Immigration Services (USCIS).[154] The completed form includes information relating to communicable diseases, any physical or mental health conditions with "associated harmful behavior," substance use disorders, and vaccination history.[155] It also includes a broad authorization to release information to USCIS from "any and all . . . records" that may be necessary to determine eligibility for the immigration benefit sought, and requires the applicant to authorize the release of the information in the form to any entity or person for immigration enforcement purposes.[156] Although, in this case, health information is being disclosed for a narrow purpose, the perception that private physicians are complicit with the administration and enforcement of immigration law may have a chilling effect.

Noncitizens' beliefs that their health care information is less protected under

150 Schweikart, *supra* note 137, at 35.

151 *See* Song, *supra* note 6, at 41-42 (highlighting the permissive aspect of the law enforcement exceptions in HIPAA). Although the patient's lack of immigration status may subsequently be discovered by law enforcement and shared with ICE, the likelihood that they will be subject to immigration enforcement as a result depends on the extent to which the jurisdiction cooperates with ICE and the seriousness of the crime. *See, e.g.*, *Immigration 101: What is a Sanctuary City?*, AMERICA'S VOICE (Oct. 9, 2019), https://americasvoice.org/blog/what-is-a-sanctuary-city/. Some who are opposed to immigration surveillance in health care generally may argue that it is justified when it is alleged that a serious crime has occurred at a health care site. *See* discussion, *supra* note 9.

152 *See Chapter 3 – Applicability of Medical Examination and Vaccination Requirement*, U.S. CITIZENSHIP & IMMIGR. SERVS. (May 28, 2021) https://www.uscis.gov/policy-manual/volume-8-part-b-chapter-3 (citing Matter of Arthur, 16 I. & N. Dec. 558 (B.I.A. 1978)).

153 *See* Immigration & Nationality Act of 1952, Pub. L. No. 414, § 212(a)(1)-(7), 66 Stat. 163, 182 (1952) (codified as amended at 8 U.S.C. § 1182(a)(1) (2018)).

154 U.S. CITIZENSHIP & IMMIGR. SERVS., FORM I-693, REPORT OF MEDICAL EXAMINATION AND VACCINATION RECORD 1, https://www.uscis.gov/sites/default/files/document/forms/i-693.pdf.

155 U.S. CITIZENSHIP & IMMIGR. SERVS., INSTRUCTIONS FOR REPORT OF MEDICAL EXAMINATION AND VACCINATION RECORD 6 (2019), https://www.uscis.gov/sites/default/files/document/forms/i-693instr.pdf.

156 U.S. CITIZENSHIP & IMMIGR. SERVS., *supra* note 154, at 2.

the law than the law mandates may be informed by knowledge of how health care institutions have participated in immigration enforcement in the past, anecdotal evidence of health care provider complicity with immigration enforcement in the present, and the general policy climate. Historically, state medical officials and hospital staff have identified noncitizens who were deportable based on mental health grounds, serving as important sources of information to immigration authorities.[157] In the current policy climate, in which undocumented noncitizens are cautiously optimistic about proposed immigration reforms after four years of heightened enforcement, accessing health care may still seem fraught with danger. For example, when the COVID-19 vaccination distribution began in early December 2020, state governors, state health officials, members of Congress, and others raised concerns about provisions in the Data Use Agreement between states and the Centers for Disease Control and Prevention (CDC) because the agreements mandated the collection of personal identifiable information and permitted this information to be shared with other federal agencies.[158] Although the CDC has since clarified that it will not seek SSNs, driver's license numbers, or passport numbers—information particularly likely to chill noncitizens from participation—and that vaccine administration data will not be used for immigration enforcement purposes,[159] health care providers and advocates for immigrants continue to report that noncitizens are afraid to obtain the vaccine.[160] News stories reporting that health care providers have declined to provide vaccines to noncitizens who are not able to provide a SSN increase fear and confusion in immigrant communities.[161] Even a direct statement from DHS supporting "equal access to the COVID-19 vaccines and vaccine distribution sites for undocumented immigrants" appears to

157 Polly J. Price, *Infecting the Body Politic: Observations on Health Security and the "Undesirable" Immigrant*, 63 KAN. L. REV. 917, 938, 940 (2015).

158 *See, e.g.*, Sheryl Gay Stolberg, *Some States Balk After C.D.C. Asks for Personal Data of Those Vaccinated*, N.Y. TIMES (Dec. 8, 2020), https://www.nytimes.com/2020/12/08/us/politics/cdc-vaccine-data-privacy.html.

159 CTRS. FOR DISEASE CONTROL & PREVENTION, DATA USE AND SHARING AGREEMENT TO SUPPORT THE UNITED STATES GOVERNMENT'S COVID-19 EMERGENCY RESPONSE JURISDICTION IMMUNIZATION AND VACCINE ADMINISTRATION DATA AGREEMENT 24 app. G (n.d.), https://www.cdc.gov/vaccines/covid-19/reporting/downloads/vaccine-administration-data-agreement.pdf.

160 *See, e.g.*, Jazmin Orozco Rodriguez, *Battling an Information Access Gap, State and Local Campaigns Work to Provide COVID-19 Vaccine Information to Latinos*, NEV. INDEP. (Feb. 14, 2021), https://thenevadaindependent.com/article/battling-an-information-access-gap-state-and-local-campaigns-work-to-provide-covid-19-vaccine-information-to-latinos (describing a targeted campaign in Nevada designed to address noncitizens' concerns such as "whether their private information will be shared and whether receiving the vaccine could affect their immigration status").

161 *See, e.g.*, Anastasiya Bolton, *Rio Grande Valley Man Denied COVID Vaccine Due to Citizenship Status*, KHOU.COM (Feb. 24, 2021), https://www.khou.com/article/news/deep-dive-texas/covid-vaccine-denied-citizenship/285-705a8c14-80ca-4eca-b83b-a94e43cedd9a (noting that at least fourteen people were turned away from the vaccine site for this reason).

be insufficient to overcome noncitizens' learned fears of immigration surveillance in health care.[162]

2. Surveillance of Publicly Funded Health Care Programs

This subsection describes the laws and policies that permit and prohibit information-sharing between the agencies that administer publicly funded health programs and DHS. These agencies collect a wide range of personal data about applicants, including immigration status. Under certain circumstances, immigration authorities can access this data, putting certain immigration applications in jeopardy and placing some noncitizens at increased risk of deportation. An analysis of the law validates some of noncitizens' beliefs that information about their enrollment in Medicaid, the Children's Health Insurance Program (CHIP), or insurance from the ACA Marketplace can compromise future immigration processes. However, it also reveals that fears of negative immigration consequences from enrolling in publicly funded health coverage are greater than warranted for many noncitizens.

Public benefit agencies possess a broad array of sensitive, personal information about applicants and recipients. Applications for Medicaid, "the single largest source of health coverage in the United States,"[163] typically request names, birthdates, SSNs, home and work addresses and telephone numbers, marital status, citizenship or immigration status, race and ethnicity, income, assets, certain household expenses, and tax filing information for every member of an applicant's household, as well as each household member's relationship to the applicant.[164] In order to qualify for certain categories of Medicaid or to obtain federal reimbursement for treatment of emergency medical conditions through emergency Medicaid, applicants must provide detailed information about medical diagnoses and treatments. Public benefits agencies possess a record of current and past

162 *DHS Statement on Equal Access to COVID-19 Vaccines and Vaccine Distribution Sites*, *supra* note 107.

163 *Eligibility*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/eligibility/index.html (last visited Feb. 16, 2021).

164 *See, e.g.*, PA. DEP'T OF HUM. SERVS., PENNSYLVANIA APPLICATION FOR BENEFITS (n.d.), https://www.dhs.pa.gov/Services/Assistance/Documents/Benefits%20Applications/PA-600-2-20-Final.pdf. In addition, applications may request information about a wide range of life circumstances, such as whether the applicant or household members are in school, the U.S. military, foster care, or treatment for drug or alcohol abuse; if they are pregnant, disabled, or survivors of domestic abuse; and if they have been disqualified from benefits in the past, have unpaid medical bills, have been offered health insurance from an employer, or have had health insurance coverage in the past. *Id*. Applicants are not required to submit all such information for household members who are not to be included in the application, even though there is space to provide it on the application. *See, e.g.*, *id*. at 2 (noting, for sections of the application relating to household members, "[a]nswer the questions below if you are applying for this person").

recipients' applications for and enrollment in public benefits. Finally, all of the major subsidized health coverage programs—Medicaid, CHIP, and insurance on the Affordable Care Act (ACA) Health Insurance Marketplace—require noncitizen applicants to provide proof of a valid immigration status.[165]

The primary way in which immigration authorities access information about noncitizens held by public benefits agencies is by compelling noncitizens to authorize the release of such information. This occurs when certain noncitizens apply to become LPRs, an immigration process. The public charge law restricts the ability of certain noncitizens to become LPRs if they are considered likely to become dependent on the U.S. government for support. New regulations—anticipated from the first days of the Trump Administration in 2017, finalized by DHS in 2019, and rescinded in 2021—expanded the scope of the law in many ways, including by adding Medicaid to the list of public benefits considered in the public charge analysis. The 2019 regulations chilled noncitizens from applying for Medicaid—even those who are exempt from the public charge determination altogether or whose use of public benefits would not be considered as a negative factor in the public charge analysis. Similarly, Trump-era policies relating to immigration sponsorship have discouraged noncitizens from enrolling in public benefits by increasing the risk that enrolling in such benefits will have immigration consequences. Finally, the Trump Administration's novel interpretations of what is considered "fraud" in immigration applications raised fears that any information submitted to public benefits agencies would be scrutinized and potentially used as a pretext for immigration enforcement activities.

Both DHS and the Department of Health and Human Services (HHS) have long acknowledged that collaboration between public benefits agencies and immigration authorities will chill noncitizen enrollment in public benefits and have thus taken some steps to counter it,[166] but the law still permits information sharing in certain circumstances. The laws relating to public charge determinations, immigration sponsorship, and the fraud exception to privacy protections in public benefits applications were in place prior to 2017; their impact was simply ratcheted up through regulations and rhetoric. Even as the Biden Administration begins to undo some of these regulations in the interest of public health, it may struggle to regain trust in immigrant communities.[167] The chilling effects of the laws still on

165 *See* Social Security Act of 1935 § 1137(d), 42 U.S.C. § 1320b-7(d) (2018); 42 U.S.C. § 18081(b)(2) (2018) (providing for the ACA Health Insurance Marketplace); 42 C.F.R. § 457.340(d) (2021) (providing for CHIP). The eligibility criteria relating to immigration status for each of these programs is different and complex. For an overview, see Medha D. Makhlouf, *Laboratories of Exclusion: Medicaid, Federalism & Immigrants*, 95 N.Y.U. L. REV. 1680, 1699-72 (2020).

166 *See, e.g.*, U.S. IMMIGR. & CUSTOMS ENF'T, CLARIFICATION OF EXISTING PRACTICES RELATED TO CERTAIN HEALTH CARE INFORMATION (2013), https://www.ice.gov/doclib/ero-outreach/pdf/ice-aca-memo.pdf.

167 *See, e.g.*, Orozco Rodriguez, *supra* note 160 (quoting an organizer with a COVID-19

the books—which also preexisted the Trump Administration—will likely persist.

a. Public Charge Determinations

One way in which immigration authorities obtain information about noncitizens' enrollment in public benefit programs is by requiring disclosure of this information from noncitizens who are subject to the public charge ground of inadmissibility and are applying to become LPRs. If USCIS determines that an LPR applicant is likely to become a public charge at any time in the future, their application is denied.[168] The public charge inadmissibility analysis involves weighing numerous factors relating to "age, health, family status, assets, resources and financial status, education, and skills, among other factors."[169] One such factor is prior receipt of public benefits, including (for a time under the 2019 regulations) Medicaid for adults in most eligibility groups.[170] LPR applicants must provide this information to USCIS under penalty of perjury *and* authorize USCIS to verify this information with the agencies administering the public benefits in question.[171]

In order to receive LPRs' Medicaid enrollment information, USCIS must request it—as well as authorization for government agencies to disclose it—from LPRs directly, because such information is otherwise protected from disclosure under federal law. The federal Medicaid statute requires states to safeguard information received about Medicaid applicants, beneficiaries, and non-applicant household members by restricting disclosure "to purposes directly connected with the administration of the plan."[172] Regulations specify that the types of activities

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vaccination campaign in Nevada who describes fear and mistrust in the Latino immigrant community as "*las secuelas* (the aftermath) of the last administration").

168 8 U.S.C. § 1182(a)(4) (2018).

169 Field Guidance on Deportability and Inadmissibility on Public Charge Grounds, 64 Fed. Reg. 28,689, 28,690 (Mar. 26, 1999).

170 Letter from Tracy L. Renaud, Senior Off. Performing the Duties of the Dir., U.S. Citizenship & Immigr. Servs., to Interagency Partners 1-2 (Apr. 12, 2021), https://www.uscis.gov/sites/default/files/document/notices/SOPDD-Letter-to-USCIS-Interagency-Partners-on-Public-Charge.pdf. Under the current policy, which is the policy that was in effect prior to the 2019 public charge regulations, enrollment in Medicaid is considered only when it is used for coverage of long-term institutional care. *Id*. at 2. Under the 2019 rule, use of Medicaid was not considered for noncitizens under the age of 21 and women during pregnancy and for sixty days after the pregnancy ends. Inadmissibility on Public Charge Grounds, 84 Fed. Reg. 41,292, 41,297 (Aug. 14, 2019) (to be codified at 8 C.F.R. pts. 103, 212, 213, 245, 248). Use of emergency Medicaid, a reimbursement mechanism for treatment of emergency medical conditions in noncitizens who are excluded from Medicaid, was also not considered under the 2019 rule. *Id*. at 41,384.

171 U.S. CITIZENSHIP & IMMIGR. SERVS., DEP'T OF HOMELAND SEC., OMB NO. 1615-0023, FORM I-485, APPLICATION TO REGISTER PERMANENT RESIDENCE OR ADJUST STATUS 13, 15 (2021), https://www.uscis.gov/sites/default/files/document/forms/i-485.pdf.

172 42 U.S.C. §§ 1320b-7(a)(5), 1396a(a)(7)(A)(i) (2018); 42 C.F.R. § 431.300(b)-(c) (2021) (stating that such safeguards apply to non-applicants, in addition to applicants and beneficiaries).

that are "directly connected with" Medicaid administration are limited to: "(a) Establishing eligibility; (b) Determining the amount of medical assistance, (c) Providing services for beneficiaries; and (d) Conducting or assisting an investigation, prosecution, or civil or criminal proceeding related to administration of the [state Medicaid] plan."[173] They further specify the types of information to be safeguarded, including names and addresses, SSNs, information used to verify income eligibility, medical information, and "[s]ocial and economic conditions or circumstances."[174] Providing information to federal immigration authorities about a noncitizen's receipt of Medicaid benefits is not a purpose directly related to Medicaid administration.[175] The Centers for Medicare & Medicaid Services (CMS), the federal agency responsible for administering Medicaid, is required to have specific criteria regarding the release and use of information about applicants for and beneficiaries of Medicaid, and may only provide access to such information to agencies that are subject to standards of confidentiality comparable to CMS's criteria.[176]

The major effect of the 2019 public charge regulations was to chill noncitizens from applying for public benefit programs, including publicly funded health insurance, because of the perception that any use of any public benefit would increase the risk that a future immigration application would be denied.[177] Many sources contribute to this widespread belief among noncitizens—even those whose enrollment in Medicaid would not trigger immigration consequences. First, there was confusion about how the 2019 public charge regulation applied. Second, there may be confusion about the extent of the privacy protections in Medicaid because public benefits agencies are generally permitted and sometimes required to disclose information about applicants for other public benefit programs to immigration authorities. Third, prior interactions with immigration authorities may have left noncitizens distrustful of any official assurances. Consequently,

173 42 C.F.R. § 431.302 (2021).

174 *Id.* § 431.305.

175 *See Id.* § 431.306(e) (stating that Medicaid agencies' policies on safeguarding information "must apply to all requests for information from outside sources, including governmental bodies, the courts, or law enforcement officials"); NAT'L IMMIGR. L. CTR., PRIVACY PROTECTIONS IN SELECTED FEDERAL BENEFITS PROGRAMS 1-2 (2018), https://www.nilc.org/wp-content/uploads/2018/03/privacy-protections-fed-programs-tbl-2018.pdf (citing Letter from Sally Richardson, Ctr. for Medicaid and State Operations, to State Medicaid Directors (Dec. 17, 1997) (on file with National Immigration Law Center); *see also* 42 C.F.R. § 431.306(f)-(h) (2021) (specifying circumstances in which a Medicaid agency may release information to courts or other agencies).

176 § 431.306.

177 Medha D. Makhlouf & Jasmine Sandhu, *Immigrants and Interdependence: How the COVID-19 Pandemic Exposes the Folly of the New Public Charge Rule*, 115 NW. U. L. REV. ONLINE 146, 151 (2020). The 2019 public charge rule stated that merely applying for a public benefit "may suggest a likelihood of future receipt" of public benefits. Inadmissibility on Public Charge Grounds, 84 Fed. Reg. 41,292, 41,366 (Aug. 14, 2019).

noncitizens tend to err on the side of caution and decline to enroll in publicly funded health insurance. Each of these sources of belief about public charge are examined in detail in the remainder of this subsection.

For good reason, noncitizens were and remain confused about how the 2019 public charge rule changed the relationship between enrollment in publicly funded health insurance and eligibility for LPR status. The 217-page final rule is so complex that it is nearly impenetrable. Basic information about how the rule applied—such as who was subject to public charge, whose public benefits use was considered in the analysis, and which public benefit programs were considered—was frequently misinterpreted.[178] For example, CHIP and ACA Marketplace coverages were not considered to be public benefits in the public charge analysis,[179] but it appears that the 2019 regulations chilled noncitizen enrollment in those programs as well.[180] Misinformation about the operation of the rule was rampant, a consequence of its complexity but also of the anti-immigrant rhetoric that surrounded its promulgation. Various versions of the rule were leaked to the media multiple times before the rule was finalized, stoking fears. Some noncitizens declined to enroll in public benefits years before the rule began to be implemented, in anticipation of a change in the law that would view such enrollment unfavorably. Finally, since immigration officers have broad discretion to weigh an applicant's use of public benefits against other factors in the public charge determination, some noncitizens may choose to "play it safe" by avoiding use of public benefits at all costs.[181] Moreover, despite the fact that the 2019 public charge rule has been rescinded, its chilling effects are likely to linger.[182] An attempt by a group of state

178 *See* Makhlouf & Sandhu, *supra* note 177, at 156.

179 In the proposed rule, DHS sought public comments on whether to add CHIP to the list of public benefits considered in the analysis. Inadmissibility on Public Charge Grounds, 83 Fed. Reg. 51,114, 51,173-74 (Oct. 10, 2018) (to be codified at 8 C.F.R. pts. 103, 212, 213, 214, 245, 248).

180 *See, e.g.*, KAISER FAM. FOUND., CHANGES TO "PUBLIC CHARGE" INADMISSIBILITY RULE: IMPLICATIONS FOR HEALTH AND HEALTH COVERAGE 4 (2019), http://files.kff.org/attachment/Fact-Sheet-Changes-to-Public-Charge-Inadmissibility-Rule-Implications-for-Health-and-Health-Coverage (describing reports of members of immigrant families declining to enroll in or disenrolling from CHIP due to fears relating to public charge); Charles Gaba & Emily Gee, *How Trump's Policies Have Hurt ACA Marketplace Enrollment*, CTR. FOR AM. PROGRESS (Apr. 16, 2020), https://www.americanprogress.org/issues/healthcare/news/2020/04/16/483362/trumpspolicies-hurt-aca-marketplace-enrollment/ (attributing, in part, declines in Marketplace coverage enrollment to the new public charge rule).

181 Makhlouf & Sandhu, *supra* note 177, at 156-57; Super, *supra* note 5, at 556 (describing how immigration officers have interpreted public charge inadmissibility unevenly because of the broad discretion they have and noting that many immigration attorneys advise their clients to "avoid virtually all public benefits").

182 *See* ALMA GUERRERO ET AL., UCLA LATINO POL'Y & POL. INITIATIVE, FOREGOING HEALTHCARE IN A GLOBAL PANDEMIC: THE CHILLING EFFECTS OF THE PUBLIC CHARGE RULE ON HEALTH ACCESS AMONG CHILDREN IN CALIFORNIA 4, 6, 12 (2021), https://latino.ucla.edu/wp-content/uploads/2021/04/LPPI_Foregoing-Healthcare-in-a-Global-Pandemic_04.07.2021.pdf.

attorneys general to defend the 2019 public charge rule, an effort abandoned by the Biden Administration, leaves open the possibility that the 2019 rule could be implemented again someday.[183]

Another reason why noncitizens may believe that enrolling in publicly funded health insurance could place future immigration applications at risk is that they are not aware of or do not trust the relatively strong privacy protections in the laws governing Medicaid,[184] CHIP,[185] and Marketplace coverage.[186] While public benefits agencies are restricted from disclosing information about applicants to or recipients of these programs for reasons unrelated to program administration, privacy protections in other public benefit programs are not as strong. Public benefits agencies are required or permitted to disclose information about applicants and recipients to immigration authorities in certain circumstances. In 1996, the Personal Responsibility and Work Opportunity Reconciliation Act (PRWORA) created a new requirement for federal and state agencies administering certain federal public benefit programs to report to immigration authorities the names, addresses, and other identifying information about people who they know to be unlawfully present in the United States.[187] Among the programs subject to the requirement is the Supplemental Nutrition Assistance Program (SNAP), a program for which many Medicaid recipients qualify. Under PRWORA and a similar

183 *See* John Kruzel & Harper Neidig, *Supreme Court Rebuffs GOP Bid to Revive Trump's 'Public Charge' Rule*, THE HILL (Apr. 26, 2021), https://thehill.com/regulation/court-battles/550244-supreme-court-rebuffs-gop-bid-to-revive-trumps-public-charge-rule.

184 *See supra* text accompanying notes 172-176. *See generally* U.S. IMMIGR. & CUSTOMS ENF'T, *supra* note 166 (confirming that information submitted in applications for Medicaid, CHIP, or Marketplace coverage are not used for immigration enforcement purposes).

185 42 C.F.R. § 457.1110(b) (2021) (requiring CHIP programs to comply with Medicaid's privacy protections).

186 Patient Protection and Affordable Care Act § 1411(g)(2), 42 U.S.C. § 18081(g)(2) (2018) (stating that information obtained from applicants for coverage through the Health Insurance Marketplace must be used for the sole purpose of "ensuring the efficient operation of the Exchange"); 45 C.F.R. § 155.260(a) (2021) (stating that personally identifiable information may only be used or disclosed for specific functions, such as eligibility determination or enrollment in health insurance plans); § 155.260(e)(3) (stating that the Marketplace's data-sharing arrangements with other agencies must "[b]e equal to or more stringent than the requirements for Medicaid programs").

187 Personal Responsibility and Work Opportunity Reconciliation Act (PRWORA) § 404(b), 42 U.S.C. §§ 608(g), 611a (2018); Responsibility of Certain Entities to Notify the Immigration and Naturalization Service of Any Alien Who the Entity "Knows" Is Not Lawfully Present in the United States, 65 Fed. Reg. 58,301, 58,302 (Sept. 28, 2000) (clarifying that state public benefits agencies subject to the reporting requirement are obligated to report information under this provision only when they find, through receipt of a Final Order of Deportation or similar documentation from an immigration agency, that an applicant is removable from the United States). The fact that this requirement has been interpreted narrowly does not weaken the argument that there are exceptions to privacy protections in public benefits programs that could reasonably lead noncitizens to tread cautiously when considering whether to apply for public benefits. Without legal assistance to confirm that their information is not at risk of disclosure to immigration authorities, noncitizens may decline to apply.

provision in the Illegal Immigration Reform and Immigrant Responsibility Act (IIRIRA) designed to facilitate information sharing between state and local government and federal immigration authorities, state and local government entities and officials may not be restricted by law from sending information about a person's immigration status to federal immigration authorities.[188] Although the constitutionality of these provisions is currently the subject of a circuit split, they remain enforceable in parts of the country.[189] Noncitizens' concerns about the risks of engaging with the public benefits system at all are understandable, given that privacy protections are uneven among programs. Such concerns are heightened when, as in many states, a single public benefits agency administers multiple public benefits programs, which often have a single application process.

Noncitizens' decisions about enrolling in publicly funded health care may also be influenced by distrust of the government, which is in turn informed by anecdotal evidence, prior interactions with immigration authorities, or their experiences applying for public benefits. If a person is arrested by immigration authorities after receiving medical treatment or enrolling in Medicaid, noncitizens may infer that the person's pursuit of health care triggered the arrest, even if there is no evidence of a connection. They may understand "medical deportations," about which news stories appear periodically, as immigration enforcement actions, even though they are privately arranged by hospitals.[190] Long-residing noncitizens may recall prior policies, some of which were ultimately struck down as unconstitutional, that encouraged information-sharing between public benefits agencies and immigration authorities.[191]

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188 Illegal Immigration Reform and Immigrant Responsibility Act (IIRIRA) § 642, 8 U.S.C. § 1373(a) (2018) (referring to the Immigration and Naturalization Service (INS), whose functions were largely assumed by USCIS, ICE, and CBP under the Homeland Security Act of 2002); PRWORA § 434, 8 U.S.C. § 1644 (2018).

189 *See* Mary Ann McNulty, Comment, *A Doctrine Without Exception: Critiquing an Immigration Exception to the Anticommandeering Rule*, 169 U. PA. L. REV. 241, 243 (2020) (discussing the Second Circuit's decision finding the provisions to be constitutional and not in violation of the anticommandeering doctrine, which diverged from the decisions of the Third, Seventh, and Ninth Circuits). These provisions have gained renewed attention in the context of a 2017 federal regulation that threatened to withdraw federal police funding from jurisdictions that refused to certify compliance with them.

190 Medical deportations typically feature noncitizens who have been injured and are in need of long-term care but cannot be discharged from the hospital because they do not have health insurance. In such cases, some hospitals have arranged to transport patients to their countries of origin to avoid incurring additional costs. *See* Price, *supra* note 157, at 938 (describing the historical context for today's fears of public charge, including the common early-twentieth-century practice of state mental health institution "engineering" the deportation of their noncitizen patients).

191 *See* PARK, *supra* note 1, at 43-45 (describing the chilling effects of a San Diego County policy that required the public benefits agency administering Medicaid to put up posters stating "[p]lease be aware that we can send any information you give us to [Immigration and Naturalization Service]").

The immigration or public benefits application processes themselves can be sources of distrust. For example, the "Declaration of Self-Sufficiency," the form used by LPR applicants to prove that they were not inadmissible under the 2019 public charge regulations, requested information about current or past receipt of Medicaid even if such receipt was categorically excluded from consideration in the public charge analysis.[192] The fact that USCIS requested information about any prior receipt of Medicaid, regardless of the circumstances or how long ago one was enrolled, only confirmed suspicions that any receipt of public benefits would be viewed unfavorably by immigration authorities. Similarly, although the Medicaid statute and ICE policy[193] protect an applicant's information from being used for immigration enforcement purposes, simply having to submit immigration documents to the public benefits agency for verification of immigration status can raise concerns about applying.[194] HHS has acknowledged the potential chilling effect of requests for information about immigration status and SSNs on noncitizens' health care access,[195] and encourages state health and welfare officials to counter the effect by clarifying the laws relating to requests for such information and making certain changes to their application forms and processes.[196] For

192 U.S. CITIZENSHIP & IMMIGR. SERVS., *supra* note 19, at 8; U.S. CITIZENSHIP & IMMIGR. SERVS., DEP'T OF HOMELAND SEC., INSTRUCTIONS FOR DECLARATION OF SELF-SUFFICIENCY 8-9 (2019); *see also* Super, *supra* note 5, at 558 (describing how application forms for cancellation of removal and suspension of deportation, two highly discretionary forms of immigration relief, request information about the applicant's and their family members' receipt of public benefits even though "[t]he legal justification for these questions is unclear").

193 U.S. IMMIGR. & CUSTOMS ENF'T, *supra* note 166, at 1 (stating that "ICE does not use information . . . that is obtained for purposes of determining eligibility for [health] coverage as the basis for pursuing a civil immigration enforcement action . . . .").

194 The Systematic Alien Verification for Entitlement (SAVE) system was established in 1986 to enable public benefits agencies to obtain immigration status information about noncitizen applicants in order to determine eligibility. Immigration Reform and Control Act of 1986 (IRCA), Pub. L. No. 99-603, § 121, 100 Stat. 3359, 3384-94 (1986). Although DHS is prohibited from using any information submitted to SAVE for immigration enforcement activities, simply requesting immigration documents may chill some noncitizens and their family members from applying for benefits. 42 U.S.C. § 1320b-7 note (Immigration and Naturalization Service to Establish Verification System by October 1, 1987) (stating that the system "shall not be used by the Immigration and Naturalization Service for administrative (non-criminal) immigration enforcement purposes").

195 U.S. DEP'T OF HEALTH & HUM. SERVS. & U.S. DEP'T OF AGRIC., POLICY GUIDANCE REGARDING INQUIRIES INTO CITIZENSHIP, IMMIGRATION STATUS AND SOCIAL SECURITY NUMBERS IN STATE APPLICATIONS FOR MEDICAID, STATE CHILDREN'S HEALTH INSURANCE PROGRAM (SCHIP), TEMPORARY ASSISTANCE FOR NEEDY FAMILIES (TANF), AND FOOD STAMP BENEFITS (2013), https://www.hhs.gov/civil-rights/for-individuals/special-topics/national-origin/tri-agency/index.html.

196 *Id.*; U.S. DEP'T OF HEALTH & HUM. SERVS. & U.S. DEP'T OF AGRIC., POLICY GUIDANCE REGARDING INQUIRIES INTO CITIZENSHIP, IMMIGRATION STATUS AND SOCIAL SECURITY NUMBERS IN STATE APPLICATIONS FOR MEDICAID, STATE CHILDREN'S HEALTH INSURANCE PROGRAM (SCHIP), TEMPORARY ASSISTANCE FOR NEEDY FAMILIES (TANF), AND FOOD STAMP BENEFITS: QUESTIONS AND ANSWERS (2006), https://www.hhs.gov/sites/default/files/triagencyq%26as.pdf.

example, HHS advises states to refrain from requiring applicants to provide citizenship or immigration status information about household members who are not applying for benefits, in line with Medicaid regulations.[197] Not all states have taken such practical steps to address chilling effects, which likely continues to discourage members of mixed-status families from applying for benefits for which they are eligible.[198]

b. Immigration Sponsorship

Noncitizens who have immigration sponsors are subject to immigration surveillance of their enrollment in Medicaid or CHIP in certain circumstances, which can deter them from applying for these programs. Specifically, public benefits agencies are required to share information about sponsored immigrants who receive federal means-tested public benefits and their sponsors with the Attorney General. In addition, if a public benefits agency obtains a final judgment against an immigration sponsor for reimbursement of the cost of benefits provided to a noncitizen, it may provide a copy of the judgment to USCIS.[199] These modes of monitoring noncitizens' involvement with the public benefits system are part of the web of immigration surveillance that generates health care system avoidance.

The purpose of the immigration sponsor requirement for certain noncitizens is to ensure that they do not become a public charge. An immigration sponsor is a U.S. resident who assumes financial responsibility for a noncitizen, typically a family member, who intends to live in the United States permanently.[200] Certain LPR applicants are required to submit an "affidavit of support" from one or more sponsors as evidence that they will not become a public charge.[201] When a

197 42 C.F.R. § 435.907(e)(1) (2021) (prohibiting states from requiring applicants to provide information that is not strictly necessary to make an eligibility determination); Medicaid Program; Eligibility Changes Under the Affordable Care Act of 2010; Final Rule, 77 Fed. Reg. 17144, 17164 (Mar. 23, 2012) (to be codified at 42 C.F.R. pts. 431, 435, 457) (stating that citizenship and immigration status information of household members who are not applying for benefits is not strictly necessary to make an eligibility determination).

198 *See* Super, *supra* note 5, at 560 (describing HHS Office of Civil Rights' investigations in the late 1990s and early 2000s finding that states continued to improperly request information from non-applicant household members). Requests for any information about an undocumented or ineligible noncitizen household member may, unfortunately, deter some eligible people from applying for Medicaid. *See id*. at 561 (noting that the process of verifying a household member's income could reveal their lack of immigration status). Such concerns are heightened in anti-immigrant policy climates. *Id*.

199 *See* 8 C.F.R. § 213a.4(c)(1)-(2) (2021).

200 8 U.S.C. § 1183a; 8 C.F.R. § 213a.2(b)-(c) (2021). Generally, sponsors must prove that they can support the sponsored immigrant at no less than 125% of the federal poverty line by providing evidence of sufficient income or assets. 8 U.S.C. § 1183a(a)(1)(A); § 213a.2(c)(2).

201 § 213a.2(a)(2) (describing who is required to submit an affidavit of support). Affidavits of support are legally enforceable contracts binding the sponsor to provide financial support to the

sponsored immigrant applies for a public benefit, the agency is supposed to "deem" all of the sponsor's income and resources to the sponsored immigrant when determining eligibility,[202] often disqualifying the noncitizen from financial eligibility for the benefit regardless of how much support their sponsor is in fact providing.[203] However, if the agency determines that a sponsored immigrant would "be unable to obtain food and shelter" if the benefit were not provided, considering the amount of support that the immigration sponsor is in fact providing, the agency may approve the application for benefits.[204] This is known as the indigence exception to the sponsor deeming rule.[205] An example of how it applies follows: A sponsored LPR is diagnosed with a chronic condition that is expensive to treat, like insulin-dependent Type II diabetes.[206] He does not have health insurance and therefore applies for Medicaid. If the public benefits agency determines that his immigration sponsor does not provide him with adequate support such that he would become indigent if he had to pay for treatment, they may approve the application.[207] In such cases, the agency must notify the Attorney General of the names of the sponsor and the sponsored immigrant.[208]

Receipt of public benefits by a sponsored immigrant may lead to another situation in which a public benefits agency shares information about sponsored immigrants and their sponsors with immigration authorities. When a noncitizen

immigrant. § 1183a(a)(B); § 213a.2(c)(2)(C)(2), (d). Under the 2019 public charge rule, affidavits of support were not dispositive in the public charge determination but were considered as one factor in the "totality of circumstances" analysis. Inadmissibility on Public Charge Grounds, 84 Fed. Reg. 41,292, 41,370 (Aug. 14, 2019) (to be codified at 8 C.F.R. pts. 103, 212, 213, 245, 248). Currently, LPR applicants can overcome public charge inadmissibility by submitting an affidavit of support alone, which was also the case prior to implementation of the 2019 rule.

202 8 U.S.C. § 1631(a) (2018).

203 Super, *supra* note 5, at 552 (noting that "deeming often will render the immigrant ineligible").

204 § 1631(e).

205 *Id*. There are other exceptions to sponsor deeming, but public benefits agencies are not required to notify the Attorney General when they are applied. *See, e.g.*, § 1631(b)(2) (providing an exception for noncitizens who have worked or can be credited with 40 qualifying quarters); § 1631(f) (providing an exception for survivors of domestic violence); Social Security Act of 1935 §§ 1903(v)(4)(B), 2107(e)(1)(N), 42 U.S.C. §§ 1396b(v)(4)(B),1397gg(e)(1)(N) (2018) (providing an exception for children 21 years of age or pregnant women); Letter from Calder Lynch, Acting Deputy Adm'r & Dir., Ctrs. for Medicare & Medicaid Servs., to State Health Officials 2-3 (Aug. 23, 2019), https://www.medicaid.gov/federal-policy-guidance/downloads/sho19004.pdf (providing an exception for applicants for emergency Medicaid).

206 Medication and supplies can cost up to $1,300 per month. *See Insulin Prices: How Much Does Insulin Cost?*, SINGLECARE (Jan. 27, 2020), https://www.singlecare.com/blog/insulin-prices/.

207 This assumes that the LPR is eligible for Medicaid in their state of residence. Medicaid eligibility varies substantially across states, but in most states, LPRs who have held that status for five years or more qualify for Medicaid so long as they meet the other eligibility criteria. *See* Makhlouf, *supra* note 165, at 1706-09.

208 § 1631(e)(2); *see* PARK, *supra* note 1, at 45 (describing how state agencies were not permitted to share information with immigration authorities prior to 1996).

qualifies for public benefits—whether eligibility is based on the indigence exception or not[209]—their sponsor is generally liable to the government for the cost of the benefit provided.[210] If a public benefits agency pursues legal action against an immigration sponsor for reimbursement of the costs of the benefits provided to a sponsored immigrant[211] and obtains a favorable judgment, it must share a copy of the judgment with USCIS to inform the agency that the immigration sponsor has not met their obligations under the affidavit of support.[212]

These notification provisions may deter some sponsored immigrants from applying for Medicaid or CHIP because of concerns about the impact on future immigration applications. Specifically, they may believe that any use of public benefits will negatively affect their own ability or their sponsor's ability to sponsor others.[213] When a noncitizen's immigration sponsor is a family member who plans to sponsor other family members in the future, as is often the case, enrolling in public benefits is perceived as a risk to family reunification.[214]

Such beliefs have long influenced noncitizens' decisions to apply for public benefits,[215] but they were validated and heightened during the Trump Administration. For example, chilling effects of the notification provisions were observed during prior administrations, even though immigration authorities at the time indicated that ICE used information obtained from the Attorney General only for "compiling statistical reports."[216] Such concerns were heightened during the Trump Administration because it stepped up enforcement of affidavits of support, including directing public benefits agencies to seek reimbursement for every dollar of public benefits provided to sponsored immigrants,[217] which is traditionally and

209 State methodologies for counting immigration sponsors' income and resources vary. *See* Letter from Calder Lynch, *supra* note 205, at 4.

210 8 U.S.C. § 1183a(a)(1)(B) (2018); 8 C.F.R. § 213a.2(d) (2021). *But see* §§ 1396b(v)(4)(B), 1397gg(e)(1)(N) (prohibiting states from seeking reimbursement for the costs of Medicaid and/or CHIP provided to lawfully present children and pregnant women).

211 State policies vary in terms of whether to pursue reimbursement from sponsors. *See* § 1183a(b); 8 C.F.R. § 213a.4(a)(1) (2021) (describing agencies' discretion to seek reimbursement).

212 § 213a.4(c)(1)-(2).

213 *See* Super, *supra* note 5, at 554.

214 *See* TIM O'SHEA & CRISTOBAL RAMÓN, BIPARTISAN POL'Y CTR., IMMIGRANTS AND PUBLIC BENEFITS: WHAT DOES THE RESEARCH SAY? 10 (2018) ("[S]ome immigrants reduced their use of Medicaid to protect their ability to sponsor family members for immigration, which requires individuals to show an ability to financially support themselves and their family members.").

215 *See, e.g.*, Super, *supra* note 5, at 553 (describing immigration sponsors' reasons for discouraging sponsored immigrants from applying for public benefits).

216 *Id.* (noting the "profound" chilling effects of the notification requirement during the Clinton, Bush, and Obama Administrations).

217 *See* Memorandum from Andrew Bremberg on Executive Order on Protecting Taxpayer Resources by Ensuring Our Immigration Laws Promote Accountability and Responsibility to Donald J. Trump, President of the U.S. §§ 2(c), 3(a)(iv), 3(i)(i) (Jan. 23, 2017) (instructing public benefits agencies and the Department of Justice to prioritize sponsor reimbursement); Press Release, Ken

legally a matter of state discretion.[218] It also proposed rules that would streamline information sharing between public benefits agencies and immigration authorities[219] and prevent immigration sponsors who had defaulted on their obligations in the past from serving in this role again.[220] The belief that one's own use of public benefits could jeopardize one's ability to serve as an immigration sponsor was often endorsed by immigration lawyers, despite the fact that DHS's policy under prior administrations was to *not* consider public benefits use by petitioning immigration sponsors when determining their ability to serve in the role.[221] The Trump Administration validated these concerns when it proposed a rule seeking to penalize petitioning immigration sponsors who had used public benefits, including Medicaid or CHIP, within the thirty-six-month period prior to filing an affidavit of support.[222] Although the Biden Administration has revoked the Trump-era Presidential Memorandum that triggered heightened enforcement of sponsors' obligations,[223] surveillance of public benefits use by sponsored

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Cuccinelli II, Acting Dir., U.S. Citizenship & Immigr. Servs., Presidential Memorandum on Enforcing the Legal Responsibilities of Sponsors of Aliens (June 14, 2019), https://www.uscis.gov/news/news-releases/presidential-memorandum-on-enforcing-the-legal-responsibilities-of-sponsors-of-aliens (directing USCIS officers "to remind individuals at their adjustment of status interviews of their sponsors' responsibilities"); Memorandum from Donald J. Trump, President of the U.S., on Enforcing the Legal Responsibilities of Sponsors of Aliens § 1 (May 23, 2019); *see also* Letter from Calder Lynch, *supra* note 205, at 4 (providing guidance to state officials administering Medicaid and CHIP on how to comply with the Presidential Memorandum on Enforcing the Legal Responsibilities of Sponsors of Aliens).

218 8 U.S.C. § 1183a(b) (2018); 8 C.F.R. § 213a.4(a)(1) (2021); *see also* O'SHEA & RAMÓN, *supra* note 214, at 5 (indicating that some states have chosen not to seek repayment from sponsors at all); ALISON SISKIN, CONG. RSCH. SERV., RL33809, NONCITIZEN ELIGIBILITY FOR FEDERAL PUBLIC ASSISTANCE: POLICY OVERVIEW 14-15 n.40 (2016) ("Despite the mandatory nature of the statutory language, Congress may lack constitutional authority to compel states to request reimbursement of state funds from sponsors, and the statute itself recognizes that the states have discretion on whether to follow up requests with further legal action.").

219 Affidavit of Support on Behalf of Immigrants, 85 Fed. Reg. 62,432, 62,447 (Oct. 2, 2020) (to be codified at 8 C.F.R. pt. 213a) (eliminating the requirement that public benefits agencies must subpoena USCIS to get a copy of an Affidavit of Support for purposes of enforcing sponsor reimbursement and revising the reporting procedure for reasons of efficiency).

220 *Id*. at 62,443 (describing a new requirement of a joint sponsor when the petitioning sponsor has been ordered to reimburse a public benefits agency for the cost of benefits provided to a noncitizen in the past).

221 *See* Super, *supra* note 5, at 554 (noting that this policy applied during the Clinton, Bush, and Obama Administrations); *see also* Affidavits of Support on Behalf of Immigrants, 71 Fed. Reg. 35,732, 35,738 (June 21, 2006) (to be codified at 8 C.F.R. pts. 204, 205, 213a, 299 (noting that any public benefits received are not considered as part of sponsor's income for purposes of meeting the income threshold, but not indicating that they are held *against* the petitioning sponsor in any way).

222 Affidavit of Support on Behalf of Immigrants, 85 Fed. Reg. at 62442 (noting that DHS considered "permanently barring" those who had ever received public benefits from becoming a sponsor but settled for a presumption that a petitioning sponsor who has received public benefits "may not have the ability to meet the support obligations while the Affidavit is in effect").

223 Exec. Order No. 14012, Restoring Faith in Our Legal Immigration Systems and

immigrants and their immigration sponsors is still required under law, and the proposed rules intensifying such surveillance remain pending.

c. Fraud Investigations

Privacy protections in Medicaid, CHIP, and the ACA Marketplace do not apply when an applicant is suspected of committing health care fraud or abuse because enforcement actions relating to benefits fraud and abuse are considered a purpose directly connected with the administration of benefits programs.[224] State Medicaid agencies are required to investigate complaints of Medicaid fraud or abuse by beneficiaries and refer such cases to law enforcement if fraud is suspected.[225] The definition of fraud "includes any act that constitutes fraud under applicable Federal or State law" and generally refers to the use of deceit or misrepresentation to receive a benefit for which one does not qualify.[226] Beneficiary abuse is defined as "practices that result in unnecessary cost to the Medicaid program."[227] The Office of Inspector General of HHS works with the Department of Justice to investigate and prosecute health care fraud and abuse in all publicly funded health insurance programs.[228] Fraud investigation units of state Medicaid agencies perform a similar function in conjunction with the state attorney general's office.

The precise process by which immigration authorities receive information about noncitizens who are investigated or prosecuted for health care fraud or abuse is not always clear,[229] but it is certain that ICE acts on such information to initiate removal proceedings. The ICE website contains several press releases describing

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Strengthening Integration and Inclusion Efforts for New Americans § 6, 86 Fed. Reg. 8,277 (Feb. 2, 2021).

224 42 C.F.R. § 431.302 (2021) (describing the exception in Medicaid*); Id.* § 457.1110(b) (describing the exception in CHIP).

225 The governing regulations describe methods for the identification, investigation, and referral of suspected Medicaid fraud. *Id.* § 455.13. Agencies are required to investigate complaints of Medicaid fraud received from any source. *Id.* § 455.14. They must refer cases of suspected fraud by beneficiaries "to an appropriate law enforcement agency." *Id*. § 455.15(b).

226 *Id.* § 455.2.

227 *Id*.

228 42 U.S.C. §§ 1320a-7c, 1395i(k) (2018) (establishing and funding the fraud and abuse control program).

229 *See, e.g.*, NAT'L IMMIGR. L. CTR., UNTANGLING THE IMMIGRATION ENFORCEMENT WEB 1-2 (2017), https://www.nilc.org/wp-content/uploads/2017/09/Untangling-Immigration-Enforcement-Web-2017-09.pdf (discussing the difficulty of describing all of the ways in which information is shared between immigration and law enforcement agencies because of a lack of transparency); Kalhan, *supra* note 10, at 76 ("[I]mmigration agencies . . . have long suffered from major transparency and accountability deficits . . . . No framework statutes govern or constrain immigration surveillance activities, which . . . also fall outside of the limited privacy protections available under the Privacy Act.").

immigration enforcement actions initiated because of health care fraud.[230] For example, one press release describes the arrest of a Jamaican citizen and New York resident who used another person's SSN to qualify for Medicaid.[231] Another describes how an investigation by ICE's Homeland Security Investigations unit led to the conviction of an undocumented noncitizen for Medicaid and SNAP fraud after she failed to accurately report her husband's income; she was likely deported after serving her prison sentence and, if so, may not be able to enter the United States ever again.[232]

The fraud exception may deter noncitizens from applying for publicly funded health insurance because of a fear that an innocent error or misunderstanding could have negative immigration consequences. As illustrated in the examples described in the previous paragraph, a conviction for health care fraud can be the basis for a finding of deportability. It can also render a noncitizen inadmissible under immigration law, meaning that they can be denied entry to the United States in the future or that their application for LPR status will be denied.[233] Any finding of health care fraud in a noncitizens' record may be considered a negative factor in future immigration applications in which a favorable exercise of discretion is required.[234]

Such fears are not unfounded, given the punitive immigration policies embraced by the Trump Administration and, before that, similar rhetoric by other politicians as well as prior instances of cooperation between public benefits and immigration agencies. A priority of the Trump Administration was to target the "abuse" of the public benefits system by noncitizens.[235] DHS, during this period,

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230 *See News Releases*, U.S. IMMIGR. & CUSTOMS ENF'T, https://www.ice.gov/newsroom?field_news_release_topics_tag_target_id=165&field_field_location_administrative_area=All&field_published_date_value%5Bmin%5D=&field_published_date_value%5Bmax%5D=&combine=medicaid&field_field_location_country_code=All (last visited July 16, 2021).

231 *HSI Arrests Jamaican Woman on Medicaid Fraud Charges*, U.S. IMMIGR. & CUSTOMS ENF'T (Aug. 23, 2013), https://www.ice.gov/news/releases/hsi-arrests-jamaican-woman-medicaid-fraud-charges.

232 *See* Report and Recommendation at 5, United States v. Puac-Gomez, No. 18-cr-3044-CJW (N.D. Iowa Feb. 7, 2019), ECF No. 31, https://www.govinfo.gov/content/pkg/USCOURTS-iand-3_18-cr-03044/pdf/USCOURTS-iand-3_18-cr-03044-0.pdf. Although it is not clear from the facts publicly available, since Ms. Puac-Gomez was not charged with identity theft or falsely claiming to be a U.S. citizen—and would not be eligible for Medicaid or SNAP based on her immigration status—it is likely that she had applied for benefits on behalf of eligible members of her household, possibly U.S.-citizen children.

233 INA § 212(a)(6)(C)(ii); *see also* Inadmissibility on Public Charge Grounds, 84 Fed. Reg. at 41,305 (discussing how false claims to U.S. citizenship in public benefits applications can result in a finding of inadmissibility).

234 Inadmissibility on Public Charge Grounds, 84 Fed. Reg. at 41,305; *see also* Jordan v. De George, 341 U.S. 223, 232 (1951) (holding that a fraud conviction is unequivocally considered a "crime involving moral turpitude").

235 *See, e.g.*, White House, *President Donald J. Trump is Ensuring Non-Citizens Do Not Abuse*

stepped up its investigations of naturalization fraud, employing a broad definition of fraud to engage in unprecedented efforts to denaturalize U.S. citizens on that basis.[236] Simultaneously, it began implementing a shadow policy of rejecting immigration applications for clerical oversights, such as leaving a response blank instead of writing "N/A" when a question does not apply to an applicant or typing an applicant's name when it was supposed to have been handwritten.[237] This contributed to a policy climate of intense scrutiny and suspicion of noncitizens in their applications for immigration and public benefits. However, such policies did not originate with the Trump Administration. In a 2006 congressional hearing titled "Examining the Impact of Illegal Immigration on the Medicaid Program and Our Healthcare Delivery System," for example, witnesses favoring stricter verification requirements of citizenship and immigration status in Medicaid testified about the "large and growing" problem of public benefits being provided to undocumented noncitizens.[238] A particularly egregious example of cooperation between immigration and public benefits agencies, purportedly to root out Medicaid fraud, occurred in California in the 1990s: the Port of Entry Detection (PED) program.[239] Immigration agents at the Los Angeles and San Francisco airports asked noncitizens returning to the United States whether they had previously used Medicaid.[240] If they had, they were advised to voluntarily reimburse the state public benefits agency for the cost of the benefits provided in order to avoid future immigration-related problems.[241] The program targeted

Our Nation's Public Benefit (Aug. 12, 2019), https://trumpwhitehouse.archives.gov/briefings-statements/president-donald-j-trump-ensuring-non-citizens-not-abuse-nations-public-benefit/?utm_source=twitter&utm_medium=social&utm_campaign=wh.

236 *See* Cassandra Burke Robertson & Irina D. Manta, *(Un)civil Denaturalization*, 94 N.Y.U. L. REV. 402 (2019).

237 *See, e.g.*, Maddy Garber, *Rejections of Correctly Filed Immigration Applications Are Senseless and Heartless*, NAT'L IMMIGRANT JUST. CTR. (Dec. 3, 2020), https://immigrantjustice.org/staff/blog/rejections-correctly-filed-immigration-applications-are-senseless-and-heartless.

238 *Examining the Impact of Illegal Immigration on the Medicaid Program and Our Healthcare Delivery System: Hearings Before the H. Comm. on Energy & Com.*, 109th Cong. 8 (2006) (statement of Rep. Marsha Blackburn, Member, H. Comm. on Energy & Com.). Some of the testimony characterizing the extent of the problem suffered from logical fallacies. For example, Abel C. Ortiz, a state policy advisor from Georgia, improperly presumed that a reduction in the Medicaid caseload after the implementation of stricter document verification rules was "strong evidence of fraud and abuse inherent" under the previous system, failing to acknowledge that the stricter rules could also pose access barriers to eligible applicants. *Id*. at 120 (statement of Abel C. Ortiz, Health & Hum. Servs. Pol'y Advisor, Off. of the Gov., State of Ga.). Dr. Marty Michaels, Chair of the Georgia Chapter of the American Academy of Pediatrics, made this point in his testimony, describing how the new rules denied access to Medicaid to low-income U.S. citizen children who did not have the required paperwork. *Id*. at 159-60 (statement of Dr. Marty Michaels, Chair, Ga. Ch., Am. Acad. of Pediatrics).

239 *See* PARK, *supra* note 1, at 59-65.

240 *Id*. at 60.

241 *Id*. at 62.

women—disproportionately Latinas and Asians—who had legally received Medicaid coverage for pregnancy-related care, who were not suspected of fraud, and who were not subject to a public charge determination.[242] The PED program was suspended after a class action lawsuit resulted in a settlement.[243] Still, noncitizens received a clear message: "using [Medicaid] can be detrimental to your immigration status."[244]

III. HEALTH CARE SYSTEM HARMS

This Part explains the health-related tradeoffs of permitting immigration surveillance in health care.[245] It does not purport to be a precise cost-benefit analysis of immigration surveillance in health care; rather, it is intended to contribute to analyses of the unintended consequences of the decades-long expansion of interior immigration enforcement.[246] When immigration policy fails to consider its health-related consequences, it incompletely assesses the risks of certain policy choices.[247] It appears to assume that any purported immigration enforcement gains outweigh the costs to public health, the health care system, and health care providers.[248]

Permitting immigration surveillance in health care (or not countering perceptions that it occurs) involves making tradeoffs between immigration and

242 *Id*. at 60-61, 63, 68-69.

243 *Id.* at 63.

244 *Id*. at 73.

245 This analysis is inspired by the Health in All Policies framework, which aims to "integrate[e] considerations of health, well-being, and equity during the development, implementation, and evaluation" of laws and policies across sectors. Dawn Pepin et al., *Collaborating for Health: Health in All Policies and the Law*, 45 J.L. MED. & ETHICS 60 (2017); *see also* Taylor, *supra* note 41, at 9 ("Many laws and policies have health effects even when, at first glance, the laws and policies do not seem to be directly related to health outcomes."). Studies have established that immigration enforcement directly impacts the health of noncitizens, including by causing psychological damage, raising cardiovascular risk factors, and reducing birth weight. *See* Rhodes et al., *supra* note 23, at 329; Saadi & McKee, *supra* note 64, at k2178; Taylor, *supra* note 41, at 3; *cf.* Taylor*, id.* at 6 ("Research has linked positive health outcomes to protective immigration laws and policies in the US."). Although these are important health-related harms of immigration policy, this Part focuses on the specific harms of health care system avoidance motivated by immigration surveillance in health care.

246 *See, e.g.*, Cade, *supra* note 90, at 500 (noting health-related consequences of "[i]mmigration crackdowns and equity-blind enforcement"); Jain, *supra* note 11, at 1510 ("Immigration enforcement decisions should take into account the long-term public health consequences of trauma or stress relating to enforcement.").

247 *See* Jain, *supra* note 11, at 1466 (noting that "policymakers have failed to appreciate the hidden costs" of heightened interior immigration enforcement); Taylor, *supra* note 41, at 9 (urging academics to "assess the nonobvious health consequences of laws and policies as a way of better understanding the consequences of the law and public policy on human health . . . ").

248 *See* Castañeda, *supra* note 37, at 55 ("The political logic of utilizing access to affordable health care as a tool of immigration policy is faulty . . . .").

health policy goals.[249] The main benefit of immigration surveillance in health care is to expand potential opportunities to enforce immigration laws against undocumented noncitizens and noncitizens who are unable to demonstrate "self-sufficiency." But it is also likely to generate health care system avoidance and therefore have negative consequences for health and health care.[250] The benefits of immigration surveillance in health care are mostly symbolic, reinforcing the climate of fear for noncitizens, while the costs—as this Part shows—are measurable and far reaching.

A. Heightened Public Health Risks

When people avoid or delay seeking health care based on fears of immigration-related consequences, they increase the risk of spreading infectious disease. This is, of course, a major concern in the era of COVID-19.[251] DHS was permitted to begin implementing its new public charge rule just as people in the United States began to die from COVID-19.[252] Predictably, the 2019 rule has deterred noncitizens from accessing testing, treatment, and vaccination for COVID-19.[253]

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249 *See* Frost, *supra* note 22, at 98 ("The federal government has always balanced immigration enforcement against other goals and values . . . ."); Jawetz & Chung, *supra* note 68 (describing how DHS typically issues statements during national disasters limiting immigration enforcement because "its 'highest priorities . . . are to promote life-saving and life-sustaining activities.'" (quoting Press Release, U.S. Dep't Homeland Sec., DHS Statement Regarding Safety and Enforcement During Hurricane Irma (Sept. 6, 2017), https://www.dhs.gov/news/2017/09/06/dhs-statement-regarding-safety-and-enforcement-during-hurricane-irma)); Kalhan *supra* note 10, at 73 ("[B]oth individuals and society as a whole have legitimate interests in preserving zones in which . . . immigration surveillance activities do not take place and in making sure that when they do take place those activities are appropriately limited and constrained.").

250 *See* Brayne, *supra* note 4, at 385 ("'[E]fforts to evade the gaze of different systems involves an attendant trade-off.' That trade-off is full participation in society." (quoting KEVIN D. HAGGERTY & RICHARD V. ERICSON, THE NEW POLITICS OF SURVEILLANCE AND VISIBILITY 619 (2006))).

251 *See, e.g.*, Makhlouf & Sandhu, *supra* note 177, at 159-62 (describing how the 2019 public charge rule discourages noncitizens from accessing health care for treatment of COVID-19 symptoms and public benefits that would enable them to better comply with social distancing recommendations); Achieving a Fair and Effective COVID-19 Response: An Open Letter to Vice-President Mike Pence, and Other Federal, State and Local Leaders from Public Health and Legal Experts in the United States 2 (Mar. 2, 2020), https://law.yale.edu/sites/default/files/area/center/ghjp/documents/final_covid19_letter_from_public_health_and_legal_experts.pdf (recommending that "[t]he COVID-19 response should not be linked to immigration enforcement in any manner.").

252 Makhlouf & Sandhu, *supra* note 177, at 166.

253 Lee et al., *supra* note 15, at 1-2; Flores et al., *supra* note 66; Raúl Grijalva et al., *An Equitable Distribution of COVID-19 Vaccine Must Include Noncitizens*, THE HILL (Jan. 26, 2021), https://thehill.com/blogs/congress-blog/healthcare/535901-an-equitable-distribution-of-covid-19-vaccine-must-include (explaining the importance of federal leadership to assure noncitizens that "vaccine recipients' information will not be shared with immigration agencies for enforcement

However, the threat that immigration-related health care system avoidance poses to the public's health transcends the current pandemic.[254] For example, if noncitizen parents avoid taking their children to the doctor for well-child appointments (or applying for health coverage that will enable them to attend those appointments), they may contribute to the loss of herd immunity for vaccine-preventable diseases, such as measles. Herd immunity provides some protection to members of the community who are unable to be vaccinated, because the spread of infectious disease is contained when a critical mass of the population *is* vaccinated. The health risks of losing herd immunity are borne primarily by infants who are too young to be vaccinated and people with compromised immune systems due to cancer treatment or other causes.

Even though the 2019 rule has been rescinded, it is likely to chill noncitizen access to health care for the long term.[255] The public health impact of chilling noncitizens' access to health care is a key rationale for protecting noncitizens from surveillance while accessing health care or coverage.[256] It is one of the "hidden costs" to larger society of expanding interior immigration enforcement to health care sites.[257] Immigration authorities have historically adopted this rationale for announcing the suspension of immigration enforcement at or near health care sites during national disasters and other public health emergencies.[258]

Immigration surveillance in health care is just one of many access barriers that

purposes or to jeopardize future immigration applications under the public charge regulations"); Shoichet, *supra* note 8.

254 This is not to say that fears of contagion by noncitizens should be the primary motivation for limiting immigration surveillance in health care. Indeed, ethnic contagion is an antiquated trope that has justified flagrant violations of liberty against noncitizens in the past. For example, fears of bubonic plague in San Francisco in 1900 were the basis of public health orders that forcibly inoculated residents of Asian descent with an experimental vaccine and imposed an unjustified quarantine of Chinatown. *See, e.g.*, Wong Wai v. Williamson, 103 F. 1, 6 (C.C.N.D. Cal. 1900); Jew Ho v. Williamson, 103 F. 10, 26 (C.C.N.D. Cal. 1900). During the COVID-19 pandemic, Anti-Asian hate crimes have surged in the United States, presumably because of the virus' origin in China. *See, e.g.*, Jaweed Kaleem et al., *Anti-Asian Hate Crimes and Harassment Rise to Historic Levels during COVID-19 Pandemic*, L.A. TIMES (Mar. 5, 2021), https://www.latimes.com/world-nation/story/2021-03-05/anti-asian-crimes-harassment.

255 *See, e.g.*, GUERRERO ET AL., *supra* note 182, at 4, 6, 12.

256 *See* Cleek, *supra* note 88, at 1000; Saadi & McKee, *supra* note 64, at k2178.

257 Jain, *supra* note 11, at 1491-92 (explaining that some of the costs of interior immigration enforcement are "structural" and "not unique to immigration"). Undocumented noncitizens are an important component of the U.S. essential workforce, especially in the fields of agriculture, housing and facilities, food services and production, transportation, and health. *See, e.g.*, FWD.US, IMMIGRANT ESSENTIAL WORKERS ARE CRUCIAL TO AMERICA'S COVID-19 RECOVERY 8-9 (2020), https://www.fwd.us/wp-content/uploads/2020/12/FWD-essential-worker-report-FINAL-WEB.pdf. Therefore, barriers to care for this population should be considered a threat to the nation's critical infrastructure.

258 Flores et al., *supra* note 66.

create heightened public health risks among noncitizens,[259] but it is one for which there is a clear remedy. It is a reasonable, logical next step for policymakers to recognize immigration surveillance in health care as a perennial threat to public health.

B. Inefficient Use of Health Care Resources

When immigration concerns cause people to delay or avoid seeking health care or coverage (a means to obtaining health care), it is harder for health care providers to generate good health outcomes and thereby reduces cost-effectiveness in the health care system.[260] Annual check-ups for older children and adults are an important way to identify emerging health issues. For younger children, more frequent well-child visits are critical for detecting growth or developmental issues and getting vaccines. It is particularly important for patients who have been diagnosed with chronic disease to see their health care provider regularly to ensure that the disease is appropriately managed.[261] When health issues are not identified early, treatment begins later—sometimes when a disease is at a more advanced stage.[262] When chronic diseases are poorly managed, the risks of becoming

259 Additional social determinants of health that increase noncitizens' risk of exposure to and negative outcomes from COVID-19 include reliance on underfunded health care providers with limited ability to manage patients' care due to lack of insurance, higher incidence of underlying health conditions linked to severe COVID-19 symptoms, "excessive stress related to poverty, trauma, and poor social support," the need to continue working jobs in which social distancing is not possible, reliance on public transportation, living in multigenerational households or with roommates, limited English proficiency, and limited access to cell phones or the internet. Eva Clark et al., *Disproportionate Impact of the COVID-19 Pandemic on Immigrant Communities in the United States*, PLOS NEGLECTED TROPICAL DISEASES, July 13, 2020, at 2-3.

260 Cost-effectiveness or "better value" is a goal of U.S. health care policy. *See* Gustavo Mery et al., *What Do We Mean When We Talk About the Triple Aim? A Systematic Review of Evolving Definitions and Adaptations of the Framework at the Health System Level*, 121 HEALTH POL'Y 629, 633 (2017) (explaining that the Triple Aim, an organizing framework for U.S. health care system reform, can be understood as a proxy for cost-effectiveness).

261 *See* Rhodes et al., *supra* note 23, at 329 (noting that delayed treatment by noncitizens who fear immigration enforcement can "lead to incomplete sequences of care [and] promote the use of nonstandard and unsafe contingencies for care").

262 *See, e.g.*, KLINE, *supra* note 44, at 126 ("[I]ncreasingly, chronic, long-term conditions are not naturally occurring ones, but are those for which the political will and economic resources are simply not brought to bear for a given community." (quoting Lenore Manderson & Carolyn Smith-Morris, *Introduction*, *in* CHRONIC CONDITIONS, FLUID STATES: CHRONICITY AND THE ANTHROPOLOGY OF ILLNESS 18 (Lenore Manderson & Carolyn Smith-Morris eds., 2010))); Arijit Nandi, Sana Loue & Sandro Galea, *Expanding the Universe of Universal Coverage: The Population Health Argument for Increasing Coverage for Immigrants*, 11 J. IMMIGRANT & MINORITY HEALTH 433, 435 (2009) (noting the higher likelihood of the undocumented population to delay seeking care and, when they do, to have preexisting disease); Saadi & McKee, *supra* note 64, at 1 ("[P]eople with preventable or chronic conditions risk delays that may worsen their condition and increase visits to emergency departments.").

seriously ill or dying increase.[263] In both cases, delayed treatment is cost-ineffective and may also be less effective clinically.[264] One example of this is late or inadequate uptake of prenatal care, which can result in pregnancy complications that lead to extremely costly postnatal and pediatric care.[265]

Delayed treatment is a source of inefficiency in the health care system in several ways.[266] First, it can contribute to driving up insurance-related costs for all. When noncitizens are deterred from accessing routine health care and only seek care when health issues become more complex or emergent, the treatment can be costlier. Consider, for example, an insulin-dependent diabetic patient who skips a doctor's appointment and is later admitted to the hospital with severe hypoglycemia—a situation that could have been avoided with routine case management. This more expensive care translates to higher costs for insurers, including public health insurance programs, if the noncitizen has or later qualifies for coverage. This could drive up insurance premiums in the private market and the costs of taxpayer-funded public health insurance. Second, when noncitizens decline to enroll in public health insurance programs for which they are eligible and are ultimately unable to pay for health care costs out-of-pocket, it can increase uncompensated care costs for hospitals and physician' offices—especially hospitals that are obligated to provide treatment to stabilize patients in emergencies.[267] Third, immigration-related health care system avoidance causes inefficiency for physician practices. Every "no-show" appointment wastes providers' time and represents a loss of potential reimbursement. Also, poor patient health outcomes caused by interrupted case management can reduce the practice's reimbursement in value-based payment programs.

263 *See* Hacker et al., *supra* note 2, at 180 (describing the health consequences of the well-known fact that noncitizens underutilize health care services); Hacker et al., *supra* note 43, at 661 (noting patients with immigration concerns are often harder "to contact . . . to [e]nsure that recommendations on health conditions are met, leading to exacerbation of chronic conditions such as diabetes and hypertension.").

264 Kullgren, *supra* note 51, at 1632 (noting that policies that cause noncitizens to delay seeking health care for conditions until they are emergent "prevents administrators from putting public resources to their most cost-effective use"); Nandi et al., *supra* note 263, at 435 (describing how delayed care-seeking by patients with diabetes and asthma can lead to unnecessary complications).

265 Lawrence O. Gostin, *Is Affording Undocumented Immigrants Health Coverage a Radical Proposal?*, 322 JAMA 1438, 1438 (2019).

266 Delayed treatment increases societal and economic costs in other ways as well, such as by increasing school absenteeism and parental work absence, but this discussion is limited to cost-effectiveness within the health care system. Lee et al., *supra* note 15, at 6.

267 *See, e.g.*, U.S. GEN. ACCT. OFF., GAO-04-472, UNDOCUMENTED ALIENS: QUESTIONS PERSIST ABOUT THEIR IMPACT ON HOSPITALS' UNCOMPENSATED CARE COSTS 12 (2004), https://www.gao.gov/assets/250/242452.pdf (describing reports from state Medicaid officials and hospital association members that "fear of being discovered by immigration authorities is one factor that can deter undocumented aliens from enrolling" in emergency Medicaid).

C. Interference with Professional Ethical Duties

Permitting immigration surveillance in health care creates ethical dilemmas for health care providers. Providers cannot act with single-minded devotion to the well-being of patients when patients' engagement with the health care system may have negative immigration consequences. As a result, providers are sometimes forced to alter clinical risk calculations and clinical recommendations for reasons relating to immigration enforcement. In addition, laws and policies that make health care providers complicit with immigration enforcement—or create the perception of complicity—negatively impact the provider-patient relationship.

Immigration surveillance in health care limits health care providers' ability to care for noncitizen patients based on their best clinical judgment.[268] When they cannot guarantee that accessing health care or coverage will not lead to negative immigration consequences for noncitizen patients,[269] patients may withdraw from their care and perhaps seek alternative sources of care.[270] Patients who remain may trust their provider less.[271] After the 2016 election, health care providers reported having to alter their clinical risk calculations and recommendations: They discounted biological risks in order to account for "the social risks of detention, deportation, and family separation" in the new immigration policy climate.[272] Providers may feel compelled to consider the potential immigration consequences of a noncitizen patient enrolling in public health insurance in order to access health care against the risks of having an untreated medical condition.[273] Others may feel compelled, for financial reasons, to "push" patients to enroll in Medicaid so that they can be reimbursed for services provided, regardless of the potential impact on a patient's future immigration options.[274] Simply having to do this type of calculation makes some providers feel complicit with immigration enforcement and contributes to provider burnout.[275]

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268 *See* PARK, *supra* note 1, at 93-94.

269 *Id*. (describing how the 1996 federal immigration law left health care providers "limited in what they can say or do for their patients"); Hardy et al., *supra* note 31, at 1250 (discussing the difficulty health care providers have with understanding their obligations under SB 1070, a 2010 Arizona law enhancing immigration policing); Licon, *supra* note 63 (quoting Dr. Elisabeth Poorman, "The ground is constantly shifting. I can tell the patient I am committed to your safety, but in the [Trump] administration we cannot tell everyone that they are 100% safe").

270 PARK, *supra* note 1, at 133 (describing how some noncitizens in San Diego who feel unsafe accessing health care self-diagnose, visit alternative healers, or obtain care and medicine from pharmacies in Mexico).

271 *Id.* at 95.

272 Van Natta, *supra* note 21, at 1; *see also* KLINE, *supra* note 44, at 124 (describing one doctor's consideration of patients' immigration status when making recommendations for follow-up care).

273 Van Natta, *supra* note 21, at 3.

274 *See* PARK, *supra* note 1, at 94.

275 Van Natta, *supra* note 21, at 5-6. Patients' fears of immigration surveillance in health care can also leave providers feeling helpless in the face of their patients' suffering, which can be

When immigration laws and policies require health care providers to cooperate with immigration authorities, it can damage provider-patient relationships and arguably constitutes an unjustified interference with their practice. Health care providers may be asked to verify a patient's identity or immigration status (or lack thereof).[276] They may be asked by immigration enforcement officers to perform examinations of detainees who are suspected of carrying drugs.[277] Whether they choose to cooperate or not, it puts providers in a difficult situation. Members of the health care profession have an ethical obligation to "act for the good of all of their patients, irrespective of their category memberships."[278] This ethical principle, which originates in the Hippocratic Oath, is often restated as "do no harm."[279] The focus of the provider-patient relationship is healing. Actual or perceived complicity with immigration enforcement interferes with this goal, as well as with providers' broad ethical obligation to protect patient privacy.[280]

D. Violation of Health Equity Norms

Policies permitting immigration surveillance in health care primarily affect noncitizens, compounding disadvantage, particularly for undocumented people and their family members.[281] Noncitizens are considered a disadvantaged,

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frustrating and distressing. PARK, *supra* note 1, at 135 (describing a health care provider's reactions to treating a patient with uterine cancer who needed a hysterectomy but repeatedly declined because of a fear of deportation).

276 *See* KLINE, *supra* note 44, at 117-18 (describing providers outrage over Georgia's HB 87, which limited providers' ability to provide care to undocumented people); PARK, *supra* note 1, at 123 (describing a case in which a CBP officer called a San Diego prenatal health clinic from a U.S.-Mexico border crossing to ask if a patient was indeed a U.S. citizen).

277 *See, e.g.*, Melissa del Bosque, *Checkpoint Nation*, TEX. OBSERVER (Oct. 8, 2018), https://www.texasobserver.org/checkpoint-nation/ (describing evidence that health care providers routinely cooperate with CBP to perform warrantless and consent-less body cavity searches and medical imaging of detainees, and how providers may feel compelled to comply with CBP officers requesting such procedures).

278 Jeff Sconyers & Tyler Tate, *How Should Clinicians Treat Patients Who Might Be Undocumented?*, 18 AMA J. ETHICS 229, 233 (2016).

279 *See* Song, *supra* note 6, at 41 (noting that the phrase itself is not contained in the original Hippocratic Oath); Robert H. Shmerling, *The Myth of the Hippocratic Oath*, HARV. HEALTH BLOG (Nov. 25, 2015), https://www.health.harvard.edu/blog/the-myth-of-the-hippocratic-oath-201511258447 (noting that the original Hippocratic Oath includes a promise to avoid harming patients).

280 *See* Song, *supra* note 6, at 59 (discussing the expansive concept of privacy in the medical context, including the obligation "to protect patient privacy in all settings to the greatest extent possible" (quoting *Code of Medical Ethics Opinion 3.1.1*, AM. MED. ASS'N, https://www.ama-assn.org/delivering-care/ethics/privacy-health-care)).

281 *See* Taylor, *supra* note 41, at 7 ("[P]opulations with multiple disadvantaged statuses have increased risk of negative health outcomes . . . ."); Brayne, *supra* note 4, at 387 (describing system avoidance as "implicated in the accumulation of disadvantage" of marginalized subpopulations).

stigmatized, and vulnerable population in the health care sphere.[282] When people delay or avoid seeking health care because of concerns about immigration surveillance, their risk of suffering or dying from treatable and preventable conditions increases.

Such policies exacerbate racial and ethnic health and health care disparities, violating health equity norms in U.S. health policy.[283] Surveillance efforts in health care settings that are focused on undocumented noncitizens may result in discrimination against noncitizens generally and the Latinx population in particular, and the misapplication of enforcement-related policies to these groups.[284] Since immigration authorities know that undocumented noncitizens are typically limited to accessing health care at community health centers and hospital emergency rooms, they may focus surveillance efforts there. Such locations are also disproportionately likely to serve low-income people, lawfully present noncitizens, and communities of color; therefore, policies permitting immigration surveillance in health care contribute to the racial and class-based stratification of the health care system.[285]

IV. LEGITIMACY HARMS

This Part describes three ways in which the state compromises its legitimacy through laws and policies permitting immigration surveillance in health care. First, these laws and policies impose severe and burdensome constraints on noncitizens' ability to understand how and when they may access publicly funded health care without incurring negative immigration consequences. Second, they require applicants for immigration benefits to waive the confidentiality rights conferred by the statutes governing publicly funded health care programs. Third, they undermine noncitizens' property rights in health-related public benefits by threatening a deprivation of liberty based on the exercise of those rights.

The complexity, inconsistency, and vagueness of the laws and policies regulating immigration surveillance in health care compromise the legitimacy of

282 *See, e.g.*, Hacker et al., *supra* note 43, at 661; Taylor, *supra* note 41, at 1.

283 *See* KLINE, *supra* note 44, at 127 (describing one doctor's opinion of an enhanced immigration policing law as racist, which threatens its legitimacy and potentially violates professional ethics); Callaghan et al., *supra* note 23, at 342 (describing politically-driven barriers to enrollment in health care programs among Hispanics); Hardy et al., *supra* note 31, at 1250 (positing that Arizona's SB 1070, which enhanced immigration policing, could exacerbate racial and ethnic health disparities); Lee et al., *supra* note 15, at 1 (noting the impact of heightened immigration enforcement on Latinos' participation in health care programs).

284 *See* KLINE, *supra* note 44, at 150 (describing racial profiling of Latinx patients in medical settings based on assumptions that they are undocumented); Rhodes et al., *supra* note 23, at 332; Taylor, *supra* note 41, at 6-7.

285 *See* Song, *supra* note 6, at 13 (describing race and class-based stratification of urgent and emergency care sites).

the state because they make it almost impossible for laypeople to understand their rights and the consequences of exercising those rights.[286] Studies have long documented how confusion about newly enacted laws impacting noncitizens' access to public benefits has chilled noncitizen enrollment in Medicaid. For example, chilling effects were observed after the 1996 immigration and welfare laws both complicated noncitizen eligibility for Medicaid and the application process.[287] The lack of clarity in the law helps to create the perception that accessing health care or public health insurance is inherently risky for all noncitizens.[288]

In addition, the laws permitting immigration surveillance in health care create legitimacy harms because they encourage or require noncitizens to relinquish their privacy rights in their public benefits records. This is especially apparent in the context of the 2019 public charge regulations, which used Medicaid, a safety-net benefit that supports health and well-being, as the means of "disciplining" noncitizens.[289] This approach makes the privacy laws appear less legitimate because it creates normative confusion around the state's commitment to ensuring privacy in health-related matters.[290] It incentivizes behaviors that lead to unjust and arbitrary consequences for noncitizens' health, as described in Part I. The gaps between privacy rights formally conferred by law and "whether the rights may be utilized and exercised" constitute a legitimacy problem for privacy law.[291]

Similarly, immigration surveillance in health care undermines noncitizens' property rights in health-related public benefits because exercise of those rights can result in a deprivation of liberty: detention and deportation. It creates normative confusion around the state's commitment to ensuring the health and wellbeing of noncitizens, expressed through laws making them eligible to receive health-promoting public benefits. The right to receive assistance from the state to access health care becomes a "paper right"—one that the right holder cannot

286 *See* KLINE, *supra* note 44, at 128 (describing confusion among providers about how to interpret new immigration policing laws that implicate health care providers); Cleek, *supra* note 88, at 989-90 (describing how state variations in enforcement of sensitive locations policies and officer-level deviations from official policy create uncertainty); Goodwin & Chemerinsky, *supra* note 149, at 1293 (describing, in a parallel context, how "the state has compromised its legitimacy by imposing insurmountably severe and burdensome constraints on reproductive health and rights such that it would require the artistry of a magician or pertinacity of an elite athlete to overcome").

287 PARK, *supra* note 1, at 36, 65 (discussing the lack of transparency and vagueness of public charge policy and "wide variations in . . . interpretation of fraudulent behavior" in the 1990s).

288 Callaghan et al., *supra* note 23, at 345 (describing how undocumented noncitizens rely on word-of-mouth information to learn about "safe" health care sites).

289 Van Natta, *supra* note 21, at 7.

290 *See* Frost, *supra* note 22, at 104 (discussing, in a related context, how use of information submitted with DACA applications to later deport noncitizens "would chill applications, undermining the purpose of these laws").

291 Goodwin & Chemerinsky, *supra* note 149, at 1298.

sensibly exercise.[292] These normative issues could become legal issues if courts were to recognize a substantive due process right to information privacy based on data-sharing or collection practices that deprive noncitizens of dignity and liberty.[293]

V. SANCTUARY AS SOLUTION

Sanctuary policies, whether public or private, "increase the ability of . . . noncitizens to engage with government or community institutions without detection or apprehension by federal immigration authorities."[294] Noncitizens' freedom to engage in the typical activities of daily life without fear of immigration surveillance is a "precedential touchstone" embraced by the U.S. Supreme Court, most evidently, in *Arizona v. United States*.[295] Health care sanctuaries can reduce immigration-related health care system avoidance by establishing and strengthening informational "safe harbors," so that noncitizens interacting with health care institutions in routine and desirable ways are not at risk of surveillance.[296] Laws and policies can create health care sanctuaries, but non-governmental organizations can also do so by limiting their cooperation with immigration enforcement to what is minimally required under the law,[297] and by providing noncitizens with physical refuge, legal assistance, or other community aid.[298]

Health care sanctuaries restore some fairness to immigration policy by balancing the indiscriminate pursuit of immigration enforcement with other public policy goals and values.[299] The previous two Parts illustrate how preferences about immigration policies may change when health and legitimacy considerations are incorporated. Immigration surveillance in health care undercuts certain health policy goals and values and is particularly detrimental to health care institutions seeking to best serve their patients. It also compromises the legitimacy of the state in several ways. This Part explains how law and institutional policies can act on those changed preferences as "an adaptive response" to the expansion of interior

292 *Id*. at 1297.

293 *See* BRIDGES, *supra* note 88.

294 Cade, *supra* note 90, at 468.

295 567 U.S. 387 (2012); *see* Cade, *supra* note 90, at 490-92.

296 Brayne, *supra* note 4, at 386 (noting that European regulations could serve as a model for a U.S. effort to limit noncitizens' risks of apprehension when accompanying a child to an appointment or signing up for public health insurance).

297 Cade, *supra* note 90, at 440 (explaining how such efforts by municipalities and campuses "impose an 'equitable screen' at the front end of the [immigration enforcement] system").

298 *Id.* at 468.

299 *Id.* at 480, 495 (arguing that sanctuary policies "can promote legitimacy in the removal system" and "promote competing norms of justice and empathy" in immigration policy).

immigration enforcement.[300] Creating health care sanctuaries is a way to address the systemic costs of interior immigration enforcement.[301]

Once health care sanctuary policies are established, well-enforced, and well-known, there is reason to believe that their positive effect on care-seeking by noncitizens will endure even if future administrations crack down on immigration enforcement. Studies of system avoidance have found that subjects do not avoid institutions generally; they specifically avoid recordkeeping institutions.[302] If health care provider sites and public benefits agencies administering health benefits are designated as sanctuaries, they will likely be considered safe spaces for noncitizens even if the political climate changes. However, to be effective, it is critical that information about health care sanctuaries is communicated clearly and deliberately to immigrant communities by trusted messengers.[303]

A. Legal Reforms

While the ultimate solution to health care system avoidance for undocumented noncitizens may be immigration reform that gives them a path to citizenship,[304] such reform may not come any time soon, nor would it address the larger issue of immigration surveillance in health care that deters lawfully present noncitizens from enrolling in public health insurance. In the meantime, there are legal reforms that can address this problem immediately. Health care sanctuary laws can address sources of health care system avoidance for both populations.

There is expressive value in legislation at any level that limits information-sharing from health care providers and public benefits agencies to immigration authorities.[305] Such laws influence cultural beliefs about where immigration enforcement activities should occur, which could ultimately influence courts' interpretations of substantive due process rights to information privacy.[306] Similarly, positive law at any level limiting immigration enforcement activities at health care provider sites based on considerations of individual autonomy and dignity could influence courts' interpretations of what is considered a reasonable

300 Jain, *supra* note 11, at 1505.

301 *Id.* at 1468.

302 Brayne, *supra* note 4, at 385 (noting that subjects with prior criminal justice involvement continued to engage with volunteer organizations and religious groups); Patler & Gonzalez, *supra* note 4, at 10 (noting that formerly detained noncitizen subjects continued participating in church activities).

303 *See* Jain, *supra* note 11, at 1506; Saadi & McKee, *supra* note 64, at 1 (describing New York City Health and Hospitals' messaging in the form of an "open letter to immigrant New Yorkers").

304 *See, e.g.*, Hacker et al., *supra* note 2, at 179.

305 Citron, *supra* note 70, at 1159 (explaining, in the context of the privacy rights of poor mothers enrolled in Medicaid, "[l]aw is our teacher and guide. It shapes social norms and behaviors").

306 *See* BRIDGES, *supra* note 88; Citron, *supra* note 70, at 1159.

expectation of privacy in health care settings.[307] This Section proposes some ways in which legislative bodies and executive branch agencies might consider creating health care sanctuaries.

The current administration has announced plans for both immigration and health reform. A national strategy on immigrant health could guide Congress, DHS, and HHS on how to balance immigration and health policy goals; national strategies are particularly well suited for addressing complex issues.[308] A national strategy arising from an executive order or federal legislation could be a catalyst for more interagency coordination on issues relating to immigrant health and health care access. It could be based on the Health in All Policies (HiAP) approach, which aims to "achiev[e] better public health outcomes through increased intersectoral collaboration."[309] An immigrant health task force could coordinate HiAP efforts involving multiple agencies.[310]

Alternatively, the President and Congress may consider creating a new agency or consolidating existing agencies to prioritize the elimination of health care access barriers in vulnerable communities, including in immigrant communities.[311] In a different context, Emily Broad Leib and Margot Pollans discuss the value of "drawing together components of several preexisting agencies" to coordinate action on important national issues.[312] This option avoids the need to coordinate across agencies, which can become complicated.[313] A single agency focused on addressing inequitable access to health care could be particularly adept at analyzing how health care sanctuary policies might also eliminate race, ethnicity, and class-related barriers for U.S. citizens and lawfully present noncitizens.[314]

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307 *See* Song, *supra* note 6, at 58-62 (proposing a reasonable expectation of privacy standard in hospital emergency rooms that is based on the concept of medical privacy).

308 *See, e.g.*, Emily M. Broad Leib & Margot J. Pollans, *The New Food Safety*, 107 CALIF. L. REV. 1173, 1240 (2019) (advocating for a national food strategy).

309 *See* Pepin et al., *supra* note 245, at 61.

310 *See id.*.

311 *See* Broad & Leib, *supra* note 309, at 1244 (discussing how a consolidated agency can "prioritize a salient issue of national importance").

312 *Id*. at 1244 (proposing new ways to regulate food safety and citing, as examples of consolidating existing agencies, the creation of the Environmental Protection Agency and the Department of Homeland Security).

313 Although there may be opportunities for several agencies to coordinate on eliminating health care access barriers for noncitizens, the two most important are HHS and DHS. Within HHS itself, several offices and operating divisions seek to address health disparities as part of their mission. These include the Office of Minority Health, the Agency for Healthcare Research and Quality, the National Institute on Minority Health and Health Disparities within the National Institutes of Health, the Office of Minority Health within the Center for Medicaid & Medicare Services, the Office of Minority Health & Health Disparities within the CDC, the Health Resources and Services Administration, and the Office for Civil Rights.

314 *See* Cade, *supra* note 90, at 493 (describing how sanctuary policies generally can discourage system avoidance among citizens and LPRs, especially Latinos).

Part of a national strategy on immigrant health could include enacting a federal Protecting Sensitive Locations Act, which would build on and improve DHS's sensitive locations policies. Political barriers in the past have prevented such an Act from being passed.[315] The Act addresses many of the weaknesses of the sensitive locations policies: It applies uniform standards to all individuals performing immigration enforcement functions; specifies a protected zone of 1,000 feet around a sensitive location; requires officers to discontinue enforcement actions that began at other locations but that move near sensitive locations; and considers "any medical treatment or health care facility" to be a sensitive location.[316] Enforcement actions that may occur at sensitive locations must have prior approval and be justified based on exigent circumstances; notably, exigent circumstances is defined with precision.[317] Finally, the Act provides some accountability measures. Most importantly, information obtained from enforcement actions that violate the law cannot be used against a noncitizen in removal proceedings, and the noncitizen may move to terminate the proceedings.[318] The Act also requires DHS to conduct annual training for officers about the sensitive locations law and to report to Congress about enforcement actions conducted at sensitive locations.[319] Passing the Protecting Sensitive Locations Act would be a positive step toward limiting immigration surveillance in health care. However, the final version of the Act should seek to limit DHS officers from conducting even the limited investigatory activities that they are permitted to conduct at sensitive locations, since such activities alone can deter noncitizens from accessing services.

DHS can immediately address concerns about surveillance at health care provider sites because it has significant discretion to set priorities and allocate resources toward this objective. Such action would fit squarely within the agency's mission of protecting life and safety, which is its highest priority, surpassing ordinary immigration enforcement practices.[320] One potential action would be to issue a new sensitive locations policy memo strengthening enforcement of the policies, clarifying points of confusion, and expanding their scope. This could be done relatively quickly.

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315 *See* Katie Mettler, *Democrats Want to Limit ICE Power by Banning Agents from Courthouses, Bus Stops*, WASH. POST (Apr. 3, 2017), https://www.washingtonpost.com/news/morning-mix/wp/2017/04/03/democrats-want-to-limit-ice-power-by-banning-agents-from-courthouses-bus-stops/. The Act was introduced in both houses of Congress in 2019. S. 2097, 116th Cong. (2019); H.R. 1011, 116th Cong. (2019). The Act was most recently introduced in the House on January 28, 2021. H.R. 529, 117th Cong. (2021).

316 S. 2097 § 2; H.R. 1011 § 2.

317 S. 2097 § 2; H.R. 1011 § 2.

318 S. 2097 § 2; H.R. 1011 § 2.

319 S. 2097 § 2; H.R. 1011 § 2.

320 Flores et al., *supra* note 66.

States could also play an important role as "privacy norm entrepreneurs" for noncitizens' health-related information, a role they have played in other contexts.[321] State public benefits agencies that have not modified their applications for public health insurance to ensure that only applicants are required to provide their citizenship and immigration status and SSN should do so. These agencies should also provide clear information on the applications themselves about how they will use applicants' personal information and the confidential protections that apply. For example, agencies could state explicitly that they will only use SSNs to verify income and will not share them with immigration authorities. This message should be reinforced throughout the eligibility determination process. States should also create applications for Medicaid and CHIP separate from applications for other public benefits because Medicaid and CHIP have stronger confidentiality protections and do not require families or households to apply for benefits as a unit. These relatively simple state-level reforms could go a long way toward addressing noncitizens' fears of applying for public health insurance.

Community outreach should also be an essential part of the state's strategy to regain the trust of immigrant communities that have felt betrayed by the punitive immigration policies of the Trump Administration. However, it will be an uphill climb. Efforts to build trust should begin at the institutions closest to the ground, such as the public benefits agencies where noncitizens apply for public health insurance.[322] A challenge for public benefits agencies is to increase trust between applicants and agency caseworkers, among whom turnover is high.[323] One strategy may be to co-locate agency caseworkers at trusted institutions, such as health care provider sites in immigrant communities.[324] Another strategy is to promote a welcoming culture at public benefits agencies and in official materials using signage, videos, and community presentations that emphasize noncitizens' rights to access publicly funded health care and transparency about any possible immigration-related consequences.

B. Institutional Reforms

In the absence of legal immigration reform that comprehensively addresses immigration surveillance in health care, health care institutions should consider what policies they can implement independently to become health care sanctuaries.[325] Health care providers have the unique role of safeguarding the

321 Citron, *supra* note 70, at 1157.

322 *See* PARK, *supra* note 1, at 41.

323 *See id.*

324 *See id.*

325 Callaghan et al., *supra* note 23, at 346 (recommending that providers "explore strategies to increase trust in the health system and to disassociate health seeking from generalized immigration fear"); Jain, *supra* note 11, at 1466; Song, *supra* note 6, at 62 (recommending institutional reform to

health and wellbeing of their patients, and this role justifies limiting cooperation with immigration enforcement to the minimum degree necessary.[326] Providers are also respected spokespeople who can potentially shape public discourse in support of immigration policies that promote individual and public health.[327] Although some health care providers and professional organizations have spoken out and acted against immigration enforcement-related interference with their professional duties,[328] it is clear that there is much more work that can and should be done.[329]

Health care providers are becoming increasingly aware of the important role they can play in countering immigration-related health care system avoidance,[330] and some have taken steps to transform their institutions to this end.[331] For example, a recent commentary described the development and accomplishments of the Immigrant Task Force at Boston Medical Center, which was created in 2017 to respond to noncitizen patients' increasing fears of accessing health care.[332] Dr. Altaf Saadi has developed a website[333] and toolkit[334] based on her study of health

limit law enforcement activities in hospital ERs).

326 *See* Cade, *supra* note 90, at 478 (arguing, in a parallel context, that colleges and universities have a unique role of educating and protecting their students, including undocumented students).

327 *Id.* at 441 (describing the importance of the credibility of institutions in the success of sanctuary efforts).

328 *See, e.g.*, KLINE, *supra* note 44, at 122 (describing a 2017 statement by the American Academy of Pediatrics expressing its opinion that the Trump Administration's immigration policies harm children's health and a 2019 American Medical Association (AMA) statement calling for an end to family separation); Licon, *supra* note 63 (describing a 2019 AMA statement that "patients should not fear that entering a hospital will result in arrests or deportation"); Meyer, *supra* note 59 (describing initiatives undertaken by Puentes de Salud, a free clinic in Philadelphia, such as posting welcoming signs and demarcating certain areas as "private property").

329 *See, e.g.*, La Charite et al., *supra* note 63, at 51 (noting that efforts to develop protocols to respond to immigration surveillance are "not widespread"); Licon, *supra* note 63 (describing the lack of universal policies for how hospital staff should interact with immigration authorities); Meyer, *supra* note 59 (describing health clinic leaders who claim there are "no good solutions" for addressing patients' fears of immigration enforcement).

330 *See, e.g.*, Mark G. Kuczewski et al., *Good Sanctuary Doctoring for Undocumented Patients*, 21 AMA J. ETHICS 78 (2019); Altaf Saadi et al., *Making a Case for Sanctuary Hospitals*, 318 JAMA 2079 (2017); *Treating Fear: Sanctuary Doctoring*, NEISWANGER INST. FOR BIOETHICS & HEALTHCARE LEADERSHIP, https://hsd.luc.edu/bioethics/content/sanctuary-doctor/.

331 *See, e.g.*, Altaf Saadi et al., *Assessment of Perspectives on Health Care System Efforts to Mitigate Perceived Risks Among Immigrants in the United States: A Qualitative Study*, JAMA NETWORK OPEN, Apr. 17, 2020, at 1 (describing policies and practices adopted by 25 health care institutions across five states to counter immigration-related health care system avoidance and generally address immigration-related fears among patients).

332 *See* Sondra S. Crosby et al., *The Boston Medical Center Immigrant Task Force: An Alternative to Teaching Immigration Law to Health Care Providers*, 49 J.L., MED., & ETHICS 59, 62 (2021).

333 DRS. FOR IMMIGRANTS, http://doctorsforimmigrants.com/ (last visited July 16, 2021).

334 ALTAF SAADI, DRS. FOR IMMIGRANTS, WELCOMING AND PROTECTING IMMIGRANTS IN HEALTHCARE SETTINGS: A TOOLKIT DEVELOPED FROM A MULTI-STATE STUDY, https://doctorsforimmigrants.com/wp-content/uploads/2020/01/WelcomingProtectingImmigrants-

care institutions that have implemented policies to address immigration-related fears of their patients. And prominent national organizations such as the American Civil Liberties Union, the National Immigration Law Center, and Physicians for Human Rights have published resources that encourage health care providers to adopt policies and practices that protect noncitizens' ability to access health care.[335] For many health care providers, such efforts align with a more general mission of providing equitable access to health care, particularly for vulnerable populations.[336] The remainder of this Section describes reforms for aspiring health care sanctuaries that have been suggested by advocacy groups and described in the scholarly literature.

Health care institutions can develop internal protocols for protecting noncitizen patients from interrogation, search, and arrest if immigration authorities come onsite.[337] Some institutions have developed "rapid response teams" of designated staff who are available on-call to respond to such appearances.[338] Members of the team may be responsible for communicating the institution's policies, ensuring that immigration authorities are complying with the laws and policies that discourage immigration surveillance activities at health care sites, and otherwise resolving any requests or actions promptly and without causing alarm to any patients present. In large health systems, members of rapid response teams may include health care providers, attorneys from the office of general counsel, social workers, privacy officers, representatives from the medical records department, members of the clinical ethics consultation service, and high-level administrators focused on patient experience. Academic medical centers may also

toolkit-3.pdf (last visited July 16, 2021).

335 *See, e.g.*, ACLU BORDER RTS. TEX. ET AL., HEALTH CARE PROVIDERS: PRESERVE ACCESS TO CARE AND PROTECT YOUR PATIENTS FROM BORDER PATROL AND ICE INTERFERENCE (2020), https://www.aclu.org/sites/default/files/field_document/nilc_aclu_healthcareprovidersguide.pdf; NAT'L IMMIGR. L. CTR.,, *supra* note 140; PHYSICIANS FOR HUM. RTS., NOT IN MY EXAM ROOM: HOW U.S. IMMIGRATION ENFORCEMENT IS OBSTRUCTING MEDICAL CARE (2019), https://phr.org/wp-content/uploads/2019/06/Not-in-my-Exam-Room_-PHR-Sanctuary-Hospitals-June-2019.pdf.

336 *See* Saadi et al., *supra* note 332, at 8-9.

337 *See, e.g.*, Crosby, *supra* note 333, at 62 (describing how the Immigrant Task Force developed a protocol in consultation with the hospital's Public Safety department); La Charite et al., *supra* note 63, at 54 (noting that development of policies to guide staff action in such situations was suggested by health care providers); Lee et al., *supra* note 15, at 6; Saadi et al., *supra* note 332, at 4. *See generally* Saadi & McKee, *supra* note 64, at 1-2 (describing efforts by health care providers to encourage noncitizens to access care without fear).

338 *See* La Charite et al., *supra* note 63, at 54 (noting that health care provider survey respondents recommended developing response teams); Lee et al., *supra* note 15, at 6; Saadi et al., *supra* note 332, at 5; Van Natta, *supra* note 21, at 5. This idea is loosely modeled on a proposal to create "rapid response teams" to address medical repatriation of immigrants upon discharge by hospitals. Nisha Agarwal & Liane Aronchick, A Matter of Life and Death: Advocates in New York Respond to Medical Repatriation 10 (Oct. 7, 2010) (unpublished manuscript) (on file with author).

draw on faculty members affiliated with the institution, such as law professors with relevant expertise and directors of law school clinics. Smaller institutions could pool their resources and coordinate community-based rapid response teams, consisting of pro bono and public interest attorneys, members of faith-based and other community groups, local government officials,[339] activists, retired physicians, students, and others willing to donate their services to the cause. Lawyers on rapid response teams should be prepared to represent patients in the event of arrests; advise patients and their family members about their rights in the ensuing legal process; and to address any ancillary legal issues that may arise. The medical-legal partnership model, which typically involves collaboration between health care provider staff and lawyers onsite, may be well-suited for this purpose.[340] Health care providers and social workers would advise patients who are arrested about any treatment needs, particularly if the patient is likely to be detained for a prolonged period. The medical records staff would be responsible for obtaining an arrested patient's consent to transmit records relating to any treatment needs to their family members and/or to the medical staff at the detention facility where the patient will be housed, to ensure continuity of care.

Health care providers can also designate certain spaces, such as private exam rooms, as "closed to the public" in order to prevent officers from conducting warrantless visual or oral surveillance of patients and patient records in supposedly "public" areas.[341] Under the plain view doctrine, an exception to the Fourth Amendment's warrant requirement, immigration officers can inspect items that are visible in plain view in locations where they are lawfully present.[342] Therefore,

339 *See* SAADI, *supra* note 334, at 10.

340 Even though medical-legal partnerships are growing in popularity, few that provide immigration legal services have published scholarly articles about their work. *See* Avery League et al., *A Systematic Review of Medical-Legal Partnerships Serving Immigrant Communities in the United States*, 23 J. IMMIGRANT & MINORITY HEALTH 163, 173 (2021). Of those that have, "[a]ll partnerships concluded that the joint work was a positive step for the immigrants they served . . . ." *Id*. at 166; *see also* Sarah Kimball et al., *Advocacy for Patients with Vulnerable Legal Status: Piloting Immigration Legal Navigation in Primary Care*, 42 SGIM F., Apr. 2019, at 1 (noting that "there is a tremendous need for immigration legal support in our patient population, and we have a potent opportunity to provide crucial support for immigrant patients [through MLPs] when they come into clinic"); Altaf Saadi et al., *Building Immigration-Informed, Cross-Sector Coalitions: Findings from the Los Angeles County Health Equity for Immigrants Summit*, 3.1 HEALTH EQUITY 431, 433 (2019) (describing medical-legal partnerships as "a prime strategy" for addressing unmet immigration legal needs); Kimberly Montez et al., *Legal Relief for Children in Immigrant Families*, PEDIATRICS (Mar. 1, 2021), https://pediatrics.aappublications.org/content/147/3_MeetingAbstract/659 (describing a pilot intervention that "demonstrates the need for immigration-related services in primary care settings that serve immigrant patients and the feasibility of implementing a novel screening tool and community-based medical-legal partnership with an immigration law firm").

341 Cleek, *supra* note 88, at 1002-03; La Charite et al., *supra* note 63, at 54 (finding that the surveyed health care providers indicated a lack of training on this topic).

342 *See* Cleek, *supra* note 88, at 1002 (discussing the application of the doctrine to ICE officer searches of health care provider sites).

providers should ensure that patient charts are not visible from areas that are arguably open to the public, like waiting rooms, and that conversations about immigration status do not occur there.[343]

Health care providers can establish liberal policies about documents that satisfy identification requirements for patient registration purposes.[344] Although driver's licenses are the most frequently used document to establish patients' identities, many states do not permit undocumented noncitizens to acquire them.[345] Therefore, providers should clarify that a variety of documents may be used to establish identity, such as foreign passports or national identification cards, school or employee identification cards, or certain medical records, such as hospital birth records or others containing photographs and biographical information.

Health care institutions should ensure that their staff is well-trained on internal policies designed to limit immigration surveillance in health care.[346] Such trainings build understanding of the importance to the organization's mission of protecting health care access for all patients, regardless of citizenship or immigration status and regardless of any person's opinion about immigration policy. Additional trainings could seek to educate staff on the laws relating to immigration consequences of enrolling in public health insurance[347] and the confidentiality of patient information,[348] how to speak openly with patients about immigration-related barriers to health care, and how to assure patients that their care is not compromised because of their immigration status.[349]

Finally, community outreach to immigrant communities about health care sanctuary policies is critical to allaying fears of immigration surveillance in health care.[350] Health care institutions are uniquely situated to provide trusted information

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343 Crosby et al., *supra* note 332, at 62 (describing a change in Boston Medical Center's policy so that government-issued photo identification is no longer required); Saadi et al., *supra* note 332, at 5; Cleek, *supra* note 88, at 1002-03.

344 *Id.* at 1003.

345 *See id.* at 1003.

346 *See* Crosby et al., *supra* note 333, at 62 (describing Boston Medical Center's "Know Your Rights" presentations for employees); La Charite et al., *supra* note 63, at 56 (noting the "significant opportunity to further expand the knowledge base regarding healthcare facility preparedness and response to immigration-related law enforcement activity," based on survey respondents' lack of knowledge about their own institutions' policies); Saadi et al., *supra* note 332, at 5, 7.

347 Hacker et al., *supra* note 2, at 180.

348 Crosby et al., *supra* note 333, at 62 (describing Boston Medical Center's "training for professionals on how to document relevant facts in the medical record without revealing a patient's immigration status, (in the remote possibility of broad subpoenas)"); Lee et al., *supra* note 15, at 6; Van Natta, *supra* note 21, at 112416.

349 Lee et al., *supra* note 15, at 6; Rhodes et al., *supra* note 23, at 336 (emphasizing the importance of "linguistically and culturally congruent and immigrant-friendly [health care] services"); Saadi & McKee, *supra* note 64, at k2178.

350 *See* PARK, *supra* note 1, at 148; Crosby et al., *supra* note 333, at 62 (describing Boston Medical Center's "targeted messaging on the COVID-19 vaccine to immigrant communities").

to noncitizens about the limited circumstances in which accessing health care or coverage can have negative immigration consequences, and to direct patients to community resources to help support their decision-making.[351] Community outreach should be conducted by community health workers, patient navigators, and other trusted messengers.[352] Community outreach may include education for patients and their families about their rights in immigration enforcement actions and the health care institution's policies relating to noncooperation with ICE.[353] Such outreach should be linguistically appropriate and could be paired with information about noncitizen eligibility for public health insurance and confidentiality protections for applicants.[354]

Although laws restricting or deterring noncitizens from accessing health care or coverage may cause some noncitizens to lose trust in their health care providers,[355] providers who are knowledgeable about these issues and who can provide resources to noncitizen patients fare better.[356] For example, health care providers should consider forming medical-legal partnerships or having legal advocates on staff to advise patients about these issues, both for the benefit of patient families and to improve health outcomes.[357] Alliances between health care providers and legal advocates could also lead to natural opportunities to jointly advocate for immigrant patients' interests.[358]

CONCLUSION

Noncitizens living in the United States are increasingly fearful of being surveilled by immigration authorities while going about the typical activities of daily life, including going to the doctor or applying for health insurance. Although immigration surveillance in health care may be justified in certain circumstances, it is a poor tradeoff in the general case. This is because the collateral consequences for public health and the health care system are severe. Policymakers should take these health-related consequences into account when weighing the utility of indiscriminate immigration enforcement, especially during a pandemic. Health

351 Lee et al., *supra* note 15, at 6.

352 Hacker et al., *supra* note 2, at 179.

353 *See, e.g.*, Saadi et al., *supra* note 332, at 6 (describing Know Your Rights programs provided to patients at health care facilities).

354 Rhodes et al., *supra* note 23, at 336; Saadi et al., *supra* note 331, at 6.

355 *See, e.g.*, PARK, *supra* note 1, at 80 (describing the impact of PRWORA and IIRIRA in 1996).

356 *Id.*

357 *See id.* at 130, 148; Lee et al., *supra* note 15, at 5; Saadi et al., *supra* note 332, at 6; Van Natta, *supra* note 21, at 5. Medical-legal partnerships may be theorized as non-governmental versions of HiAP, as they are cross-sectoral efforts to improve health. *See* Pepin et al., *supra* note 245, at 61.

358 *See* PARK, *supra* note 1, at 149; Lee et al., *supra* note 15, at 6 (describing the unique position of health care providers to support the rights of immigrant families).

care sanctuaries are a pragmatic, principled, and legitimacy-enhancing solution to the problems associated with immigration-related health care system avoidance. This approach suggests possibilities for balancing health-related policy goals with immigration policy goals in contexts beyond immigration surveillance in health care.

Adding Principle to Pragmatism: The Transformative Potential of "Medicare-for-All" in Post-Pandemic Health Reform

William M. Sage*

Abstract:

"Medicare-for-All" should be more than a badge of political identity or opposition. This Article examines the concept's potential to catalyze policy innovation in the U.S. health care system. After suggesting that the half century of existing Medicare has been as much "Gilded Age" as "Golden Era," this Article arrays the operational possibilities for a Medicare-for-All initiative. It revisits America's recent history of pragmatic rather than principled health policy and identifies barriers to more sweeping reform. It then applies to Medicare-for-All four health policy insights not known when "single-payer" reform was debated a generation ago: simultaneous inefficiency and injustice in medical care, neglect of the social determinants of health, inertia resulting from the legal architecture of health care, and the latent power of generational change. It concludes by explaining how applying a Medicare-for-All frame to post-pandemic health reform might prompt ethical re-engagement by the medical profession and help the health care system take specific steps on a path to improvement.

* James R. Daugherty Chair for Faculty Excellence, School of Law, and Professor of Surgery and Perioperative Care, Dell Medical School, The University of Texas at Austin; Visiting Professor of Population Health, New York University School of Medicine. A.B., Harvard, 1982; M.D., J.D., Stanford, 1988.

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INTRODUCTION: ESCAPING MEDICARE'S GILDED AGE

"The modern era of medicine began in the 1960s," opens a pre-pandemic commentary by Dr. Howard Bauchner, editor-in-chief of the *Journal of the American Medical Association* (*JAMA*).[1] What the commentary fails to mention is that the "modern era" resulted mainly from one watershed event: the passage of Medicare in 1965.[2]

Medicare guaranteed government health insurance to elderly Americans and moved the country significantly closer to completing the New Deal's promise of a comprehensive social safety net.[3] There were other, contemporaneous national biomedical initiatives, such as expansions of the National Institutes of Health (NIH) and the U.S. Food and Drug Administration (FDA). The simultaneous passage of Medicaid, along with support for community health centers and medical volunteerism through Great Society programming, also significantly boosted access to care for the poor. But only Medicare offered an assurance of operating revenue for nearly all health care providers and suppliers, with additional payments to boost capital investment and generous subsidies for the physician workforce—all with minimal controls beyond the ethical self-restraint of the American medical profession.

As the COVID-19 pandemic begins to recede, the United States finds itself in another "Medicare moment": an opportunity to combine principle with pragmatism in national health system design. What was denoted "single-payer" health reform in the 1990s is now called Medicare-for-All. Although "Medicare-for-All" admits a variety of meanings and interpretations,[4] the essence of the idea is to convert health coverage in the United States from a patchwork largely associated with private employment into a universal, national insurance entitlement. Proponents of Medicare-for-All offer an idealistic, ambitious vision—describing health care as a right, not a privilege, and invoking by verbal association that mid-1960s moment in U.S. health policy when solidarity seemingly triumphed over division.[5]

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1 Howard Bauchner, *Rationing of Health Care in the United States: An Inevitable Consequence of Increasing Health Care Costs*, 321 JAMA 751, 751-52 (2019). The author goes on to assert that an imminent "postmodern era of medicine" will generate even more dramatic yet expensive innovations in diagnosis and treatment. *Id.* at 751.

2 *See* Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (1965).

3 Theodore R. Marmor & Jerry L. Mashaw, *Understanding Social Insurance: Fairness, Affordability, and the 'Modernization' of Social Security and Medicare*, 25 HEALTH AFF. w114, w117 (2006).

4 *See infra* text accompanying notes 25-46.

5 A few Democratic candidates for president in 2020 endorsed Medicare-for-All in concept, and some offered moderately detailed plans. Medicare-for-All bills were introduced in the previous Congress, but never advanced through committee. *See, e.g.*, Medicare for All Act of 2019, H.R. 1384,

Revisiting Medicare as a principled program is important. In many ways, post-Medicare American medicine is a Gilded Age, not a Golden Era. The conventional assertion of American medicine's technological superiority tells only part of the story. The *JAMA* commentary offered above goes on to describe current forms of health care rationing as "linked to poverty, race, and ethnicity," and connects those disparities to public neglect of the "social determinants of health."[6] Concluding that "[g]reater rationing of care is inevitable if health care costs continue to increase," its author not only proclaims a right to health care and urges a more just distribution of medical advances, but he also calls for a public balancing of medical spending with investment in other social needs.[7] Failing to do so "in the richest country in the world," the *JAMA* editor-in-chief declares, "is a blight on the [U.S.] soul."[8]

The clearest health policy lesson from the COVID-19 pandemic year is that there remains a gulf between the health care system we have and the health care system we thought we had. There is much to celebrate about America's capacity to treat and prevent disease, as dramatic improvements in intensive care for COVID-induced respiratory failure and the rapid development and deployment of mRNA vaccines make clear. But the problems have become starker and harder to ignore, if still challenging to solve. Inadequate public health investment. Critical infrastructure funded mainly by revenue from elective procedures. Disparities that increase vulnerability in both exposure and prognosis arising from racism and injustice. Legal authorities straining for rationality in making care accessible and responsive. Cumulatively, we have learned that our much-vaunted health care system is unethical in both design and operation.

Medicare sent the United States down this path by writing a blank check for traditional medical transactions between one physician and one patient. We think

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116th Cong. (2019); Medicare Buy-In and Health Care Stabilization Act of 2019, H.R. 1346, 116th Cong. (2019) ("To amend title XVIII of the Social Security Act to provide for an option for individuals who are ages 50 to 64 to buy into Medicare, to provide for health insurance market stabilization, and for other purposes."); Medicare at 50 Act, S. 470, 116th Cong. (2019) ("A bill to amend title XVIII of the Social Security Act to provide for an option for any citizen or permanent resident of the United States age 50 to 64 to buy into Medicare.").

Comprehensive "single-payer" plans have been pursued in several states as well, creating microcosms of potential federal reform. Erin Fuse Brown and Elizabeth McCuskey identify sixty-six single-payer bills introduced at the state level between 2010 and 2019, although only Vermont's plan (later repealed) was enacted. *See* Erin C. Fuse Brown & Elizabeth Y. McCuskey, *Federalism, ERISA, and State Single-Payer Health Care*, 169 U. PA. L. REV. 389, 396-97 (2020). In addition, Massachusetts and Oregon have comprehensive multi-payer systems of coverage. *See id.* at 407, 423-28. Along with budgetary challenges, the preemptive effect of federal employee benefits law (Employee Retirement Income Security Act) constitutes a major barrier to state single-payer plans. *Id.* at 415-42.

6 Bauchner, *supra* note 1, at 751.

7 *Id.* at 752.

8 *Id.*

of Medicare as innovative because of the technical improvements it has funded over the years, and the vast medical-industrial complex it begat. In its original form, however, Medicare renounced innovation in physician practice and payment, becoming law only because it made itself unthreatening to the medical establishment.[9] Over time, Medicare's structural straitjacket distorted health system growth and bred considerable deformity in public policy.[10]

As the critical congressional vote on Medicare approached in the summer of 1965, President Lyndon Johnson capitulated to the political demands of the American Medical Association (AMA), which at the time spoke for the great majority of American physicians. Johnson's advisors estimated a price tag of $50 million a year for these concessions, beyond the previously projected cost.[11] The incremental cost of deferring to medical professional judgment on what should be funded and—at least originally—at what prices turned out to be orders of magnitudes larger. In 1975, the Medicare program cost federal taxpayers $16.3 billion.[12] By 2018, Medicare cost taxpayers $740.6 billion.[13] From 1970 to 2016,

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9 For an eyewitness account, see JOSEPH A. CALIFANO, AMERICA'S HEALTH CARE REVOLUTION: WHO LIVES? WHO DIES? WHO PAYS? (1986). In exchange for the American Medical Association (AMA) withdrawing its opposition to the program as "socialized medicine," the original Medicare legislation pledged non-interference with medical practice, paid customary fees, and replicated the familiar features of the private health insurance sector (which, at the time, was merely a passive conduit for provider payment). 42 U.S.C. § 1395, titled "Prohibition against any Federal interference," reads:

> "Nothing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person."

§ 1395.

10 Medicaid, by contrast, has had to be innovative in order to survive. Medicaid was paired with Medicare on the Johnson administration's legislative agenda not by progressive reformers, but by opponents of "socialized medicine" who thought that the public would not support social insurance to provide health care for the elderly if it were conditioned on also embracing medical welfare for the poor. For general analysis of Medicare and Medicaid politics, respectively, see LAURA KATZ OLSON, THE POLITICS OF MEDICAID (2014); and Bruce C. Vladeck, *The Political Economy of Medicare*, 18 HEALTH AFF. 22, 22-24 (1999). Threatened repeatedly with extinction in the decades since its enactment, Medicaid fought back and adapted, and now serves a larger population than Medicare at a lower annual cost. Medicaid, according to leading scholars, has become the truly "irreplaceable" federal health program. *See* Sara Rosenbaum & Elizabeth Taylor, *The Irreplaceable Program in an Era of Uncertainty*, 46 J.L. MED. ETHICS 883, 885 (2018).

11 CALIFANO, *supra* note 9, at 50-52.

12 BDS. OF TRS. OF THE FED. HOSP. INS. AND FED. SUPPLEMENTARY MED. INS. TR. FUNDS, 2019 ANNUAL REPORT OF THE BOARDS OF TRUSTEES OF THE FEDERAL HOSPITAL INSURANCE AND FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUNDS 168 (2019).

13 *Id.*

total national health expenditures grew from 6.9% to 18% of Gross Domestic Product.[14]

Because of Medicare—plus Medicaid and tax subsidies for private health coverage—descriptions of America's supposedly free market for health care as an international outlier in health policy tell a misleading story. Indeed, the United States stands alone among developed nations in lacking a true national health system. And, correspondingly, the United States spends far more private money per person on health care than any other nation. But the United States also typically spends more *public* money per person on health care than any other nation.[15]

Unlike Johnson's landslide victory in 1964—which made the original Medicare legislation politically achievable—President Joe Biden took office in 2021 with razor-thin majorities in both houses of Congress. Biden was the only candidate in the 2020 presidential field to celebrate "Obamacare," echoing the locker-room praise he had offered as Vice President when it was signed into law.[16] Given the plausible link between Biden's temperate positions and his narrow victory, it would be easy to criticize the progressive wing of the Democratic party as opening itself to accusations of confiscatory taxation and socialized medicine by endorsing Medicare-for-All while dismissing such a major legislative achievement in U.S. health policy as the Patient Protection and Affordable Care Act of 2010 (ACA).

This would be misguided. If anything, the outcome of the 2020 election gives Medicare-for-All heightened relevance as an analytical frame, beyond any utility it may have as a political rallying-cry. The conventional rhetoric of capitalism and socialism as opposing forces implies that highly efficient health care systems will be distributionally unfair, while equitable health care systems will be inefficient. This is a serious misreading of today's policy moment, in which common causes place inefficiency and inequity side-by-side.[17] The U.S. health care system has

14 *U.S. National Health Expenditure As Percent of GDP from 1960 to 2020*, STATISTA (June 8, 2020), https://www.statista.com/statistics/184968/us-health-expenditure-as-percent-of-gdp-since-1960/.

15 For specific comparisons among Organisation for Economic Cooperation and Development countries based on 2010 data, see *Health Care Spending Per Capita by Source of Funding, Adjusted by Cost of Living*, COMMONWEALTH FUND (2012), https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_in_the_literature_2012_nov_pdf_2012_oecd_chartpack.pdf. Whether the United States is at the top in per capita public funding of health care, or just near the top, has varied in recent years.

16 John Bowden, *Biden Campaign Starts Selling ObamaCare 'BFD' Stickers*, HILL, (July 31, 2019), https://thehill.com/homenews/campaign/455678-biden-campaign-starts-selling-obamacare-bfd-stickers.

17 This is literally if accidentally illustrated by a PowerPoint slide commonly used in presentations regarding "health equity." The slide shows an adult, teen, and child attempting to watch a baseball game over a solid fence, with one panel depicting an equal amount of assistance in the form of one wooden box for each to stand upon, which is excessive height for the adult and still

shown itself to be both grossly wasteful and profoundly unjust, with the COVID-19 pandemic experience inviting a serious ethical re-equilibration.

This Article's discussion of the transformative potential of Medicare-for-All proceeds as follows. Part I discusses how "Medicare-for-All" might be translated from a slogan to a program. Paired possibilities involve universal coverage, safety net reinforcement, and legal change. Part II describes the recent history of federal health reform, culminating in the passage of the Patient Protection and Affordable Care Act of 2010.[18] This policy history distinguishes principled moments from pragmatic ones, and explains what "single-payer" approaches traditionally sought to accomplish and why they were disfavored – primarily contestable perceptions of cost and fears of rationing. The events this Article describes parallel my own professional journey in health law and policy.[19] Part III outlines what researchers and policymakers have learned since the last "Medicare moment" in the early 1990s, when comprehensive federal reform failed. Concepts such as disparities, social determinants, non-medical investments, and value that are prominent in Dr. Bauchner's 2019 editorial but had been absent from earlier, similar ones.[20] Finally, Part IV discusses how a Medicare-for-All frame might take account of these new policy perspectives and promote critical improvements to U.S. health care. This Article's conclusion emphasizes ethical reengagement by physicians and other health professionals as essential to renegotiating the interplay of professional self-regulation, market processes, and the state, and therefore to defining a productive path forward.

I. SIX USEFUL MEANINGS OF "MEDICARE-FOR-ALL" (AND A CAUTIONARY

insufficient for the child. A second panel depicts no box for the adult, one for the teen, and two for the child, with all able to see. *See, e.g.*, Illustrating Equality VS Equity, INTERACTION INST. FOR SOC. CHANGE (Jan. 13, 2016), http://interactioninstitute.org/illustrating-equality-vs-equity/. The latter, equally costly but more effective approach is labeled "equity" in the graphic but is in fact efficiency. Also unaddressed in the graphic is why the three individuals, depicted as dark-skinned, must stand outside the ballpark at all.

18 Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended in scattered sections of the U.S.C.).

19 After completing a joint degree program in law and medicine and spending two years in graduate medical training and two years in corporate law practice, I had the opportunity to serve in the White House in early 1993, during the intense push to develop a national health reform proposal shortly after President Clinton took office. I returned briefly to California to resume health law practice and provide health policy advice to a gubernatorial candidate, then joined the faculty of Columbia Law School in 1995.

20 *New England Journal of Medicine* editors-in-chief Arnold Relman and Jerome Kassirer, for example, had focused their attention on access to medical services and to health insurance coverage. *See, e.g.*, Jerome P. Kassirer, *Managing Care – Should We Adopt a New Ethic*, 339 NEW ENG. J. MED. 397 (1998); Arnold S. Relman, *The Trouble With Rationing*, 323 NEW ENG. J. MED. 911 (1990).

ONE)

At the risk of stating the obvious, one should not invoke a policy concept without defining it, and "Medicare-for-All" admits a diversity of possible interpretations. Accordingly, advocates for "Medicare-for-All" might adopt a range of policy approaches to operationalizing the phrase. Leaving partisan litmus tests aside—proving one's progressive bona fides for Democrats, opposing socialism for Republicans—what forms might Medicare-for-All take, and what conditions might be conducive to a proposal that emphasizes each form?

This Section offers six possible ways to implement Medicare-for-All reform: two committing the United States to universal coverage, two strengthening the medical safety net through incremental coverage improvements, and two federalizing health care regulation without an explicit expansion of coverage. A seventh potential change to Medicare—offered by Medicare's skeptics—is also described briefly.

A. Universal Coverage

1. Medicare Eligibility for All

The most straightforward interpretation of the phrase "Medicare-for-All" is that all Americans would be automatically enrolled in Medicare, whether or not those individuals are among today's eligible population of (mainly) those age sixty-five and over.[21] This would include persons currently covered by employment-based insurance, those purchasing individual coverage (most on ACA insurance exchanges), and those who remain uninsured notwithstanding the ACA—in each case on the same terms they would be covered by Medicare at age sixty-five today. All current Medicaid recipients would become "dually eligible" for Medicare, rather than only certain subgroups as is the case now. The newly Medicare eligible would choose, as do current Medicare beneficiaries, between traditional Medicare (Parts A and B, with providers paid by the government) and Medicare Advantage (MA) plans (Part C, with providers paid by managed care

21 A bill introduced in the previous Congress by Rep. Pramila Jayapal (D-WA) and Sen. Bernie Sanders (I-VT) came closest to taking this approach. *See* H.R. 1384, 116th Cong. (2019) ("To establish an improved Medicare for All national health insurance program"); S. 1129, 116th Cong. (2019) ("To establish a Medicare-for-all national health insurance program"). Neither exactly replicates Medicare's financing and benefits structure. Both would significantly expand benefits to include Long-Term Services and Supports and other benefits more typical of Medicaid, and both would strictly limit beneficiaries' out-of-pocket costs for covered services. Both plans also rely almost exclusively on fee-for-service Medicare, essentially eliminating today's Part C governing MA plans. With respect to Part D, both of these proposals – as well as bills creating a partial expansion or public option – authorize the Secretary of Health and Human Services to negotiate prescription drug prices.

organizations in which beneficiaries enroll).[22] New Medicare members would be eligible for outpatient drug coverage from private plans operating under Part D, and could access the established, highly regulated "Medigap" market for voluntary supplemental coverage.[23]

Most Medicare financing would be borne by taxpayers, though the tax burden would be shared more broadly than in the current system as insurance coverage now paid from workers' earnings would be covered using tax dollars instead. Payroll-based income taxes would undoubtedly increase (as would equivalent taxes on non-wage income), but most compensation now paid by employers as untaxed insurance premiums likely would be retained by workers as taxable wages. States likely would remain financially responsible only for the Medicaid portion of the dually eligible, reducing their costs. Except for beneficiaries enrolled in MA plans, health care providers would be paid administered prices (i.e., Medicare-style reimbursement) for all patients in the form and amount they are currently paid for treating the elderly, although some physician specialties (e.g., pediatrics, obstetrics) would need to gain experience with Medicare.

Medicare-for-All payment would need to offer a fair return to health care providers, as the possibility for cross-subsidizing Medicare patients with funds from other payers would no longer exist (nor would private insurance be available to cross-subsidize Medicaid). Medicare's ongoing experiments with "alternative payment methods," such as accountable care organizations, bundled payments, and health homes, would adapt to the new enrollment.[24] Part D drug plans would serve a much larger population, with additional bargaining power to reduce prescription drug costs through market processes or using new authority conferred by government. The market for MA plans would grow substantially as well, with the potential for greater competition among them.

This outcome is unlikely during the Biden Administration given the President's preference for compromise, our polarized populace, and an evenly balanced Congress that would be unable to end a Senate filibuster and pass comprehensive legislation, even if recovering from the health and economic effects of the pandemic relaxed the expected fiscal constraints on entitlement legislation.

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22 *See* PETER R. KONGSTVEDT, ESSENTIALS OF MANAGED HEALTH CARE 499-525 (6th ed. 2012) (explaining managed Medicare coverage).

23 *What's Medicare Supplement Insurance (Medigap)?*, MEDICARE.GOV, https://www.medicare.gov/supplements-other-insurance/whats-medicare-supplement-insurance-medigap (last visited Aug. 1, 2021).

24 *See, e.g.,* Dawn E. Alley et al., *Accountable Health Communities—Addressing Social Needs through Medicare and Medicaid*, 374 NEW ENG. J. MED. 8 (2016) (describing demonstration and pilot programs to use Medicare and Medicaid funds for health-improving social services).

2. Medicare Advantage for All

A second possible meaning of Medicare-for-All would greatly simplify implementation and administration of an expanded Medicare program. The U.S. population not currently enrolled in Medicare would become eligible, but it would be required to enroll in MA plans where geographically available rather than in traditional, fee-for-service Medicare. This condition would not necessarily seem restrictive to new beneficiaries: most of the potential conversion population is already enrolled in employer-sponsored health plans that more closely resemble MA than traditional Medicare. Traditional Medicare would remain in place, but it would no longer be the dominant form of Medicare except perhaps in rural areas, and it would very likely fade in significance over time. Many health plans currently serving other market segments would pursue MA business (or, in large payer organizations, cede enrollment to that organization's MA product line). Individuals eligible for both Medicare and Medicaid would be served by health plans that comply with both programs' rules, as occurs today. Health care providers would negotiate with MA plans regarding network inclusion and fees, while continuing to provide residual service to fee-for-service Medicare beneficiaries. Taxpayer financing would replace premiums paid directly or through employers.

The presidential campaign proposal for universal coverage circulated by now-Vice President Kamala Harris made similar use of MA plans, enabling private insurers who currently offer employer-based and other coverage to convert those products into Medicare-regulated health insurance.[25] That proposal contemplated a ten-year transition to a system of universal, Medicare-based health plan coverage.[26] Still, this outcome remains unlikely during the Biden presidency: although it retains the structure of private insurance, it would still require a suspension or major relaxation of fiscal constraints on health care legislation.

B. A Stronger Safety Net

1. Medicare as a "Public Option"

"Medicare-for-All" need not denote immediate universalization of a Medicare entitlement. A more modest but still morally significant proposal would be to allow individuals not currently enrolled in Medicare to buy into the program as a "public option." This outcome is more likely given the political equipoise and impulse to moderation that seem to characterize the Biden presidency, as it could be

25 *See* Alexandra Hutzler, *Kamala Harris Finally Unveils Her 2020 Health Care Plan but Experts Are Skeptical About How She'll Pay For It*, NEWSWEEK (July 30, 2019), https://www.newsweek.com/kamala-harris-health-care-plan-2020-experts-skeptical-cost-1451633.

26 *Id.*

accommodated using current fiscal practices, including passage by a simple Senate majority through budget reconciliation. Following a playbook outlined by the Center for American Progress, President Biden supported a robust public option during his campaign, as did Secretary of Transportation Pete Buttigieg.[27]

To minimize its fiscal demands, a public option could be limited to purchasers of individual coverage (whether or not on ACA insurance exchanges), while those receiving employer-sponsored coverage and Medicaid beneficiaries could be ineligible. Traditional Medicare would remain important because the public option might be most attractive in geographic areas where few ACA exchange plans operate. Pricing the buy-in premium for traditional Medicare might be challenging. MA plans and Medicaid managed care plans might compete with ACA exchange plans if the public option permitted Medicare buy-in through those health plans. Health care providers would continue to work with multiple payers with varying benefit packages and payment methods.

Various public option proposals have been described or introduced. Most, including the Biden and Buttigieg campaign proposals, make public coverage voluntarily available to all Americans, not just those currently in individual health insurance. In the last Congress, Rep. Rosa DeLauro (D-CT) authored the Medicare for America Act, a public option supported by presidential candidate Beto O'Rourke.[28] The Urban Institute has described a plan that emphasizes a "Medicare-style marketplace," including a public plan option.[29] Several other proposals have offered a limited public option, not directly linked to Medicare, in connection with ACA marketplace coverage.[30] In May 2019, Washington became the first state to enact a public option for its state ACA marketplace; Colorado has authorized the development of a similar plan.[31]

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27 *Medicare Extra for All: A Plan to Guarantee Universal Health Coverage in the United States*, CTR. FOR AM. PROGRESS (Feb. 22, 2018), https://www.americanprogress.org/issues/healthcare/reports/2018/02/22/447095/medicare-extra-for-all/. Mayor Buttigieg describes his plan as "Medicare for All Who Want It." Dan Merica & Tami Luhby, *Buttigieg Outlines Middle-of-the-Road Approach to Health Care in New Plan,* CNN (Sept.. 19, 2019), https://www.cnn.com/2019/09/19/politics/pete-buttigieg-health-care-plan/index.html.

28 H.R. 2452, 116th Cong. (2019).

29 Linda J. Blumberg, John Holahan & Steven Zuckerman, *The Healthy America Program Building on the Best of Medicare and the Affordable Care Act*, URBAN INST. (May 14, 2018), https://www.urban.org/research/publication/healthy-america-program.

30 These resemble the public option in an early version of the ACA. *See, e.g.*, S. 3, 116th Cong. (2019); S. 1261/H.R. 2463, 116th Cong. (2019); Medicare X Choice Act, S. 981/H.R. 2000, 116th Cong. (2019); H.R. 2085/S. 1033, 116th Cong. (2019).

31 *See* Austin Jenkins, *Will Washington State's New 'Public Option' Plan Reduce Health Care Costs?*, NPR: SHOTS (May 16, 2019), https://www.npr.org/sections/health-shots/2019/05/16/723843559/will-washington-states-new-public-option-plan-reduce-heath-care-costs.

2. Medicare for More

In another incremental interpretation of Medicare-for-All principles, subsets of the population might be given either a Medicare entitlement or the opportunity to buy into Medicare (or Medicaid).[32] Rather than segmenting the population by age, "Medicare-for-More" proposals might provide Medicare coverage in rural areas, or in health professional shortage areas generally, or to low-income individuals, to persons with particular conditions (as with end-stage renal disease now), or to states that agree to make particular financial commitments (as with Medicaid today).

A proposal of this sort might, for example, lower the eligibility age for Medicare to fifty-five or permit buy-in at that age. Buy-in proposals for Medicaid coverage are also possible, most likely through managed care plans.[33] Medicare (or Medicaid) standards would apply to more of the population, but most parts of the country and most health care providers would experience few changes.

C. Changing the Rules

1. Medicare Pricing for All

There is a lot more to Medicare than eligibility for coverage, a point that the current debate over Medicare-for-All seldom acknowledges. To the extent that the Biden Administration applies moral pressure to overcome the inertia bred of interest group influence, Medicare-for-All has the potential to change the health care system by altering the rules of payment and practice.

A proposal with potentially universal application but less ideological baggage would require (or enable) all buyers of health care to pay as Medicare would pay for all or some products or services. The pernicious effects of "payer mix"—that hospitals and physicians expect greater remuneration for treating privately insured patients than Medicare or Medicaid beneficiaries—was immediately evident in the initial surge of the COVID-19 pandemic. Patients' fears of contracting COVID-

32 Two bills in the current Congress would expand Medicare to individuals age fifty and over: one introduced by Sen. Debbie Stabenow (D-MI), and one introduced by Rep. Brian Higgins (D-NY). At the federal level, a Medicaid buy-in bill has been introduced by Sen. Brian Schatz (D-HI) and Rep. Ben Ray Lujan (D-NM). Several state legislators have introduced bills to permit buy-in to Medicaid; the Nevada legislature passed such as bill in 2017, but it was vetoed by the governor. *See* Heather Howard, *Map: State Efforts to Develop Medicaid Buy-in Programs*, STATE HEALTH AND VALUE STRATEGIES (June 4, 2019), https://www.shvs.org/state-efforts-to-develop-medicaid-buy-in-programs/); David Montero, *Nevada Governor Vetoes Medicaid-for-All Bill*, L.A. TIMES (June 17, 2017), https://www.latimes.com/nation/la-na-nevada-medicaid-2017-story.html.

33 *See* Michelle Andrews, *Progressives Tout 'Medicare-For-All' But States Eye 'Medicaid Buy-In',* KAISER HEALTH NEWS (Feb. 26, 2019), https://khn.org/news/progressives-tout-medicare-for-all-but-states-eye-medicaid-buy-in/.

19, followed by state-mandated moratoria on elective procedures to prevent spread and preserve scarce supplies, led to a precipitous drop in demand for privately financed medical care. The Medicare and Medicaid patients most likely to need intensive treatment for COVID-19, seniors and poorer individuals with greater occupational or residential exposure and pre-existing health problems, were significantly less lucrative and put many hospitals in financial jeopardy just when they were most needed.[34]

In a payment-based interpretation of Medicare-for-All, provider or supplier prices not considered reasonable by Medicare, including high prices resulting from the exercise of market power, would be discouraged or reduced. Additional authority to negotiate or set prescription drug prices might be enacted. Uniform pricing would require standardized measurement, with attendant advantages (e.g., technical interoperability, reduction of conflict or duplication) and disadvantages (e.g., lock-in of particular delivery models or performance metrics). Cross-subsidization and "cost-shifting" among payers by hospitals and physicians would be more difficult to maintain. The effect of this change on privately negotiated health care is uncertain. As with the safety net proposals above, however, Medicare pricing for more rather than for all is possible as well, and could be targeted to specific market conditions, services, providers, or recipients.[35]

No current federal proposal takes this approach to payment without also adopting a comprehensive single-payer plan, but some state-level public option plans peg provider payment to Medicare rates. The State of Washington public option plan on the ACA marketplace pays providers at 160% of Medicare rates; Colorado's plans would be more broadly available and would pay at 175-225% of Medicare.[36]

2. Medicare (Federal) Regulations for All

It is possible to interpret "Medicare-for-All" as reversing current preferences for federalism and state authority in favor of uniform federal rules. The ACA took this approach with respect to prohibiting medical underwriting and making other changes to the rules governing the individual insurance market (which previously was subject primarily to state oversight). The ACA also standardized insurance benefits, although in practice the "essential health benefits" required by the ACA

34 The adverse financial effects on hospitals of payer mix differentials may be long-lasting if job recovery is slow and significantly more patients remain on Medicaid after the pandemic recedes than were previously enrolled. Glenn Melnick & Susan Maerki, *The Financial Impact of COVID-19 on California Hospitals*, CAL. HEALTH CARE FOUND. REPORT (June 3, 2020), https://www.chcf.org/publication/financial-impact-covid-19-california-hospitals/.

35 *See infra* notes 200-204 and accompanying text.

36 Jenkins, *supra* note 31.

reflect state norms rather than a true national consensus.

Among the laws that could be made nationally uniform are professional licensing laws, laws conferring authority to write prescriptions, laws governing the "corporate practice of medicine," health planning laws such as certificates of need, medical malpractice laws, telemedicine laws, and survey and certification practices for health facilities (many of which are already uniform because of the Joint Commission).[37] Patients, providers, and payers across the country would vary considerably in how they were affected by the nationalization of particular legal standards.

Again, the COVID-19 experience is instructive and adds to the appeal of this approach. Rapidly redeploying health professionals from lower-need to higher-need locations as infections spiked around the country was inhibited by protectionist state licensing laws and geographically limited processes for granting medical staff privileges at hospitals.[38] Provincial regulatory restrictions on populations, presentation, and payment hindered the expansion of telehealth services, as did scope of practice laws in limiting the ability of advanced practice nurses and others with demonstrably valuable skills to step up and serve to the full extent of their education and training. Although most states adopted emergency regulations to facilitate an effective pandemic response, there is already evidence of backsliding under pressure from interest groups. There is no federal constitutional obstacle to taking a more national approach to commerce in medical services, and it may well be time to do so as the nation emerges from the pandemic.

The Veterans Health Administration has adopted rules enabling its health care providers to treat patients across state lines without being limited by state laws on scope of practice or telemedicine.[39] Beyond addressing discrete problems such as "surprise medical bills," however, no federal legislative proposal takes this approach at present.

D. Medicare for None: Premium Support

Although current Democratic control of Congress and the White House provides temporary inoculation against the possibility, no compendium of potential approaches to Medicare reform would be complete without noting the longstanding desire in some conservative circles to reduce the threat that Medicare poses to their preference for a smaller national government that maintains low

37 *See infra* notes 143-162 and accompanying text.

38 *See, e.g.*, Donnie L. Bell & Mitchell H. Katz, *Modernize Medical Licensing, and Credentialing, Too—Lessons from the COVID-19 Pandemic*, 181 JAMA INTERNAL MED. 312, 312-15 (2021).

39 *See* Press Release, U.S. Dep't of Veterans Affairs, Office of Public and Intergovernmental Affairs, VA Expands Telehealth by Allowing Health Care Providers to Treat Patients Across State Lines (May 11, 2018), https://www.va.gov/opa/pressrel/pressrelease.cfm?id=4054.

taxes while avoiding fiscal catastrophe. Advocates for fiscal prudence, traditionally though not presently a hallmark of the Republican party, have long sought to shift the risk of continued increases in health care costs from the federal government by changing Medicare from a defined benefit to a defined contribution model. This is typically referred to as "premium support."

Sherry Glied has observed that Medicare premium support proposals run exactly counter to economic logic: individuals are poorly positioned to bear the additional risk, the government is well-positioned to bear that risk, and the government has far greater ability than individuals to control and limit that risk.[40] Still, conservatives whose preoccupation with moral hazard originally motivated the "consumer-directed" health care movement,[41] and who continue to endorse "high-deductible" private health plans and "block grants" as a replacement for the existing Medicaid entitlement, have never abandoned the idea of premium support in Medicare.

In the aggregate, these alternative formulations of Medicare-for-All reveal the phrase's potential to capture a variety of values and pursue a number of goals beyond the assertion of an enforceable "right" to health care and the expression of mistrust in commercial purveyors of health insurance. Principles that might be advanced include greater social solidarity around health, diversified public investment in non-medical as well as medical services, non-discriminatory access and consistent administrative oversight from person to person and place to place throughout the nation, and respect for dignity and personhood associated with illness or incapacity. Unfortunately, many of these ideals have been caricatured or short-changed by a generation of health policy pragmatism, which the next section describes in detail.

II. PRINCIPLE OR PRAGMATISM: THE EBB AND FLOW OF "SINGLE-PAYER" HEALTH REFORM

The seemingly inexorable growth of U.S. health care spending from the 1970s onward constitutes a background condition for all post-Medicare federal reform efforts. As is often observed about the 1970s, the temporal proximity of adverse economic circumstances (oil shocks, recession, and inflation) to adverse political circumstances (Vietnam and Watergate) reduced confidence in government and limited its ambition.[42] These pressures are evident in federal health policy.

Although Medicare's direct effects on overall health care spending were not

40 *See* Sherry A. Glied, *Financing Medicare Into the Future: Premium Support Fails the Risk-Bearing Test*, 37 HEALTH AFF. 1073, 1073 (2018).

41 *See infra* notes 95-97 and accompanying text.

42 *See generally* DAVID FRUM, HOW WE GOT HERE: THE 1970S: THE DECADE THAT BROUGHT YOU MODERN LIFE (FOR BETTER OR WORSE) (2000) (describing a decline of national ambition).

widely noted in the 1970s and 1980s, the uncapped financial exposure that Medicare created for taxpayers as those expenditures increased was a constant concern. As a country no longer at war turned against big government and the taxation that supported it, what had been understood as the social price of medical progress in the world's wealthiest nation came to be seen as a bottomless pit of potential public spending. Beginning with the Budget Control Act of 1974,[43] a series of disciplinary measures were adopted on a bipartisan basis to define and enforce fiscal prudence. Every substantial change in federal health policy from that point forward would either be motivated by cost reduction or have to justify (and typically offset) any costs it imposed. In health policy, principle would repeatedly yield to pragmatism.

A. Nothing Ventured: President Clinton's Health Security Act

The best example is the 1993-94 failure of national health reform, when centrist pragmatism won the policy battle but lost the political war. By 1990, Medicare expenditures were a known peril to the nation's fiscal health. The program had reconfigured its methods for paying both hospitals and physicians, but a broader reform called the Medicare Catastrophic Coverage Act (MCCA) had failed catastrophically, labelling Medicare the "third rail" of American politics.[44]

As the Democrats reclaimed the White House in 1993 after twelve years of Republican control, it was widely expected that a single-payer plan for universal health coverage would follow. As previous Democratic administrations had passed Medicare and a National Health Planning Act, there appeared to be a public mandate for health reform, and the individual charged with leading the health reform effort—First Lady Hillary Clinton—was said to be sympathetic to liberal, big-government solutions for what was labeled "health insecurity."[45]

What might a single-payer plan have achieved in 1993, had one been enacted? First, it very likely would have reduced the portion of U.S. health care spending that goes to administration rather than the delivery of care—a goal that Dr.

43 The Congressional Budget and Impoundment Control Act of 1974, Pub. L. No. 93-344, 88 Stat. 297 (codified as amended in scattered sections of 2 and 31 U.S.C.).

44 Medicare Catastrophic Coverage Act of 1988, Pub. L. No. 100-360, 102 Stat. 683. The Medicare Catastrophic Coverage Act (MCCA) expanded Medicare's covered benefits to include prescription drugs and to reduce residual cost exposure for serious illness. Unlike conventional Medicare, however, the MCCA was financed by a tax on beneficiaries, which prompted a backlash and, ultimately, repeal of the law before it ever took effect.

45 The Clinton Administration's proposal was introduced in Congress as the "Health Security Act," mock "Health Security" cards were distributed to the public in order to build political support, and the tag line associated with the campaign was "Health care that is always there." *See Clinton's Health Plan; Transcript of President's Address to Congress on Health Care*, N.Y. TIMES (Sept. 23, 1993), https://www.nytimes.com/1993/09/23/us/clinton-s-health-plan-transcript-president-s-address-congress-health-care.html.

Bauchner, writing in 2019, still strongly endorses.[46] Leaving aside the critical question of how large the denominator for medical spending *should* be, Medicare disburses a much smaller fraction of its funds on administration than do multiple private insurers who must market their policies, pay commissions to brokers, determine eligibility, and (pre-ACA) price their policies based on risk of loss—tasks typically done annually in private markets and only somewhat simplified by offering group coverage through employers.[47]

Second, a single-payer approach would have attached moral primacy to universal access to care, an expression of social solidarity that is uncontroversial abroad but seldom voiced in the United States. Third, it would have regularized the evaluation of new technologies, while potentially creating a closer connection between public funding of biomedical research and access to the resulting therapies.[48] Fourth, drawing together these strands, it would have created a collective defense of health care affordability that could function as a political counterweight to the self-interest of smaller but more motivated stakeholder groups.[49] In the United Kingdom, where health care spending remains roughly half that of the United States, citizens bind themselves collectively through the rules of the National Health Service to restrictions on high-cost care that they otherwise might resist as individuals if they became medical patients with specific desires regarding their own treatment.

When President Clinton instructed the leaders of his health care reform working group to explore options, however, single-payer reform was already off the table.[50] Instead, the favored strategy was declared to be "managed competition." A structured system of constrained choice among private health

46 Bauchner, *supra* note 1, at 752.

47 According to the Kaiser Family Foundation, traditional Medicare's cost of administration in 2018 was only 1.8% of program spending. Juliette Cubanski et al., *The Facts on Medicare Spending and Financing*, KAISER FAMILY FOUND. (Aug. 20, 2019), https://www.kff.org/medicare/issue-brief/the-facts-on-medicare-spending-and-financing/.

48 The federal Office of Technology Assessment (OTA) was established in 1977, when federal health planning and single-payer health reform were being actively considered by Congress, and was defunded in 1995, after the failure of the Clinton health reform effort. Although OTA assessed a wide range of technologies in order to improve governmental processes, its health care evaluations were among its most important and its most controversial. *See The OTA Legacy*, OFFICE OF TECHNOLOGY ASSESSMENT, http://www.princeton.edu/~ota/ (last visited Aug. 1, 2021).

49 *See* Lawrence R. Jacobs, *Politics of America's Supply State: Health Reform and Technology*, 14 HEALTH AFF. 143, 143 (1995) (noting that, unlike nations with formal commitments to universal coverage, U.S. politics prioritize expanding the supply of health care products and services over assuring broad access to those benefits).

50 I served as a "cluster leader" in the Clinton Administration's health reform effort, with responsibility for groups of experts making recommendations regarding health care quality, information systems, medical malpractice liability, the health care workforce, and academic health centers. The anecdotes related in the section are personal recollections.

plans accessed through employers that would compete on price and quality rather than avoidance of risk, managed competition was a formulation associated with a small group of moderate economists and policy experts, several from California.[51] One irony was that, in many respects, managed competition was similar to the never-introduced Nixon Administration's health plan, which had been drafted following the passage of the managed care-sympathetic Health Maintenance Organization Act of 1973.[52] A second irony was that the Clinton Administration's "health czar," a quirky management consultant named Ira Magaziner who had been a Rhodes Scholar with the President, believed fervently that reducing administrative costs was the key to successful health reform.[53] This assumption, if warranted, argued for a single-payer approach; the complexities of managed competition necessitated more rather than less administrative investment. A third irony was that Medicare, a single-payer construct, would be preserved intact rather than restructured—the federal government's largest existing system of health insurance having been rendered politically untouchable by fear of triggering the same "gray panther" uprising that had brought down the MCCA only a few years earlier.[54]

1. Fiscal Politics

What killed single-payer health reform in 1993? Several factors, all of which bridge health reform approaches but have special salience for systems of national insurance, including the Medicare-for-All proposals circulating in 2020. Foremost among these was what Lawrence Jacobs at the time called the "fiscalization of access," which has become such a formidable barrier to health system change that it is more accurately described today as the "tyranny of the budget."[55]

In 1993, as the country began its fragile recovery from a mercifully brief recession, budgetary discipline had unusual public salience because it had been the

51 *See* Alain C. Enthoven, *The History and Principles of Managed Competition*, 12 HEALTH AFF. 24, 24, 46 (1993); *see also* Alain Enthoven & Richard Kronick, *A Consumer-Choice Health Plan for the 1990s*, 320 NEW ENG. J. MED. 29 (1989) (proposing a competitive health care system that would improve both accessibility and affordability).

52 *See* President Richard Nixon, President Richard Nixon's Special Message to the Congress: Proposing a Comprehensive Health Insurance Plan (Feb. 6, 1974) (transcript available at https://www.nixonfoundation.org/2015/11/the-nixon-comprehensive-health-insurance-plan/).

53 Magaziner repeatedly asserted that his work as a management consultant on nursing homes in Rhode Island had revealed profound inefficiencies associated with, in his phrasing, "checkers checking checkers."

54 *See supra* text accompanying note 48.

55 *See* Jacobs, *supra* note 49, at 149; *see also* William M. Sage, *No, the ACA Isn't Unconstitutional: Ends and Means in a Dysfunctional Democracy*, HEALTH AFF. BLOG (Dec. 19, 2018), https://www.healthaffairs.org/do/10.1377/hblog20181219.912615/full/?fbclid=IwAR3PCLAqwDw6i94qWwkgXwGMuoHRjxeoVCTl_CVfaSb52812m2EWWdjky3E, (explaining why budgetary policy and politics have repeatedly subjected the ACA to litigation).

primary focus of Texas businessman Ross Perot in his third-party candidacy for president one year earlier. Given other budgetary needs, the Clinton Administration found itself having to demonstrate that insuring an additional 15% of the U.S. population without cutting Medicare would end up costing the government *less* money than it was already spending.[56] In factual terms, this was simply impossible, but the Administration's budgeting wizards did everything they could to situate their proposal favorably within the Congressional Budget Office's (CBO) arcane "scorekeeping" rules.[57]

The need for a benign budgetary evaluation was an absolute bar to the Clintons pursuing a single-payer program.[58] CBO scoring remains a major consideration to this day: if one follows current fiscal accounting practices, converting private, employer-sponsored coverage into a Medicare benefit would constitute an immediate nearly $1.5 trillion annual tax increase on the American people accompanied by a reciprocal annual increase in federal government expenditures, even though the money would start and end in the same places (individuals and their health plans) and be spent on the same thing (health insurance).[59]

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56 George Stephanopoulos (personal communication as a guest lecturer at Columbia Law School, May 1998).

57 "Health alliances" (previously called "health insurance purchasing cooperatives") were nonprofit bodies that would have structured regional health insurance markets, receiving contributions from employers and paying risk-adjusted premiums to the health plans in which beneficiaries had enrolled. "Global budgets" would have limited, as a matter of law, the aggregate amount that could be paid for the statutory package of health benefits, imposing various correctives that (if not revised by a subsequent Congress) would be triggered should the limits be exceeded. For insight into the role of the Congressional Budget Office, as well as its struggle to maintain impartiality, see Viveca Novak, *By the Numbers*, NAT'L J., Feb. 12, 1994, at 348.

58 *See Health Care Reform (Part 10): Joint Hearing Before the Subcomm. on Health and the Env't and the Subcomm. on Com., Consumer Prot. and Competitiveness of the H. Comm. on Energy and Com.*, 103d Cong. 10-13 (1994) (statement of Robert D. Reischauer, Director, CBO) (citing data that the limits placed on premiums and Medicare savings are sufficient to reduce national health expenditures by some $30 billion below baseline levels by 2000 and $150 billion below baseline levels by 2004, but also concluding that mandatory payments from private employers to health alliances constitute "an exercise of sovereign power" and therefore a tax).

59 Private health insurance premiums were over $1.35 trillion in 2020. Sean P. Keenan et al., *National Health Expenditure Projections, 2019–28: Expected Rebound in Prices Drives Rising Spending Growth*, HEALTH AFF. Mar. 24, 2020, at 704-05 (2020). For a superb account of how fiscal politics drives health care policy, see Timothy Westmoreland, *Invisible Forces at Work: Health Legislation and the Budget Process*, *in* OXFORD HANDBOOK OF U.S. HEALTHCARE LAW 873 (I. Glenn Cohen et al. eds., 2016). In addition to the failed Health Security Act and the ACA's individual mandate, tobacco control, physician payment, and the ACA's Medicaid expansion were all largely the product of fiscal compromise.

2. Rationing Care

A second problem was the accusation of rationing.[60] Evaluating the health reform landscape in 1990, during a period of general economic uncertainty, the editor-in-chief of the *New England Journal of Medicine* observed: "Suddenly everyone is talking about rationing."[61] After weighing arguments for and against, however—including the "discomfort" of physicians—he concluded that "a public rationing plan would not be ethically or politically acceptable at this time," and called for "improv[ing] the system rather than rationing its services."[62]

The possibility of improvement without rationing was not intuitive to the public, however. In 1993, commentators universally proclaimed American health care to be "the best in the world," and any suggestion of centralized limits on access to new therapies was both frightening to voters and an admission of weakness for leaders. This was bipartisan: neither George H.W. Bush, when evaluating (and rejecting) a Medicaid waiver for a novel system that the state of Oregon proposed for prioritizing treatments according to cost-effectiveness,[63] nor Bill Clinton, when considering the direction of his comprehensive health reform effort, was willing to echo Jimmy Carter's defeatism by becoming the first American president to concede the need to ration potentially life-saving medical care. Leading bioethicists invited to participate in the policy development phase of the Clinton reform, who imagined their role as helping craft an ethically defensible system of rationing, were unceremoniously informed that they were welcome to work on advance directives for end-of-life care, but that the "R-word" could not be uttered.[64]

The more easily a health reform proposal can be portrayed as a "government takeover," the more vulnerable it is to accusations of rationing.[65] Single-payer

60 For early, influential work on rationing health care, see GUIDO CALABRESI & PHILIP BOBBITT, TRAGIC CHOICES (1978); and VICTOR R. FUCHS, WHO SHALL LIVE?: HEALTH, ECONOMICS, AND SOCIAL CHOICE (1975).

61 Arnold S. Relman, *supra* note 20. Known to his friends as "Bud," Dr. Relman was a passionate defender of Harvard-quality academic medicine, and a strident critic of the skewed incentives and casual profligacy he observed beyond the Longwood campus and its peer institutions.

62 *Id.* at 912.

63 For perceptive analyses of the Oregon Health Plan, see James F. Blumstein, *The Oregon Experiment: The Role of Cost-Benefit Analysis in the Allocation of Medicaid Funds*, 45 SOC. SCI. & MED. 545 (1997); and Jonathan Oberlander et al., *Rationing Medical Care: Rhetoric and Reality in the Oregon Health Plan*, 164 CANADIAN MED. ASS'N J. 1583 (2001).

64 *See, e.g.,* NORMAN DANIELS & JAMES E. SABIN, SETTING LIMITS FAIRLY: CAN WE LEARN TO SHARE MEDICAL RESOURCES? (2002) (describing sources of ethical legitimacy that might be applied to rationing in connection with national health reform). Ethicists participating in the Clinton reform effort were also discouraged from using the word "right" in connection with health care, as that connoted a European-style single-payer system with its attendant fiscal-political risks.

65 *See* Frank Luntz, *The Language of Healthcare 2009: The 10 Rules for Stopping the "Washington Takeover" of Healthcare*, THINKPROGRESS 1 (2009), http://thinkprogress.org/wp-

approaches are squarely in the crosshairs for these attacks. This remained true for the ACA during the Obama administration, when Alaska Governor Sarah Palin and other opponents of health reform cited the nascent law's supposed "death panels" as evidence of extreme social control.[66] These wholly unfounded allegations forced health reform proponents not only to defend a mild provision that would have permitted Medicare to reimburse end-of-life conversations between patients and their physicians as covered services,[67] but also to explicitly prohibit any application of newly funded (and much-needed) research regarding comparative clinical effectiveness to actual coverage determinations.[68]

3. Interest Group Gridlock

The third problem was extreme risk aversion among organized interest groups. Fearmongering about "socialized medicine" had been an obstacle to a national health system in the United States since the 1940s, and it constituted the AMA's drumbeat against Medicare in the 1960s.[69] Those fears reinforced the Clinton Administration's budgetary preference for tax-subsidized private coverage rather than single-payer public insurance in 1993, but it was the overhang of the 1988 MCCA debacle that made the political climate even less hospitable to any dramatic

content/uploads/2009/05/frank-luntz-the-language-ofhealthcare- 20091.pdf (contending that "[n]othing else turns people against the government takeover of healthcare than the realistic expectation that it will result in delayed and potentially even denied treatment, procedures and/or medications").

66 *See* Jim Rutenberg & Jackie Calmes, *False "Death Panel" Rumor Has Some Familiar Roots*, N.Y. TIMES (Aug. 13, 2009), https://www.nytimes.com/2009/08/14/health/policy/14panel.html (linking conservative criticism of government "death panels" that would purportedly be created by enacting proposed health care reform to similar conservative attacks against Clinton's health care reform efforts in the 1990s).

67 *See* Benjamin W. Corn, *Ending End-of-Life Phobia —A Prescription for Enlightened Health Care Reform*, NEW ENG. J. MED., Dec. 31, 20099, at e63(1)-(2); Peter Ubel, *Why It Is So Difficult to Kill the Death Panel Myth*, FORBES (Jan. 9, 2013, 12:00 PM), http://www.forbes.com /sites/peterubel/2013/01/09/why-it-is-so-difficult-to-kill-the-deathpanel-myth/.

68 The ACA funds "patient-centered outcomes research," but eschews any use of that research to dictate health care financing decisions unless narrowly limited to clinical effectiveness. *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6301(c), 124 Stat. 119, 740 (2010) ("The Secretary shall not use evidence or findings from comparative clinical effectiveness research conducted under section 1181 in determining coverage, reimbursement, or incentive programs under title XVIII in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.").

69 Ronald Reagan, then best known as an actor, was hired by the AMA in 1961 to explain his opposition to Medicare on a 45-RPM record called "Ronald Reagan Speaks Out Against Socialized Medicine." Physicians' wives hosted social gatherings to listen to the LP and spread the word. *See* DAVID HYMAN, MEDICARE MEETS MEPHISTOPHELES 27-30 (2006).

reconceptualization of health care.

The MCCA had been negotiated within the Beltway by interest group staffers who regarded it as necessary and uncontroversial, and who were shocked when strident grassroots opposition among the elderly forced an immediate congressional retraction.[70] The result was a sharp decrease in risk-taking among stakeholder groups. Rather than offer concessions in backroom negotiations, many stakeholder organizations waited for direction from their grassroots membership, or went directly to the public to mobilize opposition and halt reform in its tracks. The "Harry and Louise" campaign by the Health Insurance Association of America to preserve "free choice of health insurer" was the best-known and most successful example.[71]

B. Compromises and Dialectics

From 1994 until the passage of the ACA in 2010, U.S. health reform legislation remained pragmatic. To put it more accurately, ideology hedged its bets. Repeatedly during this period, laws were enacted that included rival principles, with each side hoping that its assumptions would prove accurate, and its favored direction of reform would prevail.

The Clinton reform, though unsuccessful, offers a compelling example. With nary a Republican in sight, staffers at the Department of Health and Human Services pushed to include structures and safeguards familiar to them from Medicare, while advisors from beyond the Beltway, particularly California, argued for a more market-based scheme. Drawing concepts from both camps, the compromise framework for reform became "competition under a budget." Although the Clinton Administration's policy gurus tried mightily to rationalize the bifurcation,[72] one group of internal advocates believed that competitive processes would maintain quality at affordable cost while the other assumed that

70 *Id.* at 41-46.

71 *See generally* Raymond L. Goldsteen et al., *Harry and Louise and Health Care Reform: Romancing Public Opinion*, 26 J. HEALTH POL., POL'Y & L. 1325 (2001) (analyzing the Health Insurance Association of America's campaign against the Clinton Administration's health care reform proposal). A White House Correspondents' dinner video, with President Clinton playing "Harry" and the First Lady portraying "Louise," offers a fitting response. Clintonlibrary42, *A Message from Harry & Louise*, YOUTUBE (May 10, 2012), https://www.youtube.com/watch?v=1-7A8d2wptI&ab_channel=clintonlibrary42.

72 *See, e.g.*, Paul Starr & Walter A. Zelman, *A Bridge to Compromise: Competition Under a Budget*, 12 HEALTH AFF. 7 (Supp. 1993). Starr and Zelman, who were among the principal architects of the Clinton health plan, likened the dual approach to "belt and suspenders." Once it became clear that CBO would credit a statutory budget cap as limiting the fiscal profligacy of health reform, global budgeting became a political necessity. To be fair, no nation had controlled health care spending through competitive processes no matter how appealing the theoretical case might be for a market-based approach.

budgetary limits would quickly be exceeded, triggering a single-payer substitute. This dialectic persisted throughout the policy development period and was retained in the final bill because an explicit "global budget"—whether or not realistic—carried with it the strong secondary advantage of assuring that the CBO's estimate of the legislation's cost would be capped at a politically manageable amount in a plan that otherwise depended mainly on private actors whose behavior was difficult for the CBO to assess.[73]

Although it would take another fifteen years for comprehensive health reform to regain a place on the national political agenda, many of the changes that were enacted in the interim had a similar duality. In the Medicare Modernization Act of 2003, for example, a Republican administration and a Democratic Congress reached agreement on adding a Part D benefit for outpatient pharmaceuticals to the Medicare statute.[74] The Democrats drew public attention to the ends: a substantial new entitlement program that could be a step toward full universal coverage. The Republicans drew public attention to the means: competing private drug plans that could be a step toward full privatization of Medicare.[75] Apposition of principles also characterized the Health Insurance Portability and Accountability Act of 1996 (HIPAA).[76] The first health care legislation following the 1994 Republican sweep of both the House and Senate, HIPAA combined novel federal restrictions on health insurance underwriting (i.e., partially managed competition) with a federal charter for high-deductible insurance and health savings accounts. The latter approach advanced a wholly different principle: reducing rather than increasing health insurance coverage so as to combat "moral hazard" when generously insured individuals choose to utilize medical services.[77] The following year, the Balanced Budget Act of 1997 paired the preservation of Medicaid and fee-for-service Medicare, as well as restrictions on managed care (part of the national backlash described below), with an expanded and reinvigorated managed care

73 *See supra* notes 55-59 and accompanying text.

74 Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2071–2152 (2003) (setting forth Medicare prescription drug benefits).

75 *See generally* Thomas R. Oliver et al., *A Political History of Medicare and Prescription Drug Coverage*, 82 MILBANK Q. 283 (2004) (explaining why Medicare omitted outpatient drug coverage until 2003).

76 Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, § 264(c)(1), 110 Stat. 1936, 2033 (1996).

77 An allegorical account of the theory of moral hazard in health insurance is presented in Gerald L. Musgrave et al., *Lunch Insurance*, CATO INST. (1992), https://www.cato.org/sites/cato.org/files/serials/files/regulation/1992/10/reg15n4a.html (postulating a "lunch system" with subsidies similar to the current health care system). For a contrary take, see John A. Nyman, *Is "Moral Hazard" Inefficient? The Policy Implications of a New Theory*, 23 HEALTH AFF. 194 (2004) (arguing that when an individual becomes seriously ill, that individual has no higher use for funds than to pay the cost of treatment).

program for Medicare.[78] Denominated Part C and named Medicare+Choice (later rebranded as Medicare Advantage), it changed Medicare managed care from a niche enterprise to a rapidly growing, partially privatized form of national health insurance for the elderly.[79]

C. The Poorly Restrained Market

The Clinton Administration's centrist approach to health reform in the early 1990s marked a distinct turn toward market signals as the basis for federal health policy, extending both the Nixon Administration's belief in "good" HMOs such as Kaiser Permanente in California,[80] and the Reagan-Bush Administrations' savings-minded reconfiguration of Medicare payment incentives for hospitals and physicians, as well as their solicitude toward HMO participation and selective provider contracting in state Medicaid programs.[81]

Although "managed competition" was never synonymous with "managed care," it seemed sufficiently aligned with corporate incursion into the physician-patient relationship that fears over the latter were readily transferred to the former.[82] Perhaps the most widely read condemnation of the Clinton Health Plan was an essay titled "No Exit," written by a well-connected conservative polemicist and minor academic who would later serve as the lieutenant governor of New

78 Balanced Budget Act of 1997, Pub. L. No. 105–33, 111 Stat. 251.

79 According to the Kaiser Family Foundation, as of late 2018 approximately 20 million Americans were enrolled in Medicare Advantage plans, constituting 34% of total Medicare beneficiaries. *See* Gretchen Jacobson et al., *A Dozen Facts About Medicare Advantage*, KAISER FAM. FOUND. (Nov. 13, 2018), https://www.kff.org/medicare/issue-brief/a-dozen-facts-about-medicare-advantage/.

80 For a history of the Kaiser-Permanente organization, see RICKEY HENDRICKS, A MODEL FOR NATIONAL HEALTH CARE: THE HISTORY OF KAISER PERMANENTE (HEALTH AND MEDICINE IN AMERICAN SOCIETY) (1993).

81 According to the Medicaid and CHIP Payment and Access Commission (MACPAC), the principal federal advisory body on Medicaid and CHIP policy: "Section 1915(b) of the Social Security Act, enacted in 1981 as part of the Omnibus Budget Reconciliation Act (P.L. 97-35), provides states with the flexibility to modify their delivery systems by allowing CMS to waive statutory requirements for comparability, statewideness, and freedom of choice. States typically use two provisions in the law to implement managed care delivery systems." *1915(b) waivers*, MACPAC, https://www.macpac.gov/subtopic/1915b-waivers/ (last visited Aug. 1, 2021).

82 "Managed care" has never been cleanly defined or popular as a term, but in the aftermath of debate over the Clinton plan and then its demise, it became shorthand for private sector efforts to reduce health insurance costs, mainly in the employment-based health plans that cover a plurality of Americans but also by serving Medicaid and, more slowly, Medicare beneficiaries. There were three principal tools of managed care: (i) pre-approval of coverage through "utilization review" of high-cost services and through "primary care gatekeeping" of access to specialists likely to provide those services; (ii) selective contracting with hospitals and physicians, which permitted per-service price negotiation with the promise of patient volume (and under the threat of exclusion); and (iii) financial incentives such as capitation payments or percentage "withholds" from aggregate fees to induce physician cost-consciousness in clinical recommendations.

York.[83] Most of the accusations it hurled at the Administration's proposal—some foreshadowing the ACA's apocryphal "death panels"—were really about the aggressiveness of private managed care, not overreach by government.

Similar objections were raised to "enterprise liability" for medical malpractice, an academic construct that the Clinton Administration unexpectedly cast into the national spotlight as an operational proposal.[84] The core idea was that, in order to maintain incentives for quality and safety, liability in the event of negligent injury should fall not on individual physicians, but on the health plans that were no longer to be merely passive funders of care.[85] At a time when doctors hated and feared malpractice suits with unrivaled intensity, one might think the proposal would have triggered a celebration within organized medicine. Not so. Physicians recoiled at the thought of HMOs as defendants in malpractice suits—seeing in the transfer of legal accountability a harbinger of physicians' loss of control over clinical decisions.[86] One physician leader went so far as to proclaim his "constitutional right to be sued!"[87]

The Clinton reform effort collapsed, however, and when the dust cleared private managed care had a much freer rein than would have been the case under the detailed regulatory safeguards necessary for managed competition. Employers embraced HMOs to combat double-digit annual percentage increases in insurance premiums, sleepy Blue Cross and Blue Shield (BCBS) plans converted to aggressive for-profit enterprises, and a dizzying set of acronyms (EPO, PPO, IPA, POS) and associated restrictions on patient choice emerged in parts of the country that had known only fee-for-service medicine.[88] The public—already on edge—

83 Elizabeth McCaughey, *No Exit*, NEW REPUBLIC (Feb. 7, 1994), https://newrepublic.com/article/69935/no-exit (equating rationing under the Clinton reform with private managed care).

84 *See* Robert Pear, *Clinton Advisors Outline Big Shift for Malpractice*, N.Y. TIMES, May 21, 1993, at A1.

85 *See* Kenneth S. Abraham & Paul C. Weiler, *Enterprise Medical Liability and the Evolution of the American Health Care System*, 108 HARV. L. REV. 381, 415-19 (1994); William M. Sage et al., *Enterprise Liability for Medical Malpractice and Health Care Quality Improvement*, 20 AM. J.L. & MED. 1, 162-66 (1994).

86 *See The Sinking of Enterprise Liability*, AM. MED. NEWS, July 5, 1993, at 17; *cf.* Arnold S. Relman, *Medical Practice Under the Clinton Reforms—Avoiding Domination By Business*, 329 NEW ENG. J. MED. 1574, 1575-76 (1993) (expressing concern about combining clinical with cost management in large organizations).

87 This information comes from a contemporaneous conversation with Dr. Robert A. Berenson, who had been assigned the duty of explaining the Clinton malpractice proposal at a 1993 meeting of the Physician Insurers Association of America (now called the Medical Professional Liability Association). This Alice-in-Wonderland rights discourse was presumably based on the old management axiom "no responsibility without control." At the same time, of course, the managed care industry protested against enterprise liability on the ground that it could *not* control physicians' behavior.

88 *See* Jonathan P. Weiner & Gregory de Lissovoy, *Razing a Tower of Babel: A Taxonomy for Managed Care and Health Insurance Plans*, 18 J. HEALTH POL., POL'Y & L. 75, 83 (1993) (offering

reacted with alarm. Urged on by organized medicine and the hospital industry, politicians at both the state and federal levels passed "patient protection acts" that swung the balance of negotiating power back toward health care providers.[89] This fierce backlash against managed care was not seriously challenged by large employers, who feared losing valuable workers during a widening economic boom.[90]

The result was the emasculation of payers and the re-empowerment of health care providers in local markets across the country.[91] Without changing their behavior at all, hospitals and physicians were transformed in the public's imagination into heroic bulwarks against the predations of managed care. Courts, which (like physicians) tend to focus on the individual case more than the aggregate policy, were swept along by the same narrative.[92] Federal antitrust enforcers lost seven consecutive challenges to hospital mergers, an unprecedented rejection of competitive processes.[93] Hospitals that had begun to consolidate

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a taxonomy of managed care organizations).

89 *See* David A. Hyman, *Regulating Managed Care: What's Wrong with a Patient Bill of Rights*, 73 S. CAL. L. REV. 221, 223 (2000).

90 *See* Robert J. Blendon et al., *Understanding the Managed Care Backlash*, 17 HEALTH AFF. 80, 94 (1998) (examining the depth and breadth of the public backlash against managed care and the underlying causes).

91 Why even large private employers – including America's most powerful and innovative companies – have been such ineffectual health care purchasers is an enduring mystery. *See* David A. Hyman & Mark Hall, *Two Cheers for Employment-Based Health Insurance*, 2 YALE J. HEALTH POL'Y, L. & ETHICS 23, 26-30 (2001). Some contributing factors are fairly obvious: government subsidy through non-taxability of coverage offered as a fringe benefit, competition for upper-echelon workers given legal prohibitions on benefits-related discrimination, insulation of human resources departments from senior financial management, and general reluctance among high-profile companies to being seen as intruding on access to care. But these companies, which self-insure their benefit costs, seem unable to obtain fair, transparent pricing from the insurance companies they pay generously to negotiate on their behalf with providers.

92 The battle among insurers, policymakers, and courts over coverage of high-dose chemotherapy with autologous bone marrow transplantation (HDC-ABMT) for advanced breast cancer is archetypal of this period in health policy. HDC-ABMT was promoted as lifesaving by prominent cancer centers without proof of benefit, and insurers' efforts to deny coverage as experimental were reversed by courts and even some legislatures. When research studies were finally performed, the treatment was found to be both useless and harmful. *See* Michelle M. Mello & Troyen A. Brennan, *The Controversy over High-Dose Chemotherapy with Autologous Bone Marrow Transplantation for Breast Cancer*, 20 HEALTH AFF. 101, 101-02 (2001).

93 *See* FTC v. Tenet Healthcare Corp., 186 F.3d 1045 (8th Cir. 1999) (FTC and state of Missouri unsuccessfully sought to enjoin merger of two hospitals); California v. Sutter Health Sys., 84 F. Supp. 2d 1057 (N.D. Cal. 2000), *aff'd*, 217 F.3d 846 (9th Cir. 2000) (state of California unsuccessfully brought suit against two hospitals, claiming that proposed merger would have anticompetitive effect); United States v. Long Island Jewish Med. Ctr., 983 F. Supp. 121 (E.D.N.Y. 1997) (government unsuccessfully sought to enjoin merger of two not-for-profit "anchor hospitals"); FTC. v. Butterworth Health Corp., 946 F. Supp. 1285 (W.D. Mich. 1996) (FTC unsuccessfully sought preliminary injunction to prevent merger of two hospitals); United States v. Mercy Health Servs., 902 F. Supp. 968 (N.D. Iowa 1995), *vacated as moot*, 107 F.3d 632 (8th Cir. 1997) (government

mainly to reduce excess capacity and achieve economies of scale suddenly found themselves with nearly unlimited pricing power.[94]

Faced with rising health insurance premiums but unwilling to risk their recent political gains by revisiting managed care, conservative policymakers instead embraced health savings accounts and other "consumer-directed" care models that blamed costs on wastefulness by fully insured consumers (i.e., moral hazard)—a framing not unlike the dependency and fraud narrative the same policymakers applied to welfare recipients.[95] However, shifting substantial financial responsibility to consumers through high-deductible coverage, but not really assessing the functionality of the markets in which self-funded care was purchased, served mainly to conceal continued cost growth by taking it out of the visible premium.[96] Similar dynamics affected markets for prescription drugs, medical devices, and biologics, with seemingly competitive improvements such as rebates negotiated by prescription benefit management companies ultimately being co-opted by existing stakeholders to augment rather than reduce their financial returns.[97]

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unsuccessfully brought antitrust action against two hospitals to enjoin proposed merger); FTC. v. Freeman Hosp., 911 F. Supp. 1213 (W.D. Mo. 1995), *aff'd*, 69 F.3d 260 (8th Cir. 1995) (FTC unsuccessfully filed motion for preliminary injunction seeking to prohibit consolidation of hospitals pending resolution of administrative proceedings as to legality of consolidation); FTC v. Hosp. Bd. of

Dirs. of Lee County, No. 94–137–CIV–FTM–25D, 1994 U.S. Dist. LEXIS 19770 (M.D. Fla. May 16, 1994), *aff'd*, 38 F.3d 1184 (11th Cir. 1994) (FTC unsuccessfully filed complaint to prevent county hospital board's proposed purchase of private hospital in county, alleging that purchase would be anticompetitive in violation of Clayton Act).

94 Research on hospital consolidation was collected and analyzed by a Robert Wood Johnson Foundation initiative called the Synthesis Project, which published a report in 2006 and an update in 2012. *See* WILLIAM B. VOGT & ROBERT TOWN, ROBERT WOOD JOHNSON FOUND., HOW HAS HOSPITAL CONSOLIDATION AFFECTED THE PRICE AND QUALITY OF HOSPITAL CARE? 11–12 (2006); MARTIN GAYNOR & ROBERT TOWN, ROBERT WOOD JOHNSON FOUND., THE IMPACT OF HOSPITAL CONSOLIDATION—UPDATE 2 (2012). The Synthesis Project concluded that less competitive hospital markets have higher prices and may have lower quality. Moreover, both nonprofit and for-profit hospitals acquired and exercised market power to the detriment of consumers.

95 *See* Phil Gramm, *Why We Need Medical Savings Accounts*, 330 NEW ENG. J. MED. 1752, 1752–53 (1994) (claiming that waste in health care is primarily attributable spending "other people's money" at the point of service); *see also* James C. Robinson, *Consumer-Directed Health Insurance: The Next Generation*, 24 HEALTH AFF. WEB EXCLUSIVE W5-583 (2005) (interviewing then-Aetna CEO Jack Rowe, MD, about high cost-sharing models of coverage), https://www.healthaffairs.org/doi/10.1377/hlthaff.w5.583?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed.

96 *See* Sherry A. Glied & Benjamin Zhu, *Catastrophic Out-of-Pocket Spending: A Problem Mainly for Middle-Income Americans with Employer Coverage*, COMMONWEALTH FUND (Apr. 17, 2020), https://www.commonwealthfund.org/publications/issue-briefs/2020/apr/catastrophic-out-of-pocket-costs-problem-middle-income.

97 *See* NAT'L ACADS. OF SCI., ENG'G, AND MED., MAKING MEDICINES AFFORDABLE: A

This poorly restrained market lasted until the Great Recession of 2007-08, which ended what one might describe as a "lost decade" in U.S. health policy. What had begun as inadequate restraint of managed care ended as inadequate restraint of an increasingly consolidated, profit-oriented, and costly health care delivery system in which private interests massively benefited from public subsidies and regulatory protection. Buyers had retreated; sellers again were in charge. Health insurers, which also had consolidated over the course of the decade, refrained from managing care lest consumers recoil, and focused on claims processing and provider network administration. This was possible because few insurers bore significant financial risk—instead passing care costs along to self-insured employers and government programs while skimming off as profit a comfortable percentage of the enormous revenues flowing through the system.[98] Calls for comprehensive national health insurance were rare, "single-payer" advocates marginalized. Although the market rhetoric of incentives, transparency, and "skin in the game" had become pervasive, actual market discipline in the U.S. health care system was seldom to be found.

D. Threading the Needle: The Affordable Care Act

Although the ACA is often portrayed as a radical reform, it also fits the pattern of subordinating principle to pragmatism. A highly significant piece of social legislation with ambitions to simultaneously improve health insurance, health care service delivery, and population health, the ACA nonetheless represents a cautious, incremental approach to coverage expansion.[99] Even so, that it achieved passage is nothing short of miraculous.

The ACA reinvigorated a nearly moribund market for individual (as opposed to group) health insurance, expanded Medicaid coverage, and built infrastructure within Medicare to pursue improvements to both provider payment and health care

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NATIONAL IMPERATIVE 89-95 (2018) (describing pharmaceutical product promotion and distribution). The corruption of medical ethics associated with these phenomena did not go unnoticed by traditionalists within the medical profession. *See, e.g.,* JEROME P. KASSIRER, ON THE TAKE: HOW MEDICINE'S COMPLICITY WITH BIG BUSINESS CAN ENDANGER YOUR HEALTH (2004) (criticizing the profit incentives in health care).

98 *See, e.g.,* Scott Allen & Marcella Bombardieri, *A Handshake that Made Healthcare History*, BOS. GLOBE (Dec. 28, 2008), https://www.bostonglobe.com/specials/2008/12/28/handshake-that-made-healthcare-history/QiWbywqb8olJsA3IZ11o1H/story.html (describing the decision by Blue Cross Blue Shield of Massachusetts to pay very high prices to Partners Healthcare). Insurer-provider "cahoots" from the late 1990s onwards recalls the origins of Blue Cross and Blue Shield plans as provider-controlled organizations, and is at odds with the image of hard-hearted managed care companies compromising quality or access by strong-arming physicians and hospitals. *See, e.g.*, W. Pa. Allegheny Health Sys., Inc. v. UPMC, 627 F.3d 85, 91–92 (3d Cir. 2010) (describing insurer-provider cooperation in Pennsylvania).

99 *See* William Sage, *Putting Insurance Reform in the ACA's Rear-View Mirror*, 51 HOUS. L. REV. 1082, 1100-11 (2014).

delivery.[100] Unfortunately, as Dr. Arnold Relman's 1990 essay foreshadowed,[101] it left significant conceptual gaps and ambiguities with respect to the relationships between health care and health, and between health and citizenship.

As in 1993, the necessary compromises involved fiscal palatability, stakeholder appeasement, and renunciation of rationing.[102] Again, fiscal maneuvering had the greatest immediacy, as members of Congress seldom will vote to raise taxes or substantially increase the deficit, effects that federal budgetary procedures make all too visible. In that respect, the global financial crisis was a necessary precursor to health reform. Even with a newly elected Democratic president and Democratic control of both House and Senate, there would have been no ACA had the economy not been sufficiently threatened to justify federal stimulus spending (nearly $150 billion of which was spent directly on health). Between 1993 and the present, the only other time that an investment in universal coverage seemed possible was briefly in 2000 when the "dot-com bubble" burst but CBO's projected budget surpluses had not yet been revised

100 With respect to private insurance, the ACA mandates the establishment of public health insurance exchanges across the country to broker coverage for individuals and small employers. Patient Protection and Affordable Care Act, Pub. L. No. 111–148, § 1311, 124 Stat. 119, 173 (2010). Insurers participating in these exchanges operate under very different rules from traditional health plans, including offering standardized benefits and complying with a blanket prohibition on medical underwriting. *Id.* § 1201 (prohibiting underwriting based on preexisting conditions); *id.* § 1302 (outlining essential health benefits). The ACA also creates significant incentives to create or expand "private exchanges" not limited to a single employer, which are subject to slightly different rules. *Id.* §§ 1311–12. Among the ACA's reforms intended to improve health care services, many of which operate through the Center for Medicare and Medicaid Services (CMS), are the following: i) Essential Health Benefits Requirements, *id.* § 1302; (ii) zero cost sharing for U.S. Preventive Services Task Force A- or B-rated services, *id.* § 4003; (iii) the Patient-Centered Outcomes Research Institute (PCORI) (comparative effectiveness research), *id.* § 6301; (iv) the Independent Payment Advisory Board [later repealed], *id.* §§ 3403, 10320; (v) Accountable Care Organizations (Medicare Shared Savings Program), *id.* § 3022, (vi) Patient-Centered Health Homes (Medicaid), *id.* § 2703; (vii) bundled (episodic) payment pilot program for acute and post-acute care, *id.* § 3023; (viii) the Center for Medicare and Medicaid Innovation (CMI) to test new, budget-neutral models for care delivery and provider payment, *id.* § 3141, (ix) the hospital value-based purchasing program (Medicare pay-for-performance), *id.* § 10326, (x) an expanded Medicare hospital quality reporting system, *id.* § 3001; (xi) an expanded Medicare physician quality reporting system, *id.* § 3002; and (xii) the Independence at Home Demonstration Program to avoid hospitalization (Medicare), *id.* § 3024.

101 Relman, *supra* note 20.

102 Proposals based on managed competition are less threatening than single-payer reforms to health insurers as an organized interest. Indeed, health insurers saw the ACA's expansion of both private coverage and Medicaid managed care as a source of new business, a dynamic that might be repeated in a Medicare-for-All system based on Medicare Advantage plans. More generally, the Obama Administration followed the political playbook devised by "Romneycare" proponents in Massachusetts, with at least some sacrifice from each stakeholder group. *See* Christie L. Hager, *Massachusetts Health Reform: A Social Compact and a Bold Experiment*, 55 U. KAN. L. REV. 1313, 1313-29 (2007) (providing an insider's summary of and context for the Massachusetts health reform law).

downward—creating the unusual situation in which the public felt poor enough to want "health security" and the government was rich enough on paper to fund it.

Still, the Obama Administration followed the managed competition playbook rather than making an ideologically explicit commitment to universal public coverage. By building on the prevailing system of private health insurance, the ACA not only made itself as unthreatening as possible to existing stakeholders but also sidestepped the apparent, if basically illusory, budgetary cataclysm noted above that single-payer reform would trigger.[103]

The Obama Administration's decision to rely primarily on an individual mandate, rather than requiring private employers to provide coverage, was also made with budget scoring foremost in mind. Far more Americans receive health insurance through employment than purchase it individually. Even at maximum capacity, the Obamacare "marketplaces" for individual insurance purchases (so-named to project a private, voluntary character) would operate at the margins of private health coverage, which would limit their adverse fiscal impact even if the CBO were to consider them "on-budget." By contrast, putting employers at the center of government-regulated exchanges would have risked a much larger flow of annual funds being characterized by the CBO as a tax—a finding that had driven the final nail into the coffin of the Clinton Administration's reform plan two decades earlier.[104]

There was a downside to the ACA's incrementalism and fiscal prudence. Even so limited, mandating the private purchase of insurance, obligating private insurers to cover contraception, establishing state-based marketplaces, and changing Medicaid into a nationally uniform entitlement for the poor and near-poor (with some of the cost forced on the states) all proved toxic in the prevailing, hyper-partisan political environment.[105] Many of the parties affected by these provisions took their grievances to court, and because of the ACA's convoluted design had legal standing to do so.[106] In other words, the ACA's drafters accepted litigation risk in exchange for fiscal palatability. It has proved a steep price to pay.

Moreover, by adopting managed competition as its framework, the ACA

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103 William M. Sage & Timothy M. Westmoreland, *Following the Money: The ACA's Fiscal-Political Economy and Lessons for Future Health Care Reform*, 48 J.L. MED. ETHICS 434, 434 (2020); *see also supra* notes 55-59 and accompanying text.

104 *See* Novak, *supra* note 57.

105 *See generally* Sage & Westmoreland, *supra* note 103 (explaining the fiscal implications of each of these sources of political controversy).

106 *See id.* at 440-41 (discussing the *California v. Texas*, No. 19-840, slip op. (June 17, 2021), litigation, which at the time had yet to be scheduled for oral argument); *see also* Abbe R. Gluck, *Imperfect Statutes, Imperfect Courts: Understanding Congress's Plan in the Era of Unorthodox Lawmaking*, 129 HARV. L. REV. 62 (2015) (analyzing the Supreme Court's decision in *King v. Burwell*, 576 U.S. 473 (2015)). In 2021, the Supreme Court dismissed the Texas v. United States litigation for lack of standing. California v. Texas, No. 19–840, slip op. 1 (June 17, 2021).

asserted at most a consumerist vision of national health reform. As President Obama declared in celebration of his signature reform surviving a major court challenge in 2015:

> And unlike Social Security or Medicare, a lot of Americans still don't know what Obamacare is beyond all the political noise in Washington. Across the country, there remain people who are directly benefitting from the law but don't even know it. And that's okay. There's no card that says "Obamacare" when you enroll. But that's by design, for this has never been a government takeover of health care, despite cries to the contrary. This reform remains what it's always been: a set of fairer rules and tougher protections that have made health care in America more affordable, more attainable, and more about you—the consumer, the American people.[107]

Put simply, President Obama did not demand social solidarity around health or health care, and none emerged organically. The ACA regarded the citizen as coterminous with the consumer. There was no aspiration to "Americare."[108]

III. RE-THINKING THE PROBLEMS WITH U.S. HEALTH CARE

As interest in some form of Medicare-for-All builds on the political left, a question presents itself: What do we know now about improving the U.S. health care system that we did not know when single-payer proposals were last debated a generation ago? In fact, quite a lot. Four insights seem relevant to the evaluation of any new health policy proposal. The first two constitute a revised health policy consensus that is supported by extensive research and analysis, and confirm the core ethical challenge of simultaneous wastefulness and injustice in the existing

107 President Barack Obama, Remarks in the Rose Garden of the White House on the Supreme Court's Decision in *King v. Burwell* (June 25, 2015). The occasion was to celebrate the Court's 6-3 ruling that insurance exchanges operated by the federal government as well as those operated by state governments were eligible for tax subsidies under the ACA. King v. Burwell, 135 S. Ct. 2480 (2015).

108 It is only occasionally noted that the Obama Administration made virtually no attempt to associate the ACA with patriotism, democracy, or collective self-interest. *See* William M. Sage, *Brand New Law! The Need to Market Health Care Reform*, 159 U. PA. L. REV. 2121, 2138-46 (2011) (proposing a social marketing campaign for the ACA); William M. Sage, *Solidarity*, *in* CONNECTING AMERICAN VALUES WITH AMERICAN HEALTH CARE REFORM 10, 11 (Thomas H. Murray & Mary Crowley eds., 2009); William M. Sage, *Why the Affordable Care Act Needs a Better Name:"Americare*,*"* 29 HEALTH AFF. 1496, 1496-97 (2010). To be fair, Medicare itself appears to have been named fortuitously rather than strategically. *See* PETER A. CORNING, THE EVOLUTION OF MEDICARE: FROM IDEA TO LAW 75 n.3 (1969) (explaining that "Medicare" was "coined by some unknown newspaper headline writer").

health care system. The pair that follows—emphasizing structural and generational change—is less often discussed but, in my view, equally compelling. The COVID-19 pandemic experience has only enhanced these insights.

Developments in understanding are critical considerations not only for single-payer advocates, but also for proponents of other health reform models such as managed competition and consumer-directed care. Because facts should matter to policymaking whatever one's principles, it is important to revisit from time to time the assumptions underlying even well-established health policy "brands." This rather obvious point is often missed in health reform debates, where labels routinely outlast the conditions that created them, counterexamples drawn from emotionally compelling anecdotes are used to refute clearly demonstrable aggregate trends, and interest groups are assigned positions that long outlive the people who initially asserted them.

A. From Rationing to Improvement

Universal health insurance is controversial in the United States in large part because it seems to invite rationing of necessary care.[109] Conventional wisdom in the 1980s and 1990s, after Medicare's inflationary effects had become apparent, was that advances in medical technology would continually and inexorably push costs even higher.[110] Although reducing "waste, fraud, and abuse" was admittedly desirable, experts agreed that any one-time savings would do little to alter the long-term upward trend.

Health policy in the United States is typically taught as a "three-legged stool," with the legs representing access to medical care, quality of care, and cost. Inherent in the "chair" metaphor is the idea that the legs must be of roughly equal length to keep the system in balance. As costs rose, the uncomfortable implication of this analytic frame was that any effort to expand access would necessarily require a reduction in quality – almost certainly by denying individuals potentially lifesaving but very expensive treatment. Dr. William Kissick captured this belief in a 1994 book titled *Medicine's Dilemmas: Infinite Needs Versus Finite Resources*: "No society in the world," he wrote, "has ever been—or will ever be—able to afford providing all the health services its population is capable of utilizing."[111]

Technology as a driver of health spending remains a critical consideration in a few domains, such as biopharmaceuticals, and generates important tensions between futurists and skeptics in a few others, such as "precision" or

109 *See supra* notes 59-67 and accompanying text.

110 *See, e.g.,* SHERRY GLIED, WHY HEALTH REFORM FAILS (1997).

111 WILLIAM KISSICK, MEDICINE'S DILEMMAS: INFINITE NEEDS VERSUS FINITE RESOURCES 48 (1994).

"personalized" medicine powered by genetic sequencing and cellular targeting.[112] At the macro level, however, a new three-part framework arguably has superseded "cost, access, and quality" in health policy analysis. It is called the "Triple Aim."

Developed by the Institute for Healthcare Improvement (IHI), the Triple Aim consists of (1) improving the patient experience of care (including quality and satisfaction), (2) improving the health of populations, and (3) reducing the per capita cost of health care.[113] Two novel aspects of the Triple Aim are immediately evident: examining care from the patient's perspective and becoming accountable for populations as well as individuals. But a third is far more important: whereas cost, access, and quality exist in perpetual tension with one another in the traditional paradigm, the three parts of the Triple Aim are simultaneously achievable.

This is the case because the U.S. health care system is now known to be massively, recurrently wasteful.[114] Much medical practice is habitual rather than scientific. Prices are high and seemingly arbitrary. Where scientifically optimal care exists, even affluent, educated, insured patients often fail to receive it. Poorer, less educated patients and members of racial and ethnic minorities fare far worse, even if their care is publicly subsidized.[115] Many new technologies layer themselves atop flawed processes of care, adding expense but not yielding better results.

In a report titled *Best Care at Lower Cost*, the National Academy of Medicine (NAM) attributed over $750,000,000,000 annually to waste in 2010,[116] a

112 For a concise argument in favor of personalized medicine, see Margaret A. Hamburg and Francis S. Collins, *The Path to Personalized Medicine*, 353 NEW ENG. J. MED. 301 (2010).

113 *IHI Triple Aim Initiative*, INST. FOR HEALTHCARE IMPROVEMENT (2015), http://www.ihi.org/Engage/Initiatives/TripleAim/pages/default.aspx (last visited Aug. 1, 2021). IHI's founder, pediatrician Don Berwick, served briefly as acting director of the Centers for Medicare and Medicaid Services in the Obama Administration.

114 Work begun by Dr. John Wennberg at Dartmouth in the 1970s is most often credited for identifying the magnitude of waste in U.S. health care. JOHN E. WENNBERG, THE DARTMOUTH ATLAS OF HEALTH CARE IN THE UNITED STATES 2 (1996). "Small-area variation" studies revealed substantial, unexpected geographic differences in medical treatment that are neither the result of greater health care needs nor associated with superior clinical outcomes. *See FAQ*, DARTMOUTH ATLAS PROJECT, https://www.dartmouthatlas.org/faq (last visited Aug. 1, 2021). This work revealed that "best practices" were seldom available, outcomes of care were typically unmeasurable, and clear advances in medical knowledge often took years to diffuse into communities and alter the habits of local physicians.

115 *See infra* notes 123-143 and accompanying text.

116 INST. OF MED., BEST CARE AT LOWER COST: THE PATH TO CONTINUOUSLY LEARNING HEALTH CARE IN AMERICA 102 (2012); *see also* Alan M. Garber & Jonathan Skinner, *Is American Health Care Uniquely Inefficient?*, 22 J. ECON. PERSP. 27, 28 (2008) ("The fundamental cause is a combination of high prices for inputs, poorly restrained incentives for overutilization, and a tendency to adopt expensive medical innovations rapidly, even when evidence of effectiveness is weak or absent.").

staggering sum that almost certainly exceeds $1,000,000,000,000 annually today. The NAM estimated that $210 billion reflected unnecessary services, including overuse not justified by scientific evidence, discretionary use beyond established standards, and unnecessary choice of higher-cost services.[117] The report identified another $130 billion in inefficiently delivered services, including medical errors, preventable complications, fragmented care, unnecessary use of higher-cost providers, and operational inefficiency at care delivery sites.[118] Excess administrative costs accounted for $190 billion, missed prevention opportunities for $55 billion, and fraud for $75 billion.[119] The final category, "Prices That Are Too High," suggested that $105 billion reflected prices in the United States that clearly exceed benchmark amounts.[120]

Inefficiency of this magnitude is a damning indictment of post-Medicare public policy and is not merely an economic problem. The NAM's findings were derived from four decades of research into unjustified practice variation, sub-optimal quality, and poor safety.[121] For single-payer advocates, this body of new knowledge implies that American health policy, in the short to medium term, need concern itself less with developing centralized systems for allocating scarce resources (i.e., rationing), and more with facilitating (including through payment reform) incremental, decentralized improvement in the provision of medical care. It also makes clear that fifty years of deference to the expertise and judgment of individual physicians in a lavishly funded system—Medicare's Gilded Age—has in important ways proved counter-productive.

B. Social Determinants and Unjust Disparities

The opportunity cost of wasting $1 trillion each year on mispriced, poorly designed, often unnecessary, and sometimes harmful medical care arguably has been greater than the direct effects. There are two harsh realities associated with health policy in the United States: our health care system is extraordinarily expensive, and the health of our population is not particularly good.[122] In 2018,

117 INST. OF MED, *supra* note 116, at 102.

118 *Id.*

119 *Id.*

120 *Id.*

121 *See* INST. OF MED., CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY 23-25 (2001) (documenting the U.S. system's suboptimal performance in making health care safe, effective, patient-centered, timely, efficient, and equitable); INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 1 (1999) (documenting up to 100,000 annual deaths due to medical error in the United States).

122 International comparisons of health care system performance generally place the United States at or near the bottom. *See, e.g.*, Eric C. Schneider et al., *Mirror, Mirror 2017: International Comparison Reflects Flaws and Opportunities for Better U.S. Health Care*, COMMONWEALTH FUND (2017), http://www.commonwealthfund.org/~/media/files/publications/fund-report/2017/jul/schne

U.S. per capita health care spending exceeded $10,000 (16.9% of Gross Domestic Product (GDP)), 25% more in absolute amount than second-highest Switzerland (12.2%) and almost triple average per capita spending among Organisation for Economic Cooperation and Development (OECD) countries.[123] However, U.S. life expectancy at birth remained 78.6 years, more than two years lower than the average among OECD countries.[124] Infant mortality in the United States is the highest in the OECD and is improving more slowly than elsewhere.[125]

One should not be surprised. Research shows clearly that the immediate causes of death may appear medical (cancer, heart disease, kidney failure, etc.) but the underlying causes are predominantly non-medical.[126] These "social determinants" of health consist of behavioral patterns (roughly estimated as accounting for 40% of premature mortality), social circumstances (15%), and environmental exposures (5%), with 30% attributable to genetics and only 10% having to do with lack of medical care.[127] For these reasons, most health policy experts—affirming the core governmental commitments made by the ACA—consider policy changes that invest in population health to be at least as important as those that promote value-based care delivery, and recognize that there are important interactions between the two sets of interventions. For example, the ACA requires that health insurers cover the full cost (without imposing deductibles or co-payments) of screening interventions that are rated "A" or "B" by the U.S. Preventive Services Task Force.[128]

That advanced medical care is necessary but not sufficient for longevity

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ider_mirror_mirror_2017.pdf; *see also* Steven H. Woolf & Laudan Y. Aron, *The US Health Disadvantage Relative to Other High–Income Countries*, 309 JAMA 771, 772 (2013) (describing the causes of lower life expectancy in the United States.

123 *OECD Health Statistics 2021*, OECD (2021), https://stats.oecd.org/Index.aspx?DataSetCode=SHA.

124 *Id.*

125 The rate for non-Hispanic African Americans of 11.3 per 1000 live births is comparable to the infant mortality rate in Mexico, a country that spends roughly 10% of what the United States spends on health care. *Compare Infant Mortality Rate by Race/Ethnicity*, KAISER FAMILY FOUND. (2018), https://www.kff.org/other/state-indicator/infant-mortality-rate-by-race-ethnicity/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D, *with Infant Mortality Rates*, OECD (2021), https://data.oecd.org/healthstat/infant-mortality-rates.htm#indicator-chart.

126 *See* Rachel Rebouche & Scott Burris, *The Social Determinants of Health*, *in* OXFORD HANDBOOK OF U.S. HEALTH LAW 1097 (I. Glenn Cohen et al. eds., 2016).

127 J.M. McGinnis et al., *The Case for More Active Policy Attention to Health Promotion*, 21 HEALTH AFF. 78, 83 (2002). These numbers are admittedly imprecise. For a comprehensive discussion, see Laura McGovern, George Miller & Paul Hughes-Cromwick, *Health Policy Brief: Contribution of Multiple Determinants to Health Outcomes*, HEALTH AFF. (2014), https://www.healthaffairs.org/do/10.1377/hpb20140821.404487/full/healthpolicybrief_123.pdf.

128 Patient Protection and Affordable Care Act, Pub. L. No. 111–148, § 4008, 124 Stat. 173 (2010).

becomes even clearer when one examines the comparative performance now and over time of the United States and other developed countries in avoiding mortality from cancer, on one hand, and cardiovascular diseases, on the other. Heart disease deaths have plummeted in nearly all countries, but deaths other circulatory conditions and cerebrovascular disease are still strikingly high in the United States.[129] By contrast, the United States has had the greatest success among developed countries at reducing deaths from cancer, and cancer mortality in the United States is on the low end in absolute terms.[130] This is not because America's considerable innovation in cancer treatment is so much better than our innovation in drugs and surgery for heart disease but because the United States has been highly successful at reducing tobacco use, which has dropped by 80% over the past 40 years.[131] However, we have been fighting a losing battle against the obesity epidemic, even as the cardiovascular consequences of smoking declined. In 1990, not a single U.S. state had more than 15% of its adult population obese; in 2010, not a single U.S. state had less than 20% of its adult population obese.[132]

Moreover, resources to help avoid and address social determinants of ill health have skewed sharply toward medical uses in recent decades—another consequence of Medicare's Gilded Age. Non-defense federal spending is dominated by Medicare, Medicaid, and Social Security (plus interest on the national debt), leaving relatively little for all other national needs. From 1970 to the present, the federal government's financial commitment to health care programs has grown from 5% to over 10% of GDP, with a proportionate reduction in public dollars available for other uses.[133] In state budgets, rising medical spending in particular crowds out funding for education, adding an element of tragic competition to two essential building blocks for human capital.[134] The United States seems to be a negative outlier in this respect as well: it not only devotes a much higher share of GDP to medical care than do other developed countries, but also dedicates less of

129 Ellen Nolte & C. Martin McKee, *In Amenable Mortality—Deaths Avoidable Through Health Care—Progress in the US Lags That of Three European Countries*, 31 HEALTH AFF., 2114, 2118 (2012).

130 Warren Stevens et al., *Cancer Mortality Reductions Were Greatest Among Countries Where Cancer Care Spending Rose the Most, 1995–2007,* 34 HEALTH AFFS, 562, 564 (2015).

131 *See generally* U.S. DEPT. OF HEALTH & HUMAN SERVS., THE HEALTH CONSEQUENCES OF SMOKING—50 YEARS OF PROGRESS: A REPORT OF THE SURGEON GENERAL (2014) (describing the successful public health campaign against smoking).

132 *Adult Obesity Prevalence Maps*, CTRS. FOR DISEASE CONTROL & PREVENTION (2019), https://www.cdc.gov/obesity/data/prevalence-maps.html.

133 *See American Health Care: Health Spending and the Federal Budget*, COMM. FOR A RESPONSIBLE FED. BUDGET (May 16, 2018), https://www.crfb.org/papers/american-health-care-health-spending-and-federal-budget.

134 *See State and Local Expenditures*, URBAN INST. (2021), https://www.urban.org/policy-centers/cross-center-initiatives/state-and-local-finance-initiative/state-and-local-backgrounders/state-and-local-expenditures.

its national output to non-medical social services that improve health.[135] One-half to two-thirds of health-improving spending in other countries is non-medical compared to only one-fourth in the United States.[136] Medicalizing the governmental response to poverty and other social ills may be superficially appealing, but it has not proved effective.[137]

The injustice of these circumstances goes beyond denying a universal human right to medical care. It encompasses the systematic diversion of resources away from individuals and communities that suffer persistent, compound disadvantage. Profound inequalities at the community level in wealth and education, endemic violence, concentrated environmental hazards, and other resources exert negative effects on health that cannot be overcome by medical care alone. Capturing the personal, often purposeful actions that created and now perpetuate these conditions is one reason why "unjust disparities" in health and health care are a powerful descriptor that supplements the more sterile and potentially immutable phrasing of "social determinant." Disparities exist at the community as well as the family level, which further conveys the importance of place to engaging and improving health.[138]

America's shameful experience with race is a significant contributor to lack of health justice (though perhaps with less independent effect than poverty). Many studies have shown that persons of color are comprehensively disadvantaged in access to high-quality medical care, although attention to specific contexts presenting risks of clinical discrimination has helped narrow the gap.[139] Most shockingly, African-American women suffer maternal complications and infant

135 *See generally* ELIZABETH H. BRADLEY & LAUREN A. TAYLOR, THE AMERICAN HEALTH CARE PARADOX: WHY SPENDING MORE IS GETTING US LESS (2015) (discussing relative lack of social investment in the US); RICHARD COOPER, POVERTY AND THE MYTHS OF HEALTH CARE REFORM (2016) (arguing that poverty, not clinical uncertainty, explains geographic variation in health care spending); Raj Chetty et al., *The Association Between Income and Life Expectancy in the United States, 2001-2014,* 315 JAMA 1750 (2016) (examining the geography and socioeconomics of longevity).

136 BRADLEY & TAYLOR, *supra* note 135, at 14-15. These estimates are not definitive; subsequent research asserts a generally positive relationship between health and social spending, with U.S. social spending only slightly below international averages. *See* Irene Papanicolas et al., *The Relationship Between Health Spending and Social Spending in High-Income Countries: How Does the US Compare?*, 38 HEALTH AFF. 1567, 1567 (2019).

137 *See, e.g.*, William M. Sage & Jennifer E. Laurin, *If You Would Not Criminalize Poverty, Do Not Medicalize It*, 46 J.L. MED. & ETHICS 573 (2018) (using the application of criminal justice to poverty as a cautionary tale for medicine).

138 In doing so, however, one should guard against biases that may incorrectly attribute disadvantage to failures of individual character rather than long-term patterns of denial and discrimination by society at large. *See id*. at 574-76.

139 *See generally* DAYNA B. MATTHEW, JUST MEDICINE: A CURE FOR RACIAL INEQUALITY IN AMERICAN HEALTH CARE (2015) (examining causes, consequences, and treatments of race-based health disparities).); RACE, ETHNICITY AND HEALTH (Thomas A. LaVeist ed., 2002) (same); DAVID B. SMITH, HEALTH CARE DIVIDED: RACE AND HEALING A NATION (1999) (detailing racial disparities).

mortality more than double that among non-Hispanic white families—accounting for nearly all of the excess mortality compared to other OECD countries.[140] Studies strongly suggest that these mothers' exposure to toxic levels of stress is the principal cause, with explicit racism, implicit bias, and structural racism all contributing.[141] An explicit goal of health policy can be to reduce discrimination and promote justice. The original Medicare program, for example, integrated America's highly segregated acute care hospitals virtually overnight.[142]

C. The Inertial Force of Health Law

The preceding insights into wasteful care delivery, inattention to population health, and discrimination based on race, ethnicity, and socioeconomic status have been gained steadily over the past twenty-five years, and were incorporated into the ACA through its attempted Medicaid expansion, its Medicare payment and care delivery reforms (e.g., ACOs, PCMHs), and its dramatically increased (but never fully appropriated) funding for public and community health.[143] Similarly, experts in health systems management and care redesign have developed clear, evidence-based paths to improvement for hospitals and medical practices.[144]

Still, consensus objectives for the health care system—becoming safe, effective, patient-centered, timely, efficient, and equitable—largely remain unachieved. If we have known for so long where we wish to go, and how to get

140 *Infant Mortality*, CTRS. FOR DISEASE CONTROL & PREVENTION (2020), https://www.cdc.gov/reproductivehealth/maternalinfanthealth/infantmortality.htm.

141 *See* Linda Villarosa, *Why America's Black Babies and Mothers Are in a Life-or-Death Crisis*, N.Y. TIMES MAG. (Apr. 11, 2018), https://www.nytimes.com/2018/04/11/magazine/black-mothers-babies-death-maternal-mortality.html.

142 *See* DAVID BLUMENTHAL AND JAMES A. MORONE, THE HEART OF POWER: HEALTH AND POLITICS IN THE OVAL OFFICE 195-98 (2010) (detailing President Lyndon Johnson's personal commitment to hospital desegregation); *see also* Peter Ubel, *Medicare and the Desegregation of American Hospitals*, FORBES (Jan. 30, 2014), https://www.forbes.com/sites/peterubel/2014/01/30/medicare-and-the-desegregation-of-american-hospitals/#4889c59a2e1b (explaining how segregated hospitals changed their practices in order to receive federal funding). Functional segregation has persisted, of course, often through the proxy of socioeconomic status. When I was an anesthesiology resident at Johns Hopkins Hospital in the early 1990s, for example, the ward patients cared for by physicians-in-training in the older buildings were nearly all African American, while predominantly white, private-pay patients were admitted to a separate, recently constructed pavilion.

143 *See supra* notes 98-107 and accompanying text.

144 *See, e.g.,* CLAYTON M. CHRISTENSEN, THE INNOVATOR'S PRESCRIPTION: A DISRUPTIVE SOLUTION FOR HEALTHCARE (2008); MICHAEL E. PORTER & ELIZABETH O. TEISBERG, REDEFINING HEALTH CARE: CREATING VALUE-BASED COMPETITION ON RESULTS (2006); Michael E. Porter & Thomas H. Lee, *The Strategy That Will Fix Health Care*, 91 HARV. BUS. REV. 50 (2013). Quality and safety improvements have been around even longer. *See, e.g.*, DONALD M. BERWICK ET AL., CURING HEALTH CARE: NEW STRATEGIES FOR QUALITY IMPROVEMENT (1990).

there, why are we not there yet?[145] One explanation lies in the tendency among observers and analysts to ignore the principal mechanism used to impose and maintain constraints on how the health care system operates, which is the law.[146]

Put simply, governance of U.S. health care is based on an idealized image of an individual physician caring for a single patient in a private transaction.[147] The physician possesses all the characteristics one most wishes for in a caregiver: wisdom, skill, compassion, and incorruptibility. The patient possesses all the characteristics one most sympathizes with in a recipient of care: serious illness, vulnerability, and dependence. In the mind's eye, each party looks and sounds like a character in a television medical drama. The law fosters and protects these hypothesized therapeutic relationships by empowering the American medical profession to set its standards, by insulating it from direct corporate or governmental control, and by generously subsidizing its costs.[148]

Governance of the overall U.S. health care system is essentially the same fragmented legal and financial environment scaled to the population level.[149]

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145 *See, e.g.*, Nikhil Sahni et al., *How the U.S. Can Reduce Waste in Health Care Spending by $1 Trillion*, HARV. BUS. REV. (Oct. 13, 2015), https://hbr.org/2015/10/how-the-u-s-can-reduce-waste-in-health-care-spending-by-1-trillion.

146 *See generally* William M. Sage, *Relating Health Law to Health Policy: A Frictional Account*, *in* OXFORD HANDBOOK OF U.S. HEALTH LAW 3–28 (I. Glenn Cohen et al. eds., 2016) (explaining how health law sometimes works at cross-purposes with consensus health policy goals). The medical profession often feigns ignorance of its legal privilege. *See, e.g.*, William M. Sage, *Over Under or Through: Physicians, Law, and Health Care Reform*. 53 ST. LOUIS UNIV. L.J. 1033, 1033–34 (2009) ("For a physician to want regulation out of medical licensing is as absurd as the oft-quoted saw about a senior citizen telling his congressman to 'keep the government out of my Medicare.'"). For a comprehensive review of health law following the enactment of the ACA, see OXFORD HANDBOOK OF U.S. HEALTH LAW, *supra*.

147 *See* William M. Sage, *Assembled Products: The Key to More Effective Competition and Antitrust Oversight in Health Care*, 101 CORNELL L. REV. 609, 613-14 (2016) (explaining the constitutive role of regulation in health care delivery); *see also* ROBERT I. FIELD, MOTHER OF INVENTION: HOW THE GOVERNMENT CREATED FREEMARKET HEALTH CARE 24 (2014) (discussing the crucial role of public initiatives in private health care). For an early analysis of how professional control blunts competition, see Charles D. Weller, *Free Choice as a Restraint of Trade in American Health Care Delivery and Insurance*, 69 IOWA L. REV. 1351, 1392 (1984) (noting the potential for market power from unconstrained choice of physician). Some commentators have assigned traction to alternative views of health law, for example, Rand E. Rosenblatt, *The Four Ages of Health Law*, 14 HEALTH MATRIX 155 (2004), but the "professional paradigm" has proved extremely difficult to dislodge.

148 For the definitive historical overview, see PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE (2d ed. 2017) (exploring the American medical profession's centuries-long interactions with government).

149 For a comprehensive look at care fragmentation, see Einer Elhauge, *Why We Should Care About Health Care Fragmentation and How to Fix It*, *in* THE FRAGMENTATION OF U.S. HEALTH CARE: CAUSES AND SOLUTIONS 1-20 (E. Elhauge ed., 2010). For an overview of associated legal issues, *see* William M. Sage & Robert F. Leibenluft, *Overcoming Barriers to Collaboration and Alignment: Legal and Regulatory Issues*, *in* PHYSICIAN-HOSPITAL INTEGRATION 110–40 (Francis J. Crosson &

Starting about 100 years ago, state governments have repeatedly conferred legal privileges and protections on the medical profession, often relying on licensing boards and other self-regulatory bodies controlled by physicians for both standards and enforcement. Starting about fifty years ago, the federal government—largely through Medicare—has uncritically financed the system that state law created. Additional layers of essentially mandatory self-regulatory compliance—such as Joint Commission standards for hospitals and Liaison Committee for Medical Education (LCME) or Accreditation Council for Graduate Medical Education (ACGME) standards for medical education—further impede movement away from this physician-centric model of health system governance.[150]

State professional licensing laws, echoed in Medicare's payment policies, are obvious sources of inefficiency and inequity. In 1962, libertarian economist Milton Friedman was "persuaded that [restrictive] licensure has reduced both the quantity and quality of medical practice; . . . that it has forced the public to pay more for less satisfactory medical service, and that it has retarded technological development both in medicine itself and in the organization of medical practice."[151] After half a century of Medicare, this is no longer a fringe view.[152] Another important example is Medicare's decades-long expansion of civil and criminal penalties for "fraud and abuse," an epidemic the root causes of which are ultimately traceable to Medicare's original design choices such as its deference to physician judgment, its fragmented delivery structure, and its poor financial oversight.[153] Other potentially problematic laws include those governing physician-hospital relations, accountability for quality, private health insurance, and Medicare payment itself.[154] In recent years, both Democratic and Republican administrations have made note of some legal barriers to health system

Laura Tollen eds., 2010).

150 Hospitals accredited by the Joint Commission are deemed to meet the survey and certification requirements necessary to participate in (and be paid by) Medicare and Medicaid. The Liaison Committee for Medical Education (LCME) accredits M.D. degree programs, while the Accreditation Council for Graduate Medical Education (ACGME) accredits programs that train interns and residents in medical specialties. Governance of the Joint Commission, the LCME, the ACGME, and several other influential credentialing bodies in U.S. health care is shared in various ways among medical professional associations and hospital groups. *See, e.g.,* James S. Roberts et al., *A History of the Joint Commission on Accreditation of Hospitals*, 258 JAMA 936, (1987).

151 MILTON FRIEDMAN, CAPITALISM AND FREEDOM 149–59 (1962).

152 *See, e.g.*, Aaron Edlin & Rebecca Haw, *Cartels by Another Name: Should Licensed Occupations Face Antitrust Scrutiny?*, 162 U. PA. L. REV. 1093 (2014).

153 For a history and critique of the inefficiencies embedded in Medicare's fraud control regime, see James F. Blumstein, *The Fraud and Abuse Statute in an Evolving Health Care Marketplace: Life in the Health Care Speakeasy*, 22 AM. J.L. & MED. 205 (1996); and David A. Hyman, *Health Care Fraud and Abuse: Market Change, Social Norms, and the Trust "Reposed in the Workmen"*, 30 J. LEGAL STUD. 531 (2001).

154 *See* Sage, *supra* note 146, at 21-27.

improvement.[155] Unfortunately, points of bipartisan agreement often have been obscured by the concurrent emphasis on more narrowly partisan arguments, such as Republican calls for tort reform and for the relaxation of state insurance laws to facilitate cross-border marketing.

Neither party, however, has directly challenged the centrality of the medical profession to the legal architecture of American health care. Throughout the "modern era" that followed Medicare's enactment in 1965, maintaining the medical profession's autonomy and influence has been considered a bulwark against injustice. Physicians' ethics, economist Kenneth Arrow famously asserted in 1963, would help compensate for imbalances in information that might otherwise result in exploitation of the vulnerable and misappropriation of public resources by profiteers.[156] Even when the net inefficiency of physician control became evident—most obviously through critiques of "care fragmentation" that perpetuated idiosyncratic practices and precluded coordination—the ethical argument for professional rather than commercial or governmental control still appeared strong. This pro-physician sentiment and expectation, usually unspoken, occasionally became a focus of public discourse and policy activism. In the expansion of Medicare's anti-fraud authorities after Barbara Ehrenreich and others cautioned against an emerging "medical-industrial complex,"[157] for example, or in connection with the popular and legislative backlash against private managed care in the late 1990s.[158]

With the benefit of hindsight, allowing physician professionalism to dictate health system governance likely has perpetuated injustice, not reduced it. Laws

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155 *See, e.g.*, OFFICE OF ECON. POL'Y, U.S. DEP'T OF THE TREASURY ET AL., OCCUPATIONAL LICENSING: A FRAMEWORK FOR POLICYMAKERS 13–14 (July 2015), https://obamawhitehouse.archives.gov/sites/default/files/docs/licensing_report_final_nonembargo.pdf (attributing not only inefficiency but also injustice to states' over-reliance on occupational licensing in an Obama Administration report); U.S. DEPT. OF HEALTH AND HUM. SERVS. ET AL., REFORMING AMERICA'S HEALTHCARE SYSTEM THROUGH CHOICE AND COMPETITION (2018), https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf (reporting on legal barriers to health system efficiency, including restrictive licensing in a Trump Administration report).

156 Kenneth Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941, 965 (1963). For detailed commentary on Arrow's analysis, see UNCERTAIN TIMES: KENNETH ARROW AND THE CHANGING ECONOMICS OF HEALTH CARE (Peter J. Hammer et al. eds., 2003).

157 William M. Sage, *Minding Ps and Qs: The Political and Policy Questions Framing Health Care Spending*, 44 J. L. MED. & ETHICS 559, 559–60 (2016) (substituting "health care" for "military" in Eisenhower's address); *see also* BARBARA EHRENREICH, THE AMERICAN HEALTH EMPIRE: POWER, PROFITS, AND POLITICS (1970) (warning of the "medical-industrial complex"); President Dwight D. Eisenhower, Farewell Address to the Nation (Jan. 17, 1961), https://www.eisenhower.archives.gov/All_About_Ike/Speeches/Farewell_Address.pdf.

158 *See supra* notes 80-98 and accompanying text.

maintaining physicians' privileges and protections—conferring market power in the hope of fostering altruism, charity, and collaboration—can have the opposite effect.[159] For example, organized medicine has fought nearly universally to preserve its practice monopoly through restrictive medical licensing laws.[160] This has prevented large numbers of nurses and other trained health professionals from meeting the basic needs of lower-income communities, including many individuals who are more racially and ethnically diverse than the typical American physician and who are more likely to locate their practices in places where prosperous physician specialists seldom choose to work.[161]

Accreted health law tends to worsen the frictions inherent in transitioning the existing health care system to a universal model. Its relative lack of visibility in policy debate, moreover, enables American physicians to resist a holistic approach to health reform as contrary to the "free-market" ideology which they routinely yet incorrectly credit for the technology-rich environment in which they practice and for their personal financial success. Replying twenty years ago to one such physician, the late Princeton health economist Uwe Reinhardt was blunt in connecting inefficiency to injustice, and in assigning considerable responsibility to laws protecting the medical profession:

> [Dr.] Lally writes of "a fierce sense of rugged individualism, independence, and self-reliance that have been and still are the hallmarks of the American ethos." Where are these rugged individualists? . . . Would I find them in the medical profession, whose members rely so heavily on public subsidies for their education and the science they apply, who now seek a federal tax preference for medical savings accounts, who plead with government to punish managed care organizations that are late in paying bills, to impose on managed care organizations any-willing-provider laws, and to regulate managed care organizations with countless other strictures, and who have never balked at using archaic licensure laws to protect their own economic turf? . . . As

159 For classic if contrasting views of the social benefits of professionalism, compare TALCOTT PARSONS, THE SOCIAL SYSTEM (1951), which emphasizes professional altruism and expertise, with ELIOT FREIDSON, PROFESSIONAL POWERS: A STUDY OF THE INSTITUTIONALIZATION OF FORMAL KNOWLEDGE (1986), which emphasizes professional self-interest.

160 INST. OF MED., THE FUTURE OF NURSING: LEADING CHANGE, ADVANCING HEALTH 22–23 (Oct. 5, 2011); *Implementation Status Map*, NAT'L COUNCIL OF STATE BDS. OF NURSING (Jan. 25, 2021), https://www.ncsbn.org/5397.htm (showing current status of efforts to expand nursing scope of practice) (last visited Aug. 1, 2021); *see also* Daniel J. Gilman & Julie Fairman, *Antitrust and the Future of Nursing: Federal Competition Policy and the Scope of Practice*, 24 HEALTH MATRIX 143, 149–50 (2014) (connecting licensing laws to competition as well as quality control).

161 *See* Peter Buerhaus, *Nurse Practitioners: A Solution to America's Primary Care Crisis*, AM. ENTER. INST. (2018), https://aei.org/wp-content/uploads/2018/09/Nurse-practitioners.pdf.

> all of these self-styled, rugged individualists enlist their government's coercive power to protect their own fiscal health, they might more gracefully countenance the use of that power and also protect the physical health of poor children and, indeed, of all poor people.[162]

Reinhardt's questions remain unanswered.

D. Generational Change

When considering next steps in national health policy, both reform partisans and the broader public often overlook an important truth about physicians—indeed, about all professionals. Professions such as medicine invite us to imagine archetypes with deep historical roots and to assign them fixed preferences. As much as we imbue the doctor, the lawyer, the engineer, or the nurse with timeless qualities, however, professionals are merely people. And those people learn, leave, and are replaced. When one accounts for generational change, the integrated, community-engaged health care system that Medicare-for-All reform might pursue becomes markedly less threatening to medical professionalism.

In part because the political process relies so heavily on labels, looking back at professions rather than looking forward is common in public policy. Politicians seek support from groups, weighing one group's apparent interest and ideology against another's, while media coverage focuses more on the conflicts between groups than the diversity within groups. Moreover, interest groups typically represent the least innovative of their potential constituents, a bias that professional associations accentuate because leadership positions at the national level are earned only after years or decades of lesser service. As a result, the light they cast on the professional world often resembles that reaching earth from nearby stars—formed in the tumult of an earlier time and showing things as they used to be, not as they exist today. And, for the American health professions, certainly not as they will be in years to come.

The challenges of post-ACA medical practice are more tractable and less ethically jarring for younger generations of physicians than for older ones because of who they are, how they are trained, and what they believe about the goals and consequences of the tasks they are undertaking.[163] Compared to their generational

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162 Uwe E. Reinhardt, Letter to the Editor, *Articulating a Social Ethic for Health Care*, 279 JAMA 745, 746 (1998).

163 *See* Timothy Kelley, *Young Docs: The New Blood that Health Care Needs*, MANAGED CARE (Feb. 19, 2016), https://www.managedcaremag.com/archives/2016/2/young-docs-new-blood-health-care-needs. Dr. Robert Wachter, then an associate dean at UCSF School of Medicine, describes offering a sobering message to a recent class of first-year medical students. "You folks are entering

predecessors, "young docs" are gender-diverse, and they want careers that offer work-life balance.[164] They regard information, even professional expertise, as abundant and democratically accessible. Technology is a pervasive aspect of their personal and professional lives. Their social networks do not track traditional groups or hierarchies. They not only respect but expect patient autonomy, and do not find medical consumerism off-putting. They think globally about health.

By contrast, the generation that preceded them—people such as I who entered medical school in the 1980s and 1990s—had been socialized into a narrower professional orientation. We were lectured about the virtues of becoming a primary care physician while every incentive pointed us toward specialization. We were taught to fear control by hospitals and managed care organizations, and we were cautioned that we might never "have" patients but would "rent" them from others. We learned to mistrust any ethical reorientation from individual patients to populations as obligating us to ration care at the bedside. We bristled under accusations of financial conflict of interest, fretted over the effects of quality "report cards" on our professional reputations and opportunities, struggled to computerize our record-keeping, and worried about the economic viability of converting our small private practices from simple cash-flow models to complex payment negotiations.

Emerging generations of physicians see many of the same challenges through a more positive lens. Informed by the IHI's Triple Aim and supported by an improved pedagogy, they do not insist on independent practice for its own sake, and they are comfortable working in large organizations unless and until they decide to pursue specific entrepreneurial opportunities. They are acclimated to interprofessional teamwork, systems-based practice, and patient-centered care, and regard them as more than mere buzzwords. They expect to have their performance measured and compared, and to be paid for the value they deliver. They do not fear "big data," and they see the health of populations as part of their clinical and social responsibility.

Generational change enables the creation of new public policy for the medical profession that preserves its ethics and judgment without equating those to absolute decisional, organizational, and financial autonomy. When I was a medical student, I saw professional norms of self-reliance and clinical independence being both challenged by technologic change and perverted by unlimited funding. Instruction never to rely on information about a patient one did not personally *observe* by taking a history and performing a physical examination—sound guidance in a

a profession completely different from the one I entered 30 years ago, because you will be under relentless, unremitting pressure to figure out how to deliver the highest-quality, safest, most satisfying care at the lowest possible cost." The immediate question from one of the students: "What exactly were *you* trying to do?" *Id.*

164 *See id.*

simpler time ——was twisted into a peculiar command never to trust the reported results of diagnostic tests one did not personally *order*. Following this advice led to duplication, delay, communication failures, unnecessary expense, and patient harm. Similarly, my cohort of physicians who trained in the 1980s learned to posture and guess when confronted with an unfamiliar situation—admitting one's inexperience or ignorance being considered a sign of professional weakness. Our successors, thankfully, are expected to seek assistance, and to look things up using evidence-based, reliable, convenient online clinical resources.[165]

Practice structure has changed as well. A majority of physicians are now employees. Many are employed by large physician-controlled organizations.[166] The percentage of physicians in solo or small-group practice has plummeted from roughly 90% when Medicare was enacted in 1965 to about 35% today.[167] Nearly 40% of physicians work in settings fully or partially controlled by hospitals, compared to 25% as recently as 2012.[168] Younger generations of physicians tend to prefer these arrangements, which offer stable hours and benefits while freeing them from many managerial responsibilities.

This shift has health policy implications. For example, visceral opposition to malpractice lawsuits is considerably less among physicians who do not write annual checks for liability coverage and need not worry constantly about its price and availability. Physicians working in organized systems of care can also expect a better patient safety infrastructure and more robust resources to support them in the unlikely event they are involved in causing a patient serious harm.[169]

Changes in physician professionalism accompany parallel changes among recipients of care. Labelling someone a "patient" implies suffering and dependence. Patients are removed from their usual surroundings and activities, freed of their outside responsibilities, and assigned only the task of recovery (where possible, otherwise they are tasked with acceptance). Once recovery has been accomplished, or is well under way, patients are restored to their everyday lives. Sometimes today's care recipients can accurately be described as "patients,"

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165 *See, e.g.*, *UpToDate: Evidence-Based Clinical Decision Support*, WOLTERS KLUWER, https://www.wolterskluwer.com/en/solutions/uptodate (last visited Aug. 1, 2021) (online and mobile clinical information platform operated by Wolters-Kluwers publishing).

166 CAROL K. KANE, AM. MED. ASS'N, UPDATED DATA ON PHYSICIAN PRACTICE ARRANGEMENTS: FOR THE FIRST TIME, FEWER PHYSICIANS ARE OWNERS THAN EMPLOYEES 7, 13-16 (2019), https://www.ama-assn.org/system/files/2019-07/prp-fewer-owners-benchmark-survey-2018.pdf.

167 *Id.* at 13.

168 *Id.* at 14.

169 *See* William M. Sage et al., *A Quiet Revolution: Communicating and Resolving Patient Harm*, *in* SURGICAL PATIENT CARE: IMPROVING SAFETY, QUALITY, AND VALUE 649, 651-54 (Juan A. Sanchez et al. eds., 2017) (describing the growth of "communication and resolution programs" to prevent and respond to medical error in hospitals).

but in many instances the patient construct has become inapt.

Many recipients of care never cease being persons, maintaining their health and dealing with illness or disability while living their lives.[170] If one imagines an educated, insured patient twenty-five years ago diagramming her care, it is likely she would place her family's physician at the center – not only prescribing, ordering, and referring for services but also personally treating, counseling, and coordinating.[171] Such a diagram today would be much more likely to place the patient herself at the center, armed with a smartphone and the Internet while connected to a host of health-related products, services, and professionals, including several physician specialists.

Re-orienting health care to be more "patient-centered" has become a consensus goal with respect to assessing satisfaction with care, opening health care records to patient review, developing models for shared decision-making, being honest about medical errors, and relaxing overly restrictive rules governing the hospital environment (e.g., visiting hours). Recent trends are even more dramatic in reconfiguring the patient role. The benefits of care increasingly are assessed using patient-reported outcomes (PROs), and therapeutic approaches are increasingly guided by patient-directed goals whose achievement is subsequently measured.[172] These changes are generally intuitive to, and embraced by, younger generations of health professionals.

Empowerment will not be evenly distributed among care recipients, however. I posed the diagram question to an honors undergraduate health policy class a few years ago, imagining that they would have had insufficient contact with the health care system to answer meaningfully. One young woman, who suffered from a chronic disease, proved me wrong. Poignantly, she drew herself underwater, clutching a shaky ladder to the surface and struggling to climb it rung by rung as she located the services she needed. Things would be even harder for someone who is poor, who is homeless or unemployed, or who lives in a community of color. Widening income inequality and persistent racial discrimination threaten to reduce resilience among care recipients even as generational change promises to increase it among care providers.

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170 *See generally* William M. Sage & Kelley McIlhattan, *Upstream Health Law*, 42 J.L. MED. & ETHICS 535 (2014) (arguing that labeling health system users "patients" who are dependent on their physicians is inconsistent with how most people hope to manage their health and health care).

171 Indeed, experts generally agree that the "physician's pen" is the world's most expensive medical technology. *Cf.* Louis Goodman & Timothy Norbeck, *Who's to Blame for Our Rising Healthcare Costs?*, FORBES (Apr. 3, 2013), https://www.forbes.com/sites/realspin/2013/04/03/whos-to-blame-for-our-rising-healthcare-costs/?sh=721dc89b280c (citing 80% as a "frequently used number" for the percentage of health care costs that is directed by physicians).

172 *See, e.g.*, Neil W. Wagle, *Implementing Patient-Reported Outcome Measures*, NEJM CATALYST (Oct. 12, 2017), https://catalyst.nejm.org/implementing-proms-patient-reported-outcome-measures/.

Each of the foregoing developments in understanding U.S. health and health care has been intensified during the COVID-19 pandemic. With respect to the relationship between rationing care and improving it, sudden surges in infection and lack of national and regional preparedness led many communities and the hospitals within them to the brink of rationing.[173] Facilities and localities considered or adopted "crisis standards of care"—not to save money but to address physical shortages—while the nurses and physicians who found themselves unable to provide their best care suffered profound moral injury.[174] Implicit, structural, and occasional overt racism in imposing risks of severe COVID-19 infection, in providing access to life-saving treatment and then vaccination, and in protecting individuals from harassment and abuse sharpened the moral case for health justice.[175] The need for a robust public health workforce to address social determinants of health also became more apparent during the pandemic, as "trickle-down" service from private health care providers was clearly inadequate to prevent major differentials in disease burden, hospitalization, and death. Suspending or changing obstructionist laws was a priority activity for governors, health departments, and mayors who found themselves struggling to maintain an effective workforce as the disease surged. In terms of generational change, the emotional burden of caring for COVID-19 patients has alerted professional leaders, health care executives, and policymakers to the dangers of widespread burnout and post-traumatic stress disorder (PTSD) in the post-pandemic workforce, necessitating new commitments to self-care and team-based support that challenge and improve on the traditional paradigm of professional stoicism and heroism during periods of emergency service.[176]

173 *See, e.g.*, Neil A. Halpern & Kay See Tan, *United States Resource Availability for COVID-19*, SOC'Y CRITICAL CARE MED. (2020), https://www.sccm.org/Blog/March-2020/United-States-Resource-Availability-for-COVID-19; Amit Uppal et al., *Critical Care and Emergency Department Response at the Epicenter of the COVID-19 Pandemic*, 39 HEALTH AFF. 1443 (2020).

174 *See generally* INST. OF MED., CRISIS STANDARDS OF CARE: A TOOLKIT FOR INDICATORS AND TRIGGERS (2013), https://doi.org/10.17226/18338 (recommending procedures for making triage and similar decisions in response to emergency constraints on resources).

175 *See, e.g.*, Leonard E. Egede & Rebekah J. Walker, *Structural Racism, Social Risk Factors, and Covid-19—A Dangerous Convergence for Black Americans*, NEW ENG. J. MED., Sept. 17, 2020, https://www.nejm.org/doi/full/10.1056/NEJMp2023616.

176 *See generally* James G. Adams & Ron M. Walls, *Supporting the Health Care Workforce During the COVID-19 Global Epidemic*, 323 JAMA 1439 (2020) (discussing physical and psychological risks to health care workers from the COVID-19 pandemic); Ari Shechter et al., *Psychological Distress, Coping Behaviors, and Preferences for Support Among New York Healthcare Workers During the COVID-19 Pandemic*, 66 GEN. HOSP. PSYCH. 1 (2020) (urging that health care worker preferences guide programs of COVID-19 psychological support).

IV. INNOVATING THROUGH MEDICARE-FOR-ALL

Will an explicitly national policy design of the sort that Medicare-for-All represents be better equipped than the existing health policy framework—even assuming continuation of the ACA—to make progress toward a more efficient and just health care system? Perhaps, if proponents take account of the changes just described, if they adjust their arguments to align with this new knowledge, and if they choose wisely among available approaches to implementation. To reach that point, however, two related public conversations seem inescapable: one regarding the role of ethics and health professionals, and another regarding the role of the state in influencing the structure of medical care.

A. Revisiting Professional Ethics

The U.S. health care system will not change without permission from health professionals, especially America's physicians [177] Permission must be built on principle, and it should take the form of reaffirming medical ethics. The need to do so has been evident for over two decades, but COVID-19 has increased its urgency.

Resistance to reform is often rationalized as defending the idealized ethics of an established physician-patient relationship. In 1998, the editor-in-chief of the *New England Journal of Medicine*, Dr. Jerome Kassirer, authored a commentary titled "Managing Care – Should We Adopt a New Ethic?" Dr. Kassirer strongly opposed a group-oriented ethics for physicians that justified applying different medical standards to patients enrolled in particular commercial managed care plans.[178] However, he explicitly left open the question of how American medical ethics might accommodate a national single-payer system:

> The fundamental flaw in any universal ethic of medical care in this country is the structure of our health care system . . . . A system in which there is no equity is, in fact, already unethical.

177 Other health professions may play an equally important role in conveying the ethics of health system change, including a stronger commitment to social justice. Nursing is the largest U.S. health profession, counting approximately three million members with a wide range of training, experience, and care delivery functions. *See generally* INST. OF MED., THE FUTURE OF NURSING: LEADING CHANGE, ADVANCING HEALTH (2011) (making the case for nurse leadership). Social justice lies at the ethical heart of nursing, although the focus on hospital-based services in recent decades has reduced its visibility. *See* Patricia Pittman, *Rising to the Challenge: Re-Embracing the Wald Model of Nursing*, 119 AM. J. NURSING 46, 47-48 (2019). Multi-disciplinary care teams including social workers, psychologists, pharmacists, and even lawyers to address patients' health-harming legal needs are increasingly common. *See, e.g.*, JEREMY CANTOR ET AL., COMMUNITY-CENTERED HEALTH HOMES: BRIDGING THE GAP BETWEEN HEALTH SERVICES AND COMMUNITY PREVENTION (2011).

178 Jerome P. Kassirer, *Managing Care – Should We Adopt a New Ethic?*, 339 NEW ENG. J. MED. 397 (1998).

> We gave up the idea of having an equitable system when we decided several years ago to give up on a proposed national health system with consistent coverage for the entire population. Although the chance of rekindling such a proposal seems remote now, we should not stop trying.[179]

It is time for physician supporters of Medicare-for-All to take up Dr. Kassirer's ethical challenge. A national commitment to health and health care was underplayed by the ACA, for reasons described above.[180] By contrast, all Medicare-for-All proposals convey at least some degree of health-oriented social solidarity, which the medical profession should endorse as sound ethics.[181]

To that end, President Biden should invite physicians to create an ethical health care system by convening a Presidential Commission on the Ethics of Health. He should demand that physicians take seriously their mission and that they work closely with other health professions and the public, sharing their power and authority. Nearly all recent presidents—Donald Trump being the starkest exception—have convened commissions on bioethics [182] Typically, these bodies focus on new technologies offering both promise and peril, particularly those that raise dystopian possibilities or provoke religious as well as moral objections. Where U.S. health is concerned, however, a futuristic approach to bioethics is—ironically—short-sighted. The ethical problem is not what is new. The ethical problem is what is now.

Creation of an ethical health care system is the critical, indeed self-critical task. Not defense or protection. America's physicians tend to draw attention only to external threats to what they consider medical professionalism. Obstructionist

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179 *Id.* at 398.

180 *See supra* notes 105-108 and accompanying text (describing pragmatic constraints on solidarity as a core value in U.S. health reform); *see also* Donald M. Berwick, *The Moral Determinants of Health*, 324 JAMA 225 (2020) (making the case for social justice and other general principles as part of health reform).

181 During the 2009-2010 health reform debate, the AMA and many physician specialty societies supported the ACA because it expanded insurance coverage for the sick and the poor, notwithstanding the opposition of powerful state medical associations and the generally conservative politics of private practice physicians.

182 Previous commissions include the following: Presidential Commission for the Study of Bioethical Issues, 2009-2017; President's Council on Bioethics, 2001-2009; National Bioethics Advisory Commission, 1996-2001; Advisory Committee on Human Radiation Experiments, 1994-1995; Biomedical Ethical Advisory Committee, 1988-1990; President's Commission for the Study of Ethical Problems in Medicine and in Biomedical and Behavioral Research, 1978-1983; and National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1974-1978. *See* Bioethics Rsch. Libr., *U.S. Bioethics Commissions*, https://bioethics.georgetown.edu/library-materials/digital-collections/us-bioethics-commissions/ (last updated July 11, 2016).

insurance companies. Greedy pharmaceutical manufacturers. Unscrupulous malpractice lawyers. Overbearing government bureaucrats.

The greater ethical failings come from within. Not because many physicians are uncaring or unskilled or self-aggrandizing, but because continuing to do what the existing health care system has been designed to reward is not always right and is seldom enough. Physicians and those who profit off them are wont to suggest that any substantial change to where power sits in U.S. health care will endanger each of us and our parents, children, and partners. But a health care system that fetishizes the relationship between one physician and one patient ignores the degree to which effective twenty-first-century medical care departs from such nostalgic imagery and the fact that many communities lack meaningful therapeutic access and therefore receive no or paltry benefits from the status quo.

Physicians' silence in the face of massive health injustice, inefficiency, and waste must be called out by leaders of the medical profession for what it is: complicity. Defense of an ethically indefensible status quo has made much-needed reform proposals seem morally threatening, rather than representing opportunities for ethical introspection and improvement. All those who profit from the current system – a large group given $4,000,000,000,000 of annual U.S. health care spending—use physician complacency to justify their own resistance to change.

In part because we medicalize so many social problems, we fail to notice profound racial, ethnic, and economic disparities in health needs and responses—inequities that are more honestly labelled injustices. Our bloated health care system is beset by injustice-in-passing (implicit bias and microaggression) and injustice-by-design (structural racism). Although the scientific objectivity with which we tend to approach policy analysis may obscure it, there is even injustice-on-purpose in U.S. health care. In the aggregate, these moral failures demand an immediate ethical response.

It does not help to overly intellectualize injustice by speaking only the language of science and evidence and process. Where moral outrage is justified, we need to display it. Appealing to self-interest is no substitute for appealing to principle. In health reform, the "business case" for improvement is a semantic repeat offender—much overused and rarely effective. With trillions of dollars flowing so freely, it is hardly a surprise that the health care sector finds it easier to keep making money the established way than to confront deep challenges offering at best speculative savings.

Taking advantage of generational change in the professions, a Presidential Commission on the Ethics of Health might work to reset professional norms in several respects:

- To proclaim clearly that the current system, as Dr. Kassirer observed twenty years ago, is profoundly unethical.

- To refute arguments that care rationing constitutes the principal threat to professional ethics, focusing instead on unjust disparities and inattention to social determinants of health.

- To support social investment in health, even when it favors non-medical over medical approaches.

- To recognize and reverse the biases that create racism and other forms of injustice in the exercise of professional judgment.

- To do "personal justice," including finding compassionate ways for health professionals, organizations, and systems to say "no" to those whose claims on shared resources are not strong.

- To advocate for benefits to communities and populations as strongly as for the well-being of individual patients, including to address systematic problems such as climate change and mass incarceration that fall outside the usual "lanes" of medical advocacy.

- To articulate a "just science" that is less technocratic and absolute in order to create realistic expectations of medicine and preserve trust in public health.

Some proponents of government-led reform strategies have become so preoccupied with the recent history of market-based approaches to system improvement that they tend to ignore the health care system's long history of professional control.[183] This would be a mistake. Reinforced by the legal architecture explained above,[184] physician professionalism remains central to both health system operations and public confidence in health care governance.

Ethical leadership from health professionals in connection with Medicare-for-All can also help recover the humanity that seems to have been eclipsed by commercialized technology in U.S. health care. Trust between patient and caregiver risks being eclipsed by complex incentives, bureaucratic systems of information management, and associated performance metrics – all of which seem

183 *See, e.g.,* Allison K. Hoffman, *Health Care's Market Bureaucracy*, 66 UCLA L. REV. 1926 (2019).

184 *See supra* notes 143-162 and accompanying text.

remote from the core values of health and few of which have been shown to improve quality or safety.[185] For this reason, some commentators again emphasize caring relationships as the most enduring aspect of health care and therefore as a core goal of policy change. Notably, both Donald Berwick and Avedis Donabedian—two pioneers of quality measurement and safety improvement—returned late in their careers to the central role of humanity in healing.[186]

B. Key Structural Goals For Medicare-Led Innovation

With an assertive grounding in professional ethics, the operational approaches to "Medicare-for-All" previously identified could help achieve specific objectives that the next generation of health reformers would be wise to embrace. This Section describes some of the more challenging steps on the path to health system improvement, while offering a thumbnail sketch of whether and how Medicare-for-All could make a difference. The structural changes suggested below are intended to help address root causes of inefficiency and inequity that become apparent only when the health care system is examined from the "middle-distance." This approach, uncommon in health policy analysis, is sensitive to ground-level conditions of professional and industrial organization as well as to the policy levers available under federal law.

These objectives are all important to pursue, and they need not be approached in any particular order. Still, they share attributes that make them amenable to a Medicare-for-All project of national health reform. They each can be communicated using principles of empowerment, effectiveness, and justice—particularly if younger generations of physicians and other health professionals reject ethical complacency and help draw attention to the failings of the status quo. They do not have an overtly partisan valence, nor do they rely on labelling particular political stakeholders as heroes or as villains. They invite a long-overdue communitarian and collective perspective on health and medical care, as befits the Medicare-for-All frame. And they persist in large part because of outdated or self-interested legal constraints, which the COVID-19 pandemic has helped reveal and in some ways has begun to change.

185 Donald M. Berwick, *Era 3 for Medicine and Health Care*, 315 JAMA 1329, 1329 (2016) (criticizing excessive measurement and performance incentives for individual physicians); *See also* INST. OF MED., VITAL SIGNS: CORE METRICS FOR HEALTH AND HEALTH CARE PROGRESS (2015) (reviewing and critiquing health care performance metrics).

186 Berwick, *supra* note 185, at 1330; Fitzhugh Mullan, *A Founder of Quality Assessment Encounters a Troubled System Firsthand*, 20 HEALTH AFF. 137, 141 (2001) (according to quality pioneer Avedis Donabedian, "The secret of quality is love."); *cf.* KARL W. GIBERSON & FRANCIS S. COLLINS, THE LANGUAGE OF SCIENCE AND FAITH: STRAIGHT ANSWERS TO GENUINE QUESTIONS (2011) (reconciling expertise with belief).

1. Improving Cost Discipline

Health care providers, especially hospitals but also physicians, tend to know more about their revenue flows than about their cost structures, and they manage their enterprises accordingly. This phenomenon has several causes. First, hospital revenues are determined largely by "payer mix" (i.e., disparate revenue streams for insured patients from multiple sources with variable terms of payment). Private health insurers pay more generously than the Medicare program, which in turns pays more generously than state Medicaid programs. Second, physicians make many of the decisions that drive hospital costs without bearing administrative or financial responsibility themselves. Third, services tend to be defined not by direct utility to patients, but instead in terms of disaggregated professional process steps and associated components that can be assigned a billing code.[187] Finally, prices for many inputs are outrageously high—distorted by lack of cost discipline at many points along what is often a needlessly complex supply chain.[188]

Information exchange has not much helped, even in the electronic age. The reason is a simple one. Health care enterprises have tended to collect the information they needed to collect in order to get paid, and very little more.[189] Researchers and progressive clinicians frequently note the inadequacies of this "claims data" as a clinical improvement tool, but seldom acknowledge its pervasiveness in the information ecosystem of medical care or its parallel inadequacies as a cost management tool.

Could Medicare-for-All help? Possibly. Under most scenarios, the Medicare program would possess the ability and authority to redefine services and payment so as to better approximate their actual utility to both individual patients and covered populations. Bundled payment programs attempt the former; accountable care organizations attempt the latter. For health care organizations that assume

187 *See* William M. Sage, *Assembled Products: The Key to More Effective Competition and Antitrust Oversight in Health Care*, 101 CORNELL L. REV. 609, 617-33 (2016) (arguing that "getting the product right" is a precondition to improving health care market outcomes through competition).

188 America's extremely high health care prices routinely prompt criticism, even outside consolidated markets. *See, e.g.*, Gerard F. Anderson et al., *It's the Prices, Stupid: Why the United States Is So Different from Other Countries,* 22 HEALTH AFF. 89 (2003); Erin Fuse-Brown, *Irrational Hospital Pricing*, 14 HOUS. J. HEALTH L. & POL'Y 11 (2014); Ezra Klein, *21 Graphs That Show America's Health-care Prices Are Ludicrous*, WASH. POST (Mar. 26, 2013, 12:40 PM), https://www.washingtonpost.com/news/wonk/wp/2013/03/26/21-graphs-that-show-americas-health-care-prices-are-ludicrous/; *see also* INST. OF MED., BEST CARE AT LOWER COST: THE PATH TO CONTINUOUSLY LEARNING HEALTH CARE IN AMERICA 102 (2012) (attributing $105 billion of $750 billion total estimated annual waste to "prices that are too high").

189 In 2015, U.S. health plans processed 5.4 billion transactions. CAQH EXPLORATIONS, 2016 CAQH INDEX: A REPORT OF HEALTHCARE INDUSTRY ADOPTION OF ELECTRONIC BUSINESS TRANSACTIONS AND COST SAVINGS 3 (2016), https://www.caqh.org/sites/default/files/explorations/index/2016-caqh-index-report.pdf?token=qV_hI4H5.

responsibility for serving entire geographic areas, Medicare could impose global budgets that create incentives for non-medical community investment.[190] Both actual expansions of Medicare coverage and proposals that generalize Medicare payment practices to all payers might make this possible. A weakness is that Medicare tends to construct its payment bundles by combining the payments for items that it previously reimbursed individually, rather than by estimating a packaged price from observable markets in assembled services. For this reason, MA plans might be able to restructure payment more flexibly than traditional fee-for-service Medicare, and MA plans can exclude lower performing or less adaptive providers in ways that traditional Medicare by law cannot.

With respect to physician cost discipline, countering "surprise medical bills" from anesthesiologists, assisting surgeons, and other physicians who turn out, unexpectedly, to not have network contracts with insurers become a significant regulatory challenge in recent years. Federal legislation in 2020 first prohibited billing by providers for COVID-19 care.[191] Later, broader "No Surprises Act" protections were put in place, holding patients harmless beyond in-network cost-sharing amounts in both emergencies and certain non-emergency situations in which patients are unable to choose an in-network provider, with payment disagreements between providers and insurers resolved by independent dispute resolution.[192] Medicare-based payment reforms could do even more to avoid unexpected balance or surprise billing.[193] By law, Medicare Advantage plans can cap out-of-network exposure at fee-for-service Medicare rates, including a

190 Medicare and Medicaid recently revised definitions of permissible services to enable MA plans, Medicaid managed care plans, and hospitals to expend government funds on transportation, housing, and similar services that enable the delivery of effective medical care. *See* NAT. ACADS. OF SCIS., ENG'G, AND MED., INTEGRATING SOCIAL CARE INTO THE DELIVERY OF HEALTH CARE: MOVING UPSTREAM TO IMPROVE THE NATION'S HEALTH 117 (2019) (describing federal legal authorizations for health-related social services). At the state level, Maryland has a federal waiver in place that allows it to pay hospitals based on total cost of care. *Maryland Total Cost of Care Model*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://innovation.cms.gov/initiatives/md-tccm/ (last visited Aug. 1, 2021); *see also* Jesse M. Pines et al., *Maryland's Experiment with Capitated Payments for Rural Hospitals: Large Reductions in Hospital-Based Care*, 38 HEALTH AFFS 594 (2019) (measuring effects of Maryland's initial pilot program).

191 *See* AM. MED. ASS'N., ISSUE BRIEF: BALANCE BILLING FOR COVID-19 TESTING AND CARE - FEDERAL AND STATE RESTRICTIONS (2020), https://www.ama-assn.org/system/files/2020-05/issue-brief-balance-billing-covid-19-testing-care.pdf (explaining CMS position on balance billing in the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Pub. L. No. 116-136, § 3202, 134 Stat. 281, 367 (2020))

192 Consolidated Appropriations Act of 2021, H.R. 133, 116th Cong. § 101-118 (2021) (No Surprises Act).

193 *See* Kevin A. Schulman et al., *Resolving Surprise Medical Bills*, HEALTH AFF.: BLOG (July 10, 2019), https://www.healthaffairs.org/do/10.1377/hblog20190628.873493/full/. Private equity firms have selectively invested in specialty physician groups who can maintain non-network status, not only worsening surprise billing practices but also enhancing those groups' leverage to negotiate higher network contract rates.

prohibition on "balance billing" patients for amounts not reimbursed by insurance.[194]

Because traditional Medicare's convoluted approach to fee-for-service payment is a principal cause of the underlying problem, however, MA plans alone probably have limited ability to engineer a comprehensive solution unless and until they represent the substantial majority of Medicare beneficiaries. Medicare expansion plans based on MA plans could accelerate this trend.

2. Reducing Claims Middlemen

Many "health insurers" are merely contract administrators, with true risk of financial loss borne by self-funded employers (for private coverage) or by government programs. Traditional Medicare became a substantial cause of such intermediation when—bowing to the AMA's demand for unthreatening payment mechanisms—the federal government entered into contractor agreements to perform those functions with established BCBS plans (which were originally called "fiscal intermediaries" for Medicare Part A and "carriers" for Medicare Part B).[195] As mentioned previously, the principal tasks associated with the administrative role in employer-based health plans include verifying eligibility, assembling and maintaining provider networks, negotiating provider payment, and processing claims.

For different reasons, neither governments nor private employers have proved to be demanding customers for most health plans, which in turn are seldom disciplined negotiators with providers or innovators with respect to benefit design. For political reasons, government insurance programs tend to disfavor competitive bidding or other measures that selectively channel enrollees to more cost-conscious organizations. On the private side, even the largest national employers seldom have sufficient geographic concentration to exert meaningful leverage over health care providers and would suffer very high switching costs if they attempted to withdraw business from one giant insurance administrator in favor of another. As a result, the health plan sector essentially takes a percentage of the vast sums of money passing through them from true payers to health care providers, which limits its incentive to pursue innovations that might substantially decrease that flow of funds.[196]

194 Robert A. Berenson et al., *Why Medicare Advantage Plans Pay Hospitals Traditional Medicare Prices*, 34 HEALTH AFF. 1289, 1292 (2015).

195 *Medicare Administrative Contractors*, CTRS. FOR MEDICARE AND MEDICAID SERVICES (2019), https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/MedicareAdministrativeContractors.

196 There are exceptions, of course. Some employers, typically medium-sized companies with locally concentrated workforces, have greater ability to find or induce insurers to be effective third-

Again, Medicare-for-All might help. An undoubted strength of single-payer programs is to lower administrative costs. Greater transparency associated with the Medicare Administrative Contractor process could avoid overpayment for ministerial tasks, while changes in Medicare benefits that rationalize services and reduce claims volume could further streamline administration. For approaches centering on managed care, MA plans seem to do better than commercial health plans at keeping members healthier and costs down, partly because Medicare beneficiaries who choose MA plans tend not to switch plans in subsequent years, and partly because a higher percentage of elderly patients are at risk of serious illness.[197] Whether this would hold true for a universal MA entitlement is unclear.

3. Disintermediating Physicians from Many Transactions

The U.S. health care system still conceptualizes its products and services—no matter how expensive, technologically advanced, physically substantial, or dependent on a broader workforce—as extensions of the "black bag" that accompanied physicians on house calls a century ago. Often by law, physicians retain exclusive decisional authority over most health care services through prescription, order, or referral. Similarly, health insurance payment is generally limited to services that physicians request, which helps insurers demarcate the boundary between covered medical benefits and excluded non-medical services. Physician intermediation also permits certification of necessity, both for processing coverage and for deterring fraud.

However, continual physician intermediation imposes expense and delay, restricts other health professionals (and non-professionals) from practicing at the top of their training, and discourages self-care even for straightforward conditions. It is only a slight exaggeration to say that the U.S. health care system is perfectly crafted to prevent people from taking care of their own health-related needs. Bringing physicians into so many transactions also adds complexity to addressing social determinants of health, which is generally a non-medical endeavor.[198]

Because the drivers of physician control and intermediation are often state laws and federal payment policies, one might welcome a Medicare-for-All approach that emphasizes nationally uniform practice regulations, coverage, and reimbursement categories less tethered to the traditional professional hierarchy, and facilitation of self-care (including remote or asynchronous services delivery

party administrators of their coverage. Some health plans operate disease-management programs that successfully reduce emergency department visits and hospitalizations.

197 *See* Gretchen Jacobson et al., *Medicare Advantage Plan Switching: Exception or Norm?*, KAISER FAM. FOUND. (Sept. 20, 2016), https://www.kff.org/report-section/medicare-advantage-plan-switching-exception-or-norm-issue-brief/ (describing how about 10% of MA plan members switch each year).

198 *See supra* notes 122-142 and accompanying text.

through telehealth). This would be a major change from existing Medicare practices, however, which often cede authority to physician-led advisory bodies (e.g., the Relative Value Scale Update Committee for Medicare physician payment) and which continue to rely on physicians as gatekeepers for non-fraudulent federal expenditures.[199] As a result, progress on workforce flexibility and patient direction likely would depend on the degree to which those advocating for policy change could resist the political influence of established interest groups when crafting rules and guidelines for a Medicare expansion.

4. Managing Consolidated Provider Markets

When competition is threatened in the private economy, one expects a response from the U.S. Department of Justice or the Federal Trade Commission, the two public enforcers of the federal antitrust laws. In health care, this expectation is frustrated by (at least) two facts. First, competition is constrained more by other laws governing the health care system than by purely private conduct, and federal antitrust laws have limited purchase over that regulatory architecture.[200] Second, U.S. antitrust law is better suited to preventing corporate mergers and acquisitions that might confer market power than to restoring competition in markets that have already consolidated, which has become the case for the majority of American hospitals, many physician specialists, and many health insurers.[201] This is because antitrust enforcers and reviewing courts prefer structural remedies that promote actual competition to conduct remedies that simulate competitive outcomes – and structural remedies are difficult to impose on an existing monopolist.[202] COVID-19 appears to be further consolidating health

199 The Relative Value Scale Update Committee (RUC) is composed of thirty-two physician members approved by the AMA, with twenty-two nominated by major national medical specialty societies. *Composition of the RVS Update Committee*, AM. MED. ASS'N, https://www.ama-assn.org/about/rvs-update-committee-ruc/composition-rvs-update-committee-ruc (last visited Aug. 1, 2021 (providing an overview of RUC composition). For a detailed analysis of the RUC's anticompetitive effects, see MIRIAM J. LAUGESEN, FIXING MEDICAL PRICES: HOW PHYSICIANS ARE PAID 3-5, 23-46 (2016).

200 *See* William M. Sage & David A. Hyman, *Antitrust as Disruptive Innovation in Health Care: Can Limiting State Action Immunity Help Save a Trillion Dollars?*, 48 LOY. U. CHI. L.J. 724,730-34 (2017) (examining the potential effects of recent Supreme Court rulings on reducing anti-competitive professional regulation in health care).

201 *See* HEALTHCARE FINANCIAL MANAGEMENT ASS'N, HEALTH CARE 2020: CONSOLIDATION (2016), https://www.hfma.org/industry-initiatives/health-care-2020.html.

202 *See* Thomas L. Greaney, Commentary, *Competition Policy After Health Care Reform: Mending Holes in Antitrust Law's Protective Net,* 40 J. HEALTH POL., POL'Y & L. 897, 900 (2015) (describing the problem of extant market power); *see also* William M. Sage, *Antitrust Enforcement and the Future of Healthcare Competition*, *in* OXFORD HANDBOOK OF U.S. HEALTHCARE LAW 606 (I. Glenn Cohen et al. eds., 2016) (examining the limited power of competition law in health care). The Herfindahl-Hirschman Index (HHI) is calculated by summing the squares of the percentage of the

care markets, as smaller competitors who were more vulnerable to the financial volatility produced by the pandemic are bought out by their larger, better capitalized rivals.[203]

Medicare-for-All approaches could be beneficial for three reasons. Most obviously, a true single-payer plan creates a regulatory counterweight to anti-competitive behavior in consolidated markets. Whether Medicare could play this role effectively depends on political factors, notably the ability to overcome interest-group favoritism and act in the broader public interest. Second, approaches that would apply Medicare pricing throughout a market could blunt the pricing power associated with consolidation. Along these lines, a novel bill was introduced in Congress in early 2019 that offered health care providers in consolidated markets a choice: reduce concentration to below a prescribed threshold (using the Herfindahl-Hirschman Index), or accept Medicare pricing.[204] Third, many of the state laws that Medicare could supersede on a nationally uniform basis, such as professional licensing laws and certificate-of-need requirements for capital investments, constitute barriers to entry for new competitors. Consolidation is less likely to have anti-competitive effects in markets where entry barriers are low.

5. Reining in Drug Costs by Rethinking Innovation Funding

Extremely high prices for innovative prescription drugs and other biopharmaceuticals are common motivators for further health care reform. Novel therapies to ameliorate serious chronic conditions routinely generate charges exceeding $100,000 annually, while prices for established drugs have increased rapidly in recent years.[205] One problem is that supply chains for drug distribution and purchasing have become bizarrely complex—often involving non-transparent cash flows in both directions—and can be simplified by federal regulation. Examples include recent proposals by FDA to require price transparency in direct-to-consumer drug advertising and to repeal exceptions to fraud and abuse laws that had allowed a system of hidden but sizeable "rebates" to flourish.[206] The core

market served by each competitor. The HHI for five firms each with 20% of the market is 2,000; the HHI for two firms each with 50% of the market is 5,000.

203 *See* Reed Abelson, *Buoyed by Federal COVID Aid, Big Hospital Chains Buy Up Competitors*, N.Y. TIMES (May 21, 2021), https://www.nytimes.com/2021/05/21/health/covid-bailout-hospital-merger.html?searchResultPosition=1.

204 Hospital Competition Act of 2019, H.R. 506, 116th Cong. (2019).

205 NAT'L ACADS. OF SCI., ENG'G, AND MED., MAKING MEDICINES AFFORDABLE: A NATIONAL IMPERATIVE 11-17 (2018).

206 *See* Alex M. Azar, Sec'y, U.S. Dep't Health & Hum. Servs. Remarks on Drug Pricing to the National Academy of Medicine (Oct. 15, 2018). The Trump Administration formulated a rule to make drug rebates unlawful, but then withdrew the rule after push-back from industry. *See* Peter Sullivan, *White House Withdraws Controversial Rule to Eliminate Drug Rebates*, HILL (July 11, 2019), https://thehill.com/policy/healthcare/452561-white-house-withdraws-controversial-rule-to-

challenge of prescription drug policy, however, remains unsolved. It is to reconcile the trivial marginal cost of producing additional doses of most drugs with the staggering initial investment necessary to invent those therapies and to demonstrate their safety and effectiveness.

The solution, simply put, is to begin to decouple the costs of drug development from the price paid at the point of care for an individual patient. Medicare-for-All creates a significant opportunity to do so. Those seeking to lower drug prices often focus on using the government's greater negotiating power, backstopped by the threat of imposing direct price controls or altering intellectual property rights. Purchasing at the population level makes it possible to pursue truly radical approaches to making lifesaving therapies widely available. Australia, for example, recently negotiated a fixed-fee license for curative Hepatitis C medication.[207]

Moreover, FDA regulation of biopharmaceuticals is the most extensive health-related gatekeeping function that operates through federal rather than state law. The federal government also acts as the principal funder of biomedical research through the NIH, National Science Foundation, and other entities. These synergies would enable a Medicare-for-All system to pursue comprehensive reform—combining better technology assessment, fully aligned coverage standards, novel purchasing strategies, streamlined FDA regulation, and enhanced direct research funding—that substantially lessens the perceived tension between present pricing and future innovation.

6. De-Medicalizing Social Problems

The apparent imbalance in government expenditures between medical care and non-medical social services is one of the most damning consequences of Medicare's Gilded Age. As the social determinants and disparities literatures demonstrate, the easiest way to improve health is to increase wealth, education, and community cohesiveness.[208] Instead, the United States often treats poverty and other social problems as medical ones.[209] This has increased expense, widened injustice, distorted community support, and—because of the dependency inherent in the patient role – arguably diminished individual initiative far more than would have resulted from providing substantially greater cash assistance to the poor.

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eliminate-drug-rebates.

207 *See* Suerie Moon & Elise Erickson, *Universal Medicine Access through Lump-Sum Remuneration—Australia's Approach to Hepatitis C*, 380 NEW ENG. J. MED. 607, 607 (2019). This subscription approach, sometimes called the "Netflix model," is being pursued domestically at the state level, notably in Washington State and Louisiana.

208 *See supra* notes 127-147 and accompanying text.

209 BRADLEY & TAYLOR, *supra* note 136, at 78; Sage & Laurin, *supra* note 138, at 575-76.

With sufficient political will, Medicare-for-All could help public policy turn the corner toward substantially greater non-medical social investment. Small steps are already being taken, such as authorizing MA plans and some Medicare providers to use federal funds for housing, transportation, and other social needs that benefit health.[210] Much greater change—achievable only if still-daunting fiscal barriers are overcome—would be possible if Medicare-for-All were fully "on-budget," forcing taxpayers to compare directly the costs and benefits of medical versus non-medical expenditures. The risk is that, in the short term, further enhancing the percentage of the federal budget devoted to health will make entrenched interest groups stronger rather than weaker in their pursuit of privileges and subsidies. Over the longer term, however, one would hope it would become difficult for those groups to justify maintaining the status quo.

CONCLUSION

If one looks closely at medicine's "modern era" of technological progress—funded largely by the original Medicare program—several gilded aspects become apparent. Scratching the surface of the American health care system reveals far less impressive characteristics: waste, injustice, and neglect.[211] Many of the services the health care system funds and provides are simultaneously inefficient and inequitable, while medicalizing the social safety net crowds out fairer and more cost-effective investments in health-related but non-medical support for individuals and communities.

As the Biden Administration explores options for post-pandemic health reform, Medicare-for-All offers a test of both discourse and decision-making in liberal democracy, which increasingly seems under siege in the United States and abroad. Because over a trillion dollars of annual medical spending currently languishes less productively than it might, rebalancing the nation's health-related policy priorities presents substantial opportunities to both address disparities and enhance welfare.[212] Partisan sniping over single-payer proposals as "socialized medicine" is counter-productive. Instead, the political conversation around Medicare-for-All might deepen, both morally and in response to what has been

210 *See* NAT. ACADS. OF SCI., ENG'G, AND MED., *supra* note 190, at 109-36 (discussing how to finance social care); Maria Castellucci, *Insurers Want to Lead if CMS Pilots Payments for Housing, Social Determinants of Health*, MOD. HEALTHCARE (Dec. 15, 2018), https://www.modernhealthcare.com/article/20181215/NEWS/181219967/insurers-want-to-lead-if-cms-pilots-payments-for-housing-social-determinants-of-health.

211 For a perceptive and entertaining examination of Medicare's arguable flaws, see DAVID A. HYMAN, MEDICARE MEETS MEPHISTOPHELES 27–39 (2006) (providing a C.S. Lewis-style epistolary analysis of Medicare as the devil's handiwork).

212 *See generally* William M. Sage, *Fracking Health Care: The Need to Safely De-Medicalize America and Recover Trapped Value for Its Peop*le, 11 N.Y.U. J.L. & LIBERTY 635 (2017) (noting the potential for wasteful health care expenditures to be captured and repurposed).

learned about deficiencies and opportunities in the current system.

Politics may be the art of the possible, but pragmatism that renders principle invisible is not something to be celebrated. For the Biden Presidency to be transformational in health policy, it must keep progressive principles at the forefront. The Biden Administration will get things done by being strategic in priority-setting, procedure, and messaging—not by retreating to an incrementalism that discards principle out of misperceived necessity. Considering its substantial collective responsibility for current conditions, moreover, the American medical profession cannot sit on the sidelines during this effort. It must help lead.

A principled re-evaluation of post-pandemic health policy through a Medicare-for-All lens enables diverse democratic values to be considered: welfare, justice, freedom, and civic republicanism among them. Justice and self-governance were clear elements of the original Medicare program, which redistributed resources toward an aging generation that had forgone earnings during the Great Depression and World War, as well as connecting the patriotism of that generation to democratic renewal, including racial desegregation, in a country that had benefited from its sacrifices. Tensions among these values can be explored as well, such as the unexpected distance that America's prolific but distorted medical marketplace often inserts between entering into seemingly voluntary medical transactions and actually experiencing improvements in subjective welfare.[213]

Can the United States build social solidarity around health as a collective obligation even if not as an individual right? Without such a commitment, it is difficult to counter both special interests and the constraints of fiscal politics. What guardrails should be placed around market processes in medical care in order to generate better social outcomes? Original Medicare's blank-check approach sent many medical industries into overdrive, with unpredictable and ultimately hazardous consequences. Medicare-for-All might facilitate developing a channeled competitive framework closer to the National Health Service's "internal market" in Great Britain.[214] Universalizing Medicare might also generate a different dialogue about the "Nanny State." The language of opportunity almost universally resonates with the American public. In some situations, however, direct investments in health may be necessary to overcome community characteristics that render individual choice illusory. In other situations, providing cash assistance

213 Legal theorists have periodically engaged these issues, but sometimes have posited a dichotomy between free markets and government control that, while intellectually engaging, does not capture the range of possibilities for actual health system governance. *See, e.g.*, RICHARD A. EPSTEIN, MORTAL PERIL: OUR INALIENABLE RIGHT TO HEALTH CARE (1997) (arguing both liberty and efficiency).

214 In terms drawn from popular culture, regularizing how government helps structure medical markets might bring the U.S. health care system a bit closer to *The Truman Show*, instead of today's *Jurassic Park*-like environment.

outside of the medical frame may enhance both liberty and welfare.

America is a decade into the Affordable Care Act, a law that ascribed considerable importance to care delivery and population health. Despite the deadliest pandemic in over a century, the political process has yet to move past the ACA's relatively straightforward provisions regarding insurance expansion.[215] As a result, the nation has barely begun to confront the deeper shortcomings of U.S. medicine and health discussed in this Article.

A critical first step for the Biden Administration is demanding ethical leadership from the American medical profession, which U.S. law continues to charge with substantial responsibility for health system design and operation. This requires a forward-looking commitment to innovation in justice as well as effectiveness, not misguided nostalgia for a golden age that never was.

215 *See generally* William M. Sage, *Putting Insurance Reform in the ACA's Rear-View Mirror*, 51 HOUS. L. REV. 1082 (2014) (noting that the ACA's most significant reforms go beyond health insurance to encompass health care delivery and underlying health).

No Parking Here: A Review of Generic Drug 180-Day Exclusivity and Recent Reform Proposals

Victor L. Van de Wiele, LL.B., LL.M.[*]

Jonathan J. Darrow, S.J.D., LL.M., J.D., M.B.A.[^]

Aaron S. Kesselheim, M.D., J.D., M.P.H. [†]

Abstract:

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act) to facilitate the market entry of generic drugs after brand-name drugs' patent exclusivity ended. To incentivize generic manufacturers to challenge brand-name manufacturers' patents, a 180-day exclusivity accrued to the first manufacturer to successfully litigate the validity or scope of a brand-name drug patent. However, brand-name and generic manufacturers have found ways to strategically "park" the 180-day exclusivity to delay generic entry and competitive drug markets. Congress revised the statute in 2003, but concerns continued. In 2019, three congressional bills were introduced to further revise the 180-day exclusivity framework. This Article reviews the history of the 180-day provision, evaluates what types of strategic behavior remained after 2003, and considers whether the recent legislative proposals are likely to offer improvement.

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* Affiliated researcher at the Program On Regulation, Therapeutics, And Law (PORTAL) in the Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital. His work is supported by Arnold Ventures.

^ Associate Professor of Law at Bentley University, an Assistant Professor of Medicine at Harvard Medical School, and an Associate Scientist at PORTAL in the Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital. LL.M. waived. His work is supported by ACCISS, Arnold Ventures, the Commonwealth Fund, the Greenwall Foundation, the Kaiser Permanente Institute for Health Policy, West Health, and under a Novo Nordisk Foundation grant for a scientifically independent Collaborative Research Programme (grant NNF17SA0027784).

† Professor of Medicine at Harvard Medical School and the Director of PORTAL in the Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital. His work is supported by Arnold Ventures and by a Novo Nordisk Foundation grant for a scientifically independent Collaborative Research Programme (grant NNF17SA0027784).

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INTRODUCTION

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act) to rebalance the interests of patent holders and generic drug companies in the wake of the 1962 Kefauver-Harris Drug Amendments. One of the law's major innovations was a new framework designed to facilitate the market entry of generic drugs by incentivizing generic manufacturers to challenge brand-name manufacturers' patents.[1] To this end, the law required brand-name manufacturers to disclose to the Food and Drug Administration (FDA) those patents that were claimed to cover their drugs. The agency would then list those patents in a publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (informally known as the "Orange Book"). Because it can be difficult to determine which of the approximately 350,000 patents issued each year are relevant to a given drug,[2] this new system promoted transparency and helped generic drug manufacturers assess the risk and feasibility of entering the market. The Act also provided that filing a generic drug application with the FDA could be an act of patent infringement, allowing any patents listed by the brand-name manufacturers to be reviewed in court and potentially invalidated.[3] Traditional patent infringement rules generally require patent owners to wait to sue until a potentially infringing product is made, used, sold, offered for sale, or imported into the United States. Through the Act's process, the intellectual property landscape could potentially be resolved sooner than was previously possible.

Patent litigation, however, is expensive, time-consuming, and, if successful, could in some cases immediately open the market to all competitors and not just the patent challenger.[4] To incentivize a generic drug manufacturer to engage in patent challenges, the Act offered as a prize a period of generic drug exclusivity to the first manufacturer that asserted the invalidity or non-infringement of the brand-name patents. Exclusivity would be granted even if the patent holder did not bring suit or if the case settled rather than leading to patent invalidation or a finding of non-infringement.[5] Then, for 180 days after the FDA received notice

1 Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585; 21 U.S.C. § 355(j)(5)(B)(iv) (2018).

2 Reed F. Beall & Aaron S. Kesselheim, *Tertiary Patenting on Drug-Device Combination Products in the United States*, 36 NATURE BIOTECHNOLOGY 142, 143 tbl.1 (2018) (indicating an average of approximately three unique patents per new drug by 2016).

3 35 U.S.C. § 271 (2018).

4 Evan J. Wallach & Jonathan J. Darrow, *Federal Circuit Review of USPTO Inter Partes Review Decisions, by the Numbers: How the AIA Has Impacted the Caseload of the Federal Circuit*, 98 J. PAT. & TRADEMARK OFF. SOC'Y 105, 118 (2016).

5 Food & Drug Admin., *Guidance for Industry: 180-Day Exclusivity: Questions and Answers*, U.S. DEP'T HEALTH & HUM. SERVS. 10 (Jan. 2017), https://www.fda.gov/regulatory-

that the first generic was being marketed, the FDA could not approve other competing generics. Free-riding by other generic manufacturers on the patent challenger's efforts would therefore be temporarily curtailed. For those 180 days, only the first generic product and the brand-name product could be sold, creating a potentially lucrative duopoly for the generic manufacturer that would allow it to sell its product for a much higher price than it could if other generic competitors were allowed to enter the market.

The Hatch-Waxman Act has been widely viewed as a success. In the years following its enactment, annual generic drug approvals increased from a median of 136 in the years 1970–1984, to 284 in 1985–2012, and to 588 in 2013–2018.[6] But the 180-day exclusivity incentive has remained controversial. Generic manufacturers consider it to be a crucial feature supporting the growth of the international generic drug industry.[7] But enterprising brand-name and generic manufacturers have found ways to strategically use the 180-day exclusivity to delay generic entry and competitive drug markets. For example, in the years following 1984, some brand-name and generic manufacturers settled patent litigation with payments made to the generic that prevented or delayed the start of the 180-day period. Such "parking" also prevented entry of other generic competitors that were required by law to wait until the 180-day period had elapsed.

Congress substantially revised the statute in 2003 to address parking, yet sixteen years later, legislators and commentators continue to worry about it.[8] In 2019, three congressional bills were introduced that sought to further revise the 180-day exclusivity framework. To understand whether such additional changes to the 180-day exclusivity period are needed, we reviewed the history of the provision and evaluated what types of strategic behavior remained after 2003. Finally, we considered whether the recent legislative proposals are likely to improve the current framework.

I. THE 180-DAY EXCLUSIVITY FRAMEWORK

Under the Hatch-Waxman Act, brand-name manufacturers were required to

information/search-fda-guidance-documents/guidance-industry-180-day-exclusivity-questions-and-answers.

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

7 *AAM Position Paper on the HHS 180-Day Exclusivity Proposal*, ASS'N FOR ACCESSIBLE MEDS. (Mar. 2018), https://accessiblemeds.org/resources/fact-sheets/aam-position-paper-hhs-180-day-exclusivity-proposal.

8 *House E&C Health Subcommittee Holds Hearing on Reducing Barriers to Market Competition for Prescription Drugs*, ERNST & YOUNG: TAX NEWS UPDATE (Mar. 13, 2019), https://taxnews.ey.com/news/2019-0671-house-e-and-ampc-health-subcommittee-holds-hearing-on-reducing-barriers-to-market-competition-for-prescription-drugs.

list with the FDA information about key patents claiming their drugs. Generic manufacturers later seeking FDA approval of copies of brand-name drugs were required to make one of four certifications with respect to these patents: (1) that no patents covering the drug had been listed by the FDA (Paragraph I certification); (2) that any listed patents had expired (Paragraph II certification); (3) that the drug would not be marketed until the patents expired (Paragraph III certification); or (4) that listed patents were invalid or would not be infringed by the generic product (Paragraph IV certification). A Paragraph IV challenge was deemed an artificial act of infringement, which allowed brand-name manufacturers to initiate litigation over the validity and scope of the patents years earlier than under traditional patent law rules. The Act provided that the generic drug could not be approved until that litigation ended or thirty months elapsed from when the patent holder received notice of the Paragraph IV certification, whichever came first. In facilitating litigation and adjudication of patents protecting a brand-name drug, Paragraph IV challenges served a social utility function: since a Paragraph IV challenge could lead to the invalidation of patents that should not have been granted in the first place or could help demonstrate how to manufacture a bioequivalent generic product without infringing the patents, cheaper generics could be made available to patients sooner. To incentivize Paragraph IV challenges, the Act offered the first generic filer of an application containing a Paragraph IV certification the ability to earn 180 days of generic exclusivity.

The 180-day duopoly could be very lucrative for generic manufacturers. Unlike in many countries around the world, drug manufacturers in the United States are treated like manufacturers of nearly all other products in that they can freely set the prices of their offerings. When the existing patent system (established in 1790) and this traditional free-market pricing philosophy were joined by expanding drug insurance coverage beginning with the federal Medicare and Medicaid programs in the 1960s, U.S. drug prices were free to rise to unprecedented levels, at least until patents expired.[9]

Following patent expiration, drug prices can drop dramatically. Generic manufacturers have much lower research, development, and marketing expenditures than brand-name manufacturers and can sell their products at a profit for a price much closer to the marginal cost of production. For large markets that can attract ten or more generic manufacturers, prices have eventually dropped 79% or more compared to the brand-name price[10] (though

9 Jonathan J. Darrow & Donald W. Light, *Beyond the High Prices of Prescription Drugs: A Framework to Assess Costs, Resource Allocation, and Public Funding*, 40 HEALTH AFFS. 281 (2021).

10 Chintan V. Dave, Abraham Hartzema & Aaron S. Kesselheim, *Prices of Generic Drugs*

most generic drug markets have four or fewer competitors[11]). Even in markets that will eventually attract many competitors, the duopoly facilitated by the 180-day exclusivity period means that the sole generic manufacturer is not pressured by other generics to sell its product for such low prices and may introduce its product at only a 10–15% discount compared to the brand-name product.[12] Generic manufacturers could therefore make substantial profits during the six-month period when prices would be close to the brand-name drug price.

A. Early Problems with 180-Day Exclusivity

With massive revenues sometimes at stake, manufacturers figured out how to strategically deploy the Hatch-Waxman Act process in ways that did not result in a timely court resolution facilitating widespread generic entry. These tactics were motivated by the manufacturers' goal of disincentivizing generic entry and preserving market exclusivity which, in turn, would safeguard profits. In some cases, generic and brand-name drug manufacturers entered into settlement agreements arising from the patent litigation, leaving the patents intact. When these settlements involved an agreement to delay generic entry (and thereby the start of the 180-day exclusivity period) in return for cash payments from the brand-name manufacturer to the alleged generic infringer, they became known as "reverse payment" (or "pay-for-delay") agreements. These agreements caught the attention of the Federal Trade Commission (FTC) for potentially violating antitrust laws.

In a 2002 report, the FTC observed that from 1992 through 2000 there were 82 brand-name drug products associated with a Paragraph IV certification (excluding 22 products for which patent litigation was pending court resolution).[13] Of these, the patent holder did not sue the first filer in 29 instances (35%). Of the remaining 53 brand-name products with resolutions, 14 ended with settlement agreements, including 9 (11% of 82) that involved cash payments of between $1.75 million and $132.5 million by the brand-name manufacturer to the first generic applicant.[14] Although reverse-payment settlements were therefore

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Associated with Numbers of Manufacturers, 377 NEW ENG. J. MED. 2597, 2598 fig.1 (2017).

11 Chintan V. Dave, Aaron S. Kesselheim, Erin R. Fox, Peihua Qiu & Abraham Hartzema, *High Generic Drug Prices and Market Competition: A Retrospective Cohort Study*, 167 ANNALS INTERNAL MED. 145, 146 tbl.1 (2017).

12 *Id.*

13 *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, FED. TRADE COMM'N 15 (July 2002), https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf. A total of 130 brand-name drug products were subject to at least one Paragraph IV certification from 1984 to January 2001, but the FTC study included only the most recent 104 of these. *Id.* at 10.

14 *Id*. at 32 tbl.3-3; *In re Nexium Antitrust Litigation*, PUB. CITIZEN, https://www.citizen.org//re-nexium-antitrust-litigation (discussing *In re* Nexium Antitrust Litig.,

small in number compared to the 8,019 generic drug applications filed between 1984 and 2000,[15] the incentive to enter into such settlements would be greatest in markets with the largest profit potential, and could thus exert a significant impact on public expenditures.

Brand-name manufacturers used other tactics to undermine the 180-day exclusivity incentive. For example, brand-name manufacturers could sell their already-approved product in the form of an "authorized generic." Although the authorized generics are exactly the same drug products as those packaged and sold under the corresponding brand name, they simulate a three-manufacturer oligopoly that increases price competition and thereby reduces the value of the 180-day exclusivity to the first generic entrant. Another tactic involved brand-name manufacturers listing with the FDA new patents covering their drugs that were issued after the filing of the generic drug application, which in turn meant that the first-filer had to provide a new Paragraph IV certification as to those patents. Because the FDA considered each Paragraph IV certification to trigger a 30-month stay during which time no other generics could be approved, brand-name manufacturers could obtain additional exclusivity when such patents were issued.[16] Yet another brand-name manufacturer strategy involved delisting patents that were the subject of Paragraph IV challenges if it appeared the patents would be invalidated in court. The FDA initially took the position that the practice of patent delisting canceled the 180-day exclusivity, but the FDA's interpretation was later overturned in court, removing the incentive to delist.[17]

Gaming related to the 180-day exclusivity period also arose on the generic side. For example, in their zeal to win the race to be first-filers, some generic manufacturers submitted their Paragraph IV certifications even before their testing, applications, and manufacturing facilities were ready. With the right to 180-day exclusivity in hand, the generic manufacturer might then take an extended period of time to cure application deficiencies and obtain FDA approval, preventing other generic drug companies from marketing their products in the meantime.[18] For example, in 2002, Ranbaxy submitted its application for generic atorvastatin (Lipitor), a blockbuster treatment for high cholesterol, which

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777 F.3d 9 (1st Cir. 2015)); *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, *supra* note 13, at 31.

15 *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, *supra* note 13, at 10; *ANDA (Generic) Drug Approvals in 2002*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/first-generic-drug-approvals/anda-generic-drug-approvals-previous-years

16 Apotex, Inc. v. Thompson, 347 F.3d 1335, 1340 (Fed. Cir. 2003).

17 Ranbaxy Lab'ys Ltd. v. Leavitt, 469 F.3d 120 (D.C. Cir. 2006).

18 Shashank Upadhye, *There's a Hole in My Bucket Dear Liza, Dear Liza: The 30-Year Anniversary of the Hatch-Waxman Act: Resolved and Unresolved Gaps and Court-Driven Policy Gap Filling*, 40 WM. MITCHELL L. REV. 1307, 1326 (2014).

the FDA did not approve until 2011, following 14 amendments.[19] Another example of delaying the 180-day exclusivity trigger entailed a manufacturer that sought approval of a generic version of carbamazepine (Tegretol), a treatment for seizures.[20] Its Abbreviated New Drug Application (ANDA) had been submitted in 2003 and was amended over 20 times before it was finally approved in 2011.[21]

B. Reforms of the 2003 Medicare Modernization Act

Recognizing that the Hatch-Waxman Act created opportunities for strategic behavior that undermined the goals of the 180-day exclusivity incentive, legislators included corrective provisions in the 2003 Medicare Prescription Drug, Improvement, and Modernization Act (MMA).[22] The MMA included provisions to reduce the problem of brand-name manufacturers listing later-issued patents necessitating additional challenges and leading to multiple 30-month stays. Only one 30-month stay could be obtained per ANDA, regardless of the number of patents listed with the FDA, and these stays would be triggered based only on patents listed at the time of ANDA filing.[23] Legislators addressed patent delisting by providing that delisting would generally not result in canceling the 180-day exclusivity.[24]

The MMA also provided that 180-day exclusivity could be triggered only by commercial launch, rather than by either commercial launch or a final court decision on patent infringement, as was the case under the Hatch-Waxman Act.[25]

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19 Letter from Food & Drug Admin. to Ranbaxy Inc. (2011), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/076477Orig1s000ltr.pdf (regarding ANDA 076477).

20 Nostrum Pharms., LLC v. U.S. FDA, 2011 No. 11-3111 (JAP), 2011 WL 2652147 (D.N.J. July 6, 2011).

21 *Approval Package for: Application Number: ANDA 76-697*, FOOD & DRUG ADMIN. 225 (May 20, 2011), https://www.accessdata.fda.gov/drugsatfda_docs/anda/2011/076697Orig1s000.pdf Using the search tool at *Drugs@FDA: FDA-Approved Drugs*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov////.cfm, one can count the number of amendment dates listed by the FDA for an ANDA; this application shows twenty amendments.

22 Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, Pub. L. No. 108-173, 117 Stat. 2066; Federal Food, Drug, and Cosmetic Act (FFDCA), Pub. L. No. 75-717, § 505(j)(5)(D)(i), 52 Stat. 1040 (1938).

23 21 U.S.C. § 355 (j)(5)(D)(iii) (2018); *see also* 149 Cong. Rec. 31,783 (2003) (statement of Sen. Kennedy) ("The Hatch-Waxman provisions in this bill also make the exclusivity available only with respect to the patent or patents challenged on the first day generic applicants challenge brand drug patents, which makes the exclusivity a product-by-product exclusivity rather than a patent-by-patent exclusivity.").

24 MMA § 1102(a), 117 Stat. at 2457-60. The MMA was not retroactive, and the D.C. Circuit later interpreted the pre-MMA statute in a similar manner. See *supra* note 17 and accompanying text.

25 21 U.S.C. § 355 (j)(5)(B)(iv) (2018) (amended in 2003 by the MMA); FFDCA § 505(j)(5)(B)(iv)(I); *see also* 21 C.F.R. § 314.3(b) (2020) ("Commercial marketing is the

In situations in which a generic firm challenged a secondary patent while waiting for the underlying active ingredient patent to expire, eliminating the court-decision trigger helped to ensure that the 180-day period would not begin to run before the generic manufacturer was lawfully able to enter the market. By providing assurance to generic manufacturers that they would enjoy the entire exclusivity period, the MMA maximized the incentive to bring a Paragraph IV challenge. The change also encouraged earlier challenges of secondary patents.[26]

Even before the MMA, if the FDA concluded that a first generic applicant was not "actively pursuing" FDA approval, the FDA could immediately approve subsequent generic applicants that were otherwise eligible.[27] Strengthening the law to ensure against intentional delays by generic manufacturers (either for their own gain or as part of an agreement with a brand-name manufacturer), the MMA specified six events that would trigger first-filer generics to forfeit their 180-day exclusivity. Forfeiture would occur under the MMA if all patents as to which Paragraph IV certifications were filed had expired, preventing the 180-day period from extending the total exclusivity period beyond that otherwise permitted under the patent laws (Event #1). To prevent delays caused by agreements by which the first-filer refrained from or delayed market entry, forfeiture would occur if the first-filer withdrew its application (Event #2), amended its certification from a Paragraph IV to, for example, a Paragraph III (i.e., indicating it would wait until patent expiration to market its product) (Event #3), or failed to market its drug within 75 days after FDA approval (Event #4).[28] To minimize the delays caused by premature filing of generic drug applications that were not ready for FDA review and approval, or by failure to diligently shepherd applications through approval, the MMA provided that forfeiture would occur if the first-filer failed to obtain FDA approval of its ANDA within 30 months of the

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introduction or delivery for introduction into interstate commerce of a drug product described in an ANDA, outside the control of the ANDA applicant, except that the term does not include transfer of the drug product for investigational use under part 312 of this chapter or transfer of the drug product to parties identified in the ANDA for reasons other than sale. Commercial marketing includes the introduction or delivery for introduction into interstate commerce of the reference listed drug by the ANDA applicant.").

26 *Examining the Senate and House Versions of the "Greater Access to Affordable Pharmaceuticals Act": Hearing before the S. Comm. on the Judiciary*, 108th Cong. 96-97 (2003).

27 *See* Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28872, 28895 (proposed July 10, 1989) (to be codified at 21 C.F.R. pt. 314). This regulation was implemented in 1994. *See* Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. 50338, 50354 (Oct. 3, 1994) (to be codified at 21 C.F.R. pt. 314); 21 C.F.R. § 314.107(c)(3) (2020).

28 Complaint for Declaratory Judgment at 8, Cobalt Pharms. Inc. v. Bayer AG, No. 1:07-cv-05875 (N.D. Ill. Oct. 17, 2007); Kurt R. Karst, *FDA Determines that Cobalt Forfeited 180-Day Exclusivity for Generic PRECOSE; Agency Is Sued Yet Another Time*, FDA L. BLOG (May 11, 2008), https://www.thefdalawblog.com/2008/05/fda-determines/.

filing date (unless caused by a change in FDA approval requirements) (Event #5).[29] Finally, forfeiture would occur if the first-filer entered into an anticompetitive settlement agreement with the patent holder, a provision that directly discouraged such settlements (Event #6).[30]

C. Post-2003 Implementation of 180-Day Exclusivity

After the MMA, Paragraph IV challenges continued to increase in frequency and occur ever sooner after approval of the brand-name product. The share of new drugs experiencing such a challenge increased from 9% of those first facing generic competition in 1995 to 76% in 2014.[31] The number of years from brand-name approval to first Paragraph IV challenge decreased from 18.7 years for drugs experiencing first generic competition in 1995 to 5.9 years in 2014.[32]

The growth of the generic drug industry and the continued popularity of Paragraph IV challenges after 2003 show that the MMA's anti-parking provisions did not undermine the incentive effects of the 180-day exclusivity provision. However, while parking of the 180-day exclusivity period became more difficult after the MMA, some concerns remained. One of these concerns was that, although the MMA provided for forfeiture of 180-day exclusivity in the case of settlement agreements, it did so only if a final FTC or court decision determined the settlement agreement violated antitrust laws. It was unclear, however, when settlements would meet this criterion. In 2013, the U.S. Supreme Court in *FTC v. Actavis* affirmed that settlements were subject to FTC scrutiny and the potential for liability even if the settlement agreement stayed within the exclusionary scope of the patent.[33] While settlements have continued since *Actavis*, few have involved reverse payments that might violate antitrust laws. By 2016, of the 232 Paragraph IV litigation settlements reported to the FTC, only 16 (7%) involved transfers of cash from the brand-name to the generic manufacturer, all of which involved payment only for litigation costs.[34] The FTC

29 FFDCA § 505(j)(5)(D)(i)(IV).

30 MMA § 1102(a)(2), 117 Stat. at 2458-60.

31 Henry Grabowski, Genia Long, Richard Mortimer & Ani Boyo, *Updated Trends in US Brand-Name and Generic Drug Competition*, 19 J. MED. ECON. 836 (2016) [hereinafter Grabowski et al., *Updated Trends*]; Henry G. Grabowski, Margaret Kyle, Richard Mortimer, Genia Long & Noam Kirson, *Evolving Brand-Name and Generic Drug Competition May Warrant a Revision of the Hatch-Waxman Act*, 30 HEALTH AFFS. 2162 (2011).

32 Grabowski et al., *Updated Trends*, *supra* note 31.

33 FTC v. Actavis, Inc., 570 U.S. 136 (2013).

34 *Pharmaceutical Agreement Filings*, FED. TRADE COMM'N, https://www.ftc.gov/advice/guidance/guidance/care/agreement-filings; Brad Albert, Armine Black & Jamie Towey, *MMA Reports: No Tricks or Treats—Just Facts*, FED. TRADE COMM'N: COMPETITION MATTERS (Oct. 27, 2020, 5:15 PM), https://www.ftc.gov/news-events/blogs/competition-matters/2020/10/mma-reports-no-tricks-or-treats-just-facts.

has nevertheless emphasized the need to monitor settlements for less transparent forms of compensation that might constitute illegal reverse payments, such as agreements by which patent holders refrain from selling authorized generics in the United States[35] or that allow generic manufacturers to enter foreign markets before patents in those markets expire.

One other source of delay was observed after the MMA but was both uncommon and not clearly attributable to strategic manufacturer behavior. This type of delay occurs when a first-filer fails to obtain FDA approval within thirty months due to a change in FDA-approval requirements rather than the fault of the applicant,[36] in which case forfeiture of 180-day exclusivity will not result.[37] Between 2007 and 2012, changes to FDA review standards were estimated to have led to delays in approximately 20 cases among the more than 3,500 generic drug applications approved in those years (0.006%).[38] For example, a generic version of clobetasol propionate shampoo (Clobex) used to treat eczema and psoriasis was submitted in 2007 but was not approved until 2011,[39] thereby not triggering its 180-day exclusivity for more than fifty months due to changes by the FDA in standards related to vasoconstrictor bioassays that the generic manufacturer needed to conduct to demonstrate bioequivalence and receive FDA approval.[40] A generic version of levocetirizine (Xyzal) allergy tablets retained 180-day exclusivity after a delay of five months beyond the thirty-month limit due to a change in the indication of the brand-name drug from children of "6 months to 5 years of age" to "children 2 years of age and older," among other labeling changes.[41] Specifically, during its bioequivalence review, the agency asked the drug sponsor, Actavis, to perform comparative vasoconstrictor bioassay studies; the agency later told Actavis the agency was reviewing the appropriateness of vasoconstrictor bioassay studies for topical corticosteroid drug products that are applied to the hirsute scalp, which caused the five-month delay.

35 Albert et al., *supra* note 34.

36 FFDCA § 505(j)(5)(D)(i)(IV).

37 *Id.*

38 Kurt R. Karst, *Excuses, Excuses! A Round-Up of Exceptions Under the Failure to Obtain Timely Tentative Approval 180-Day Exclusivity Forfeiture Provision*, FDA L. BLOG (Nov. 1, 2012), http://www.fdalawblog.net//11/excuses-a-round-up-of-exceptions-under-the-failure-to-obtain-timely-tentative-approval-180-d.

39 Letter from Food & Drug Admin. to Actavis Mid Atlantic LLC (2011), https://www.accessdata.fda.gov/_docs///ltr.pdf (regarding ANDA 078854). The shampoo contains vasoconstrictive properties in its chemical structure. *Id.* at 2.

40 *Id.*

41 Letter from Food & Drug Admin. to Synthon Pharms., Inc. (2010), https://www.accessdata.fda.gov/_docs///ltr.pdf (regarding ANDA 090229); *Highlights of Prescribing Information: Xyzal*, FOOD & DRUG ADMIN. (2009), https://www.accessdata.fda.gov/_docs///,022157s003lbl.pdf.

II. THE PROSPECT OF ADDITIONAL 180-DAY EXCLUSIVITY REFORM

In 2019, three legislative proposals were introduced in Congress to address remaining opportunities for parking: the BLOCKING Act, the Expanding Access to Lower Cost Generic Drugs Act, and the Lower Health Care Costs Act.[42] The BLOCKING Act[43] would have allowed later-filed generic applications to be approved if over 30 months passed since submission of the first-filer's application,[44] even if the first-filer's lack of marketing within 30 months was caused by changes to FDA review standards. But because it can be difficult to predict when or how review standards will change, the BLOCKING Act may disincentivize bringing patent challenges by placing the risk on the first-filer that changes to the regulatory review process—which are generally beyond its control—will delay an application's approval.[45]

The BLOCKING Act thus seeks to address a parking problem that has arisen in an extremely small fraction of generic drug approvals and that may not be the fault of generic drug applicants, at the potential cost of reducing incentives intended to motivate all generic manufacturers to engage in the Paragraph IV certification process in the first place. If reintroduced, the BLOCKING Act could be amended to allow first-filers to justify delays, but this would increase administrative costs and fail to completely eliminate uncertainty. Alternatively, a second, longer time limit (e.g., 40 months) could be added to the bill to apply when review standards change. Yet, this too would increase complexity without eliminating the uncertainty that could chill generic manufacturer incentives for bringing Paragraph IV challenges were the BLOCKING Act to pass.[46] Despite the potential to dampen first-filer enthusiasm, the BLOCKING Act received a Congressional Budget Office score report in 2019 estimating that the bill would save an average of $44.2 million per year on federal drug spending over the next ten years.[47] By comparison, the U.S. prescription drug market is nearly $500

42 Blocking Act of 2019, H.R. 938, 116th Cong. (2019); Expanding Access to Lower-cost Generics Act of 2019, S.3092, 116th Cong. (2019); Lower Health Care Costs Act of 2019, S.1895, 116th Cong. (2019).

43 Michael A. Carrier, Opinion, *Solving the 'Parking' Problem in the Drug Monopoly Game*, HILL (Dec. 27, 2019, 9:30 AM EST), https://thehill.com///solving-the-parking-problem-in-the-drug-monopoly-game.

44 This assumes the ANDA contains deficiencies if still not approved after 30 months.

45 Scott Gottlieb, *The HELP Committee's Fix for 180-Day Generic Marketing Exclusivity: Does It Solve the Problem?*, HEALTH AFFS. BLOG (May 30, 2019), https://www.healthaffairs.org/do/10.1377/hblog20190529.223594/full/.

46 Kurt R. Karst, *The BLOCKING Act: "Oh You Know, Strikes and Gutters, Ups and Downs,"* FDA L. BLOG (June 3, 2019), https://www.thefdalawblog.com/2019/06/the-blocking-act-oh-you-know-strikes-and-gutters-ups-and-downs/ (proposing a 42-month alternative period to apply when review standards change).

47 *H.R. 938: BLOCKING Act of 2019*, SPENDING TRACKER, https://spendingtracker.org

billion per year, with generic drugs accounting for about 20% of that spending. Although a Congressional Budget Office score showing even small amounts of savings can impact a bill's chance of enactment, the estimate of the BLOCKING Act's economic impact may not accurately account for the extent to which first-filers will experience reduced incentives to submit applications.[48]

A second bill, the Expanding Access to Lower Cost Generic Drugs Act, is intended to address two parking-related problems. "First applicants" are defined more broadly than under current law to include later applicants filing Paragraph IV certifications for each of the patents addressed by a previous Paragraph IV certification of an earlier applicant. The bill would cause first applicants to lose their first-filer status if they enter into "disqualifying agreements," defined as those in which a generic applicant agrees with the manufacturer of the brand-name reference product to delay marketing until after the expiration of the 180-day exclusivity period of another applicant. This section of the bill is intended to combat reverse payment settlement agreements, although such agreements are both increasingly rare and already subject to challenge under antitrust laws. The bill also seeks to reduce parking by allowing subsequent filers that challenge patents through a Paragraph IV certification to share the 180-day exclusivity period with first-filers.[49] The threat of having to share the exclusivity could potentially motivate first-filers to trigger the exclusivity as early as possible to avoid overlap with the commercial time frame of a subsequent filer reaching FDA approval and resolving litigation. This would increase the number of competitors during the 180-day window if subsequent filers are able to quickly resolve litigation, but it is unclear how frequently this occurs, and invalidation of previously-challenged patents by subsequent filers is believed to be rare.[50] As with the proposed BLOCKING Act, the bill could lead to reduced incentives to challenge patents, since the potential to share exclusivity would increase uncertainty and, when it occurs, reduce the profits of the first generic manufacturer.

A third bill, the Lower Health Care Costs Act would allow the FDA to approve a subsequent generic application if a first-filer did not receive final approval of its ANDA within 33 months of submitting its application. This grants

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/bills/hr938-116.

48 EZEKIEL J. EMANUEL, REINVENTING AMERICAN HEALTH CARE: HOW THE AFFORDABLE CARE ACT WILL IMPROVE OUR TERRIBLY COMPLEX, BLATANTLY UNJUST, OUTRAGEOUSLY EXPENSIVE, GROSSLY INEFFICIENT, ERROR PRONE SYSTEM 75 (2014).

49 Expanding Access to Low Cost Generic Drugs Act, S. 2476, 115th Cong. (2018).

50 Kurt R. Karst, *Reshaping 180-Day Exclusivity: The FAIR Generics Act Returns as the Expanding Access to Low Cost Generic Drugs Act*, FDA L. BLOG (MAR. 5, 2018), https://www.thefdalawblog.com/2018/03/reshaping-180-day-exclusivity-the-fair-generics-act-returns-as-the-expanding-access-to-low-cost-generic-drugs-act/.

three additional months for the first-filer to seek FDA approval in comparison with the time period offered by the BLOCKING Act (i.e., 30 months). Such a provision may be intended to motivate first-filers not to delay seeking FDA approval by setting a firm deadline on when its ability to claim first-filer exclusivity benefits expires.[51] Notably, current law already provides that first-filers forfeit their 180-day exclusivity if no tentative approval is obtained within 30 months of submitting the application.[52] The provision appears to be directed toward those cases in which FDA-approval requirements are changed and the 30-month forfeiture provision does not apply, but such cases are infrequent and occur largely outside the control of the applicant. Thus, this bill, like the other two, offered the possible benefit of fostering competitive markets in a very small number of cases, along with the very real risk of further destabilizing the existing 180-day exclusivity system. None of the bills were taken up by Congress.

CONCLUSION

The 180-day generic exclusivity period was established in the Hatch-Waxman Act to provide an incentive for generic manufacturers to invest the time and resources needed to challenge brand-name manufacturers' drug patents without risk that other manufacturers would immediately free-ride on their investments in patent litigation. Unforeseen loopholes in the 1984 legislation created the opportunity for strategic behavior by manufacturers intending to delay generic competition, which Congress addressed in the 2003 MMA, including the addition of a provision for forfeiture of 180-day exclusivity in the case of anticompetitive settlement agreements. In the 2013 *Actavis* decision, the Supreme Court clarified that a broad range of reverse payments could potentially violate antitrust laws, expanding the impact of the MMA. However, concerns about misuse of the 180-day incentive remained, leading to proposals to further reform the law.

Our review of available data suggests that remaining parking issues occur infrequently and, when they do occur, tend to relate to changes in FDA review standards over which generic manufacturers have little or no control. Recently proposed changes to the Hatch-Waxman Act's statutory framework are therefore unlikely to substantially improve generic availability. In addition, such changes risk upsetting existing incentives for generic manufacturers to bring Paragraph IV challenges in the first place by increasing uncertainty with respect to the ability to obtain or retain exclusivity and the extent to which the exclusivity period will be shared. In cases in which exclusivity is in fact shared, profits of first-filers will be reduced.

51 Lower Health Care Costs Act, S. 1895, 116th Cong. § 205 (2019).

52 149 Cong. Rec. 32,290-93 (2003) (statement of Sen. Hatch); 21 U.S.C. § 355(j)(5)(iv).

It is possible that strategic behavior has become less transparent, rather than less frequent, and further research may uncover more examples of gaming the 180-day exclusivity incentive. Until additional evidence of the frequency, length, and financial impact of strategic behavior emerges, Congress should refrain from revising a system that has helped increase the share of generic drugs from 19% in 1984 to 90% in 2020, and that has led to generic drug prices in the United States that are generally among the lowest in the world. As revisions to the law are considered, legislators must recognize that any changes could inadvertently undo gains, as well as close loopholes. Legislators should avoid statutory amendments that undermine existing incentives to file generic applications containing Paragraph IV certifications.

Pharmaceutical (Re)Capture

Liza Vertinsky*

Abstract:

This Article makes the case that pharmaceutical companies, along with other powerful corporate actors in the pharmaceutical industry, are in effect designing their own markets, often at the expense of, rather than in pursuit of, public health. The influence exerted by these corporate actors extends beyond traditional forms of regulatory capture, rising to what this Article refers to as pharmaceutical capture—a concept that encompasses the exercise of holistic and systemic control over the operation of pharmaceutical markets and their regulation.

After developing a framework for thinking about pharmaceutical capture, this Article uses the evolution of the opioid epidemic as a case study of capture at work. It argues that the patterns of corporate influence highlighted in the case study are not unique to opioids, but rather are structural features of U.S. pharmaceutical markets.

A popular political response to concerns about the power exerted by corporate actors in the pharmaceutical industry has been to pin the blame on government regulation as impeding the discipline of the "free market." But pharmaceutical markets rely on government regulations to function, and this push for deregulation is in many cases simply an effort to substitute one governance structure for another more favorable to incumbent corporate interests. This Article concludes that it is not deregulation, but rather a redesign of regulation, that is needed to improve the public health impact of the pharmaceutical industry. Drawing lessons from pharmaceutical capture, it suggests guidelines for a regulatory recapture.

* Associate Professor, Emory Law School. The author would like to thank Jamie Siegel, Yaniv Heled, Ana Rutschman Santos, Reuben Guttman, Thomas Kadri, and participants in IPSC 2020 for valuable comments.

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INTRODUCTION

The United States is unique in its reliance on a market-based, "consumer"-driven approach to the delivery of health care—an approach that has continued to yield among the highest profits, the highest spending, and the poorest health outcomes of all high-income countries.[1] The United States is the only industrialized country without universal health coverage,[2] and one of the few industrialized countries without some kind of single-payer system, relying instead on a fragmented and incomplete mix of public and private insurance.[3] Despite its limited coverage, the United States spends two or three times more the amount per capita on health care than most other industrialized countries, much of this paid by federal, state, and local governments.[4] This high spending level correlates with high levels of profit. Biotech, generic, and major pharmaceutical companies rank among the top ten most profitable industries in the United States, competing with and even beating many industries within the financial sector, with profit margins in the 24% to 30% range.[5] Profits have also boomed for the largest U.S. health

1 *See, e.g.*, Roosa Tikkanen & Melinda K. Abrams, *U.S. Health Care from a Global Perspective, 2019: Higher Spending, Worse Outcomes?*, COMMONWEALTH FUND (Jan. 30, 2020), https://www.commonwealthfund.org/publications/issue-briefs/2020/jan/us-health-care-global-perspective-2019 (showing that the United States continues to spend more on health care as a share of the economy—nearly double that of the average OECD country—and perform worse on health care outcomes as compared to other developed economies); *see also* Amanda Holpuch, *Profits Over People, Costs Over Care: America's Broken Healthcare Exposed by a Virus*, THE GUARDIAN (Apr. 16, 2020, 2:00 AM EDT), https://www.theguardian.com/us-news/2020/apr/16/profit-over-people-cost-over-care-americas-broken-healthcare-exposed-by-virus ("In the wealthiest country in the world, the Covid-19 pandemic has exposed the core of a healthcare system that is structurally incapable of dealing with the pandemic. . . . The pandemic crisis is being further exacerbated by the system's devotion to profits over people."). For an in-depth analysis of industry involvement in the U.S. health care system see, for example, ELISABETH ROSENTHAL, AN AMERICAN SICKNESS (2017) (exploring the myriad ways in which health care has been transformed into a business focused largely on profits, and how this focus has in turn transformed U.S. health care).

2 *See, e.g.*, Analisa Merelli, *The Story of Why the U.S. Is the Only Rich Country Without Universal Healthcar*e, QUARTZ (July 18, 2017), https://qz.com/1022831/why-doesnt-the-united-states-have-universal-health-care.

3 *See, e.g.*, Luca Lorenzoni, Annalisa Belloni & Franco Sassi, *Health-Care Expenditure and Health Policy in the USA Versus Other High-Spending OECD Countries*, 384 LANCET 83 (2014), https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(14)60571-7/fulltext; Alicia Adamczyk, *What Is Single-Payer Healthcare and Why is it So Popular?*, MONEY (Apr. 13, 2017), https://money.com/what-is-single-payer-healthcare-system (stating that the United States is one of the only countries in the developed world without a single-payer health care system); *see also* Elisabeth Rosenthal, *How an Industry Shifted from Protecting Patients to Seeking Profits,* STAN. MED. (2017), https://stanmed.stanford.edu/2017spring/how-health-insurance-changed-from-protecting-patients-to-seeking-profit.html (looking at the role that for-profit health insurance has played in shifting the focus from patients to profits).

4 *See, e.g.*, Merelli, *supra* note 2.

5 *See* Liyan Chen, *The Most Profitable Industries in 2016*, FORBES (Dec. 21, 2015, 4:19 PM EST) https://www.forbes.com/sites/liyanchen/2015/12/21/the-most-profitable-industries-in-2016.

insurance companies, with the top five earning $4.5 billion dollars in net earnings in the first three months of 2017.[6] Pharmaceutical company executives rank among the most highly compensated of any industry.[7]

While this high spending on health care has generated large profits, and may well have contributed to comparatively high rates of biomedical innovation, it has not produced better health outcomes.[8] According to United Nations measures, the United States ranks 28th out of 188 countries in terms of health care outcomes.[9] The Commonwealth Fund has ranked the U.S. health care system at the bottom of the eleven developed nations it analyzes.[10] The U.S. system fares particularly poorly in measures of population health such as infant mortality, life expectancy, and mortality amenable to health care.[11] When compared to people in other advanced economies, Americans have the lowest average life expectancy and are more likely to die from preventable diseases or complications.[12] Overall, as these

6 *See* Bob Herman, *Profits Are Booming at Health Insurance Companies*, AXIOS (May 24, 2017), https://www.axios.com/profits-are-booming-at-health-insurance-companies-1513302495-18f3710a-c0b4-4ce3-8b7f-894a755e6679.html; *The Profitability of Health Insurance Companies*, COUNCIL ECON. ADVISORS (Mar. 2018), https://trumpwhitehouse.archives.gov/wp-content/uploads/2018/03/The-Profitability-of-Health-Insurance-Companies.pdf.

7 *See, e.g.*, Eric Sagonowsky, *The Top 15 Highest-Paid Biopharma CEOs of 2019*, FIERCEPHARMA (June 1, 2020, 3:00 AM), https://www.fiercepharma.com/special-report/top-15-highest-paid-biopharma-ceos-2019; Elizabeth Whitman, *Healthcare and Pharma CEOs Paid More Than Top Execs in Any Other Industry, Analysis Finds*, INT'L BUS. TIMES, (May 25, 2016, 12:15 PM), https://www.ibtimes.com/healthcare-pharma-ceos-paid-more-top-execs-any-other-industry-analysis-finds-2374013.

8 *See, e.g.*, Irene Papanicolas, Liana R. Woskie & Ashish K. Jha, *Healthcare Spending in the United States and Other High-Income Countries*, 319 JAMA 1024, 1025 (2018) ("In 2016, the United States spent nearly twice as much as 10 high-income countries on medical care and performed less well on many population health outcomes."); David Squires & Chloe Anderson, *U.S. Health Care from a Global Perspective: Spending, Prices, and Health in 13 Countries*, COMMONWEALTH FUND (Oct. 8, 2015), http://www.commonwealthfund.org/publications/issue-briefs/2015/oct/us-health-care-from-a-global-perspective (arguing that higher spending is largely driven by greater use of medical technology and higher health care prices, and that despite spending more, the system covers fewer residents and produces relatively poor health outcomes).

9 *See* GBD 2015 SDG Collaborators, *Measuring the Health-Related Sustainable Development Goals in 188 Countries: A Baseline Analysis from the Global Burden of Disease Study 2015*, 388 LANCET 1813, 1838 (Sept. 21, 2016), https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(16)31467-2.pdf.

10 *See* Eric C. Schneider et al., *Mirror, Mirror 2017: International Comparison Reflects Flaws and Opportunities for Better U.S. Health Care*, COMMONWEALTH FUND (2017), https://interactives.commonwealthfund.org/2017/july/mirror-mirror (identifying performance shortcomings in access, administrative efficiency, and equity and health care outcomes, and suggesting poor performance is attributable in particular to lack of universal coverage and barriers to accessing primary care).

11 *See, e.g.*, Olga Khazan, *What's Actually Wrong with the U.S. Health System*, ATLANTIC (July 14, 2017), https://www.theatlantic.com/health/archive/2017/07/us-worst-health-care-commonwealth-2017-report/533634.

12 *See* Melissa Etehad & Kyle Kim, *The U.S. Spends More on Healthcare than Any Other*

metrics suggest, U.S. health care markets seem to have done a much better job of generating profits than improving health outcomes.

The persistence of the country's unique market-based approach to health care, even in the face of clear evidence that it yields comparatively poor health outcomes, reflects a seemingly unshakeable belief in the efficiency of markets.[13] While competitive markets generally work well, albeit not perfectly, as mechanisms for satisfying some types of consumer needs, the American approach over recent decades has been to extend the reach of markets indiscriminately to ever-increasing domains of human activity.[14] Even imperfectly competitive markets, of which there are many, are thought to work better than the alternatives for satisfying our daily needs and wants. Even in the midst of a pandemic.[15] This expansion of market-driven activity has been accompanied by subtle, and not so subtle, limitations on mechanisms of government oversight.[16] The intertwining of market forces with all aspects of life and all aspects of government decision-making has expanded the range and scope of market pressures on lawmakers and the lawmaking process in ways that, ironically, often undermine the economic health and competitiveness of these same markets. These pressures are of particular concern in those markets that depend most heavily on regulation in order to function.

The pharmaceutical industry is one of the most highly regulated industries, with government interventions playing critical roles at every stage of pharmaceutical development and distribution.[17] It is also, not surprisingly, an

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Country—But Not with Better Health Outcomes, L.A. TIMES (July 18, 2017, 4:25 PM PT), http://www.latimes.com/nation/la-na-healthcare-comparison-20170715-htmlstory.html.

13 *See, e.g.*, *Regulation and the Economy, The Relationship and How to Work to Improve It*, COMM. FOR ECON. DEV. CONF. BD. (Sept. 27, 2017), https://www.ced.org/reports/regulation-and-the-economy; *see also* Alexander Zaitchik, *How Big Pharma Was Captured by the One Percent*, NEW REPUBLIC (June 26, 2018), https://newrepublic.com/article/149438/big-pharma-captured-one-percent ("That narrative, that America's drug economy represents a complicated but beneficent market system at work, is so ingrained it is usually stated as a fact, even in the media.")

14 *See, e.g.*, ROBERT KUTTNER, EVERYTHING FOR SALE: THE VIRTUES AND LIMITS OF MARKETS (1996) (discussing the expansion of market ideology in U.S. political thinking and the emphasis on market solutions for social and economic problems).

15 *See, e.g.*, Yaniv Heled, Ana Santos Rutschman & Liza Vertinsky, *The Problem with Relying on Profit-Driven Models to Produce Pandemic Drugs*, 7 J. L. & BIOSCIENCES 1 (2020).

16 *See, e.g.*, COUNCIL ECON. ADVISORS, THE ECONOMIC EFFECTS OF DEREGULATION SINCE JANUARY 2017: AN INTERIM REPORT (2019) (examining the deregulatory approach of the Trump Administration); Dominique Tobbell, *Understanding Pharmaceutical Relations and the Limits of Regulatory Reform,* SCI. HIST. INST. (Apr. 2, 2009), https://www.sciencehistory.org/distillations/understanding-pharmaceutical-relations-and-the-limits-of-regulatory-reform.

17 *See, e.g.*, Aaron S. Kesselheim et al., *Pharmaceutical Policy in the United States in 2019: An Overview of the Landscape and Avenues for Improvement*, 30 STAN. L. & POL'Y REV. 421 (2019); *see also Competition and Regulation Issues in the Pharmaceutical Industry*, OECD (Feb. 6, 2001), https://www.oecd.org/competition/sectors/1920540.pdf (documenting extensive regulation across the product life cycle for pharmaceuticals; also documenting concentration and profitability in the

industry in which the largest companies exercise significant influence over the regulatory process.[18] But the extent of pharmaceutical influence is not limited to overly friendly relationships with regulators or isolated instances of excessive influence over the design and enforcement of regulations; it extends to every aspect of the pharmaceutical marketplace. The largest corporate actors in the industry have adopted a holistic, systemic approach towards shaping the design of pharmaceutical markets and their regulation.[19] The magnitude and scope of the influence exerted by the largest corporate actors in the pharmaceutical industry over all commercially important aspects of pharmaceutical markets and their regulation, and the success of this influence in changing the incentives and decision-making of key public and private stakeholders in the industry in ways that facilitate desired corporate objectives, amounts to what this Article defines as "pharmaceutical capture."[20]

This Article uses this concept of pharmaceutical capture to inform policy debates over how best to improve the public health impact of the pharmaceutical industry.[21] Pharmaceutical companies, along with other large and sophisticated

pharmaceutical industry).

18 *See, e.g.*, Kesselheim et al., *supra* note 17 (discussing aspects of the regulatory structure that significantly limit competition and the industry actions that seek to further limit it); *see also* Nicholas Florko & Lev Facher, *How Pharma, Under Attack from All Sides, Keeps Winning in Washington*, STAT (July 16, 2009), https://www.statnews.com/2019/07/16/pharma-still-winning (describing the power and influence of the pharmaceutical lobby in avoiding regulations that would increase competition).

19 While this Article limits its focus to the pharmaceutical industry, this level of holistic, systemic capture may well exist in other industries, both within and outside of health care. A good example is the financial industry. *See, e.g.*, Lawrence G. Baxter, *"Capture" in Financial Regulation: Can We Channel It Toward the Common Good?*, 21 CORNELL J. L. & PUB. POL'Y 175 (2011) (discussing the concept of deep capture as it applies to the financial industry).

20 *See, e.g.*, Julie Margetta Morgan & Devin Duffy, *The Cost of Capture: How the Pharmaceutical Industry Has Corrupted Policymakers and Harmed Patients*, ROOSEVELT INST. (May 2019), https://rooseveltinstitute.org/wp-content/uploads/2020/07/RI_Pharma_Cost-of-Capture_brief_201905.pdf (exploring the range of ways in which pharmaceutical companies influence policymakers). In addition to the literature on regulatory capture, this notion of pharmaceutical capture builds on concepts of institutional corruption in the pharmaceutical industry as discussed by scholars such as Lawrence Lessig, Jonathan J. Darrow, and others. *See, e.g.*, Lawrence Lessig, Foreword, *"Institutional Corruption" Defined*, 41 J. L. MED. & ETHICS 553 (2013); Donald W. Light, Joel Lexchin & Jonathan J. Darrow, *Institutional Corruption of Pharmaceuticals and the Myth of Safe and Effective Drugs*, 41 J. L. MED. & ETHICS 590 (2013).

21 *See supra* note 20 and accompanying text. It also reflects recent scholarship critiquing existing concepts of regulatory capture and delving more deeply into the nature and reasons for regulatory failure. *See generally* PREVENTING REGULATORY CAPTURE: SPECIAL INTEREST INFLUENCE AND HOW TO LIMIT IT (Daniel Carpenter & David A. Moss eds., Cambridge Univ. Press 2014) [hereinafter PREVENTING REGULATORY CAPTURE] (reorienting discussions of regulatory capture and providing a rigorous definition of and approach to investigating different forms of regulatory capture); Michael E. Levine & Jennifer L. Forrence, *Regulatory Capture, Public Interest, and the Public Agenda: Toward a Synthesis*, 6 J. L. ECON. & ORG. 167 (1990) (exploring the limits of both

corporate actors in the industry such as, but not limited to, distributors, retailers, intermediaries such as pharmacy benefit managers, and insurers, exercise significant control over the construction, operation, and regulation of pharmaceutical markets from start to finish of the pharmaceutical product life cycle. The often hidden role of business interests in industry design extends to every level of government, ranging from local regulations[22] to international pressures on guidelines prepared by the World Health Organization.[23] It extends from the inception of an idea to post-sale product liability, encompassing the research that shapes our understandings of health and disease in the first place and our understanding of product risks and benefits after the fact.[24] There is even an industry role in shaping the way that we think about regulation and deregulation,[25] with significant industry effort targeted at controlling health and drug policy narratives—as illustrated by recent private sector efforts to make "innovation" synonymous with an expansion of private sector incentives and a limitation of government rights over even publicly funded technology.[26] But industry influence

regulatory capture and public interest theories).

22 *See, e.g.*, Jayne O'Donell, *Family Matters: EpiPens Had High-Level Help Getting Into Schools*, USA TODAY (Sept. 20, 2016, 12:46 PM ET), https://www.usatoday.com/story/news/politics/2016/09/20/family-matters-epipens-had-help-getting-schools-manchin-bresch/90435218 (explaining how the head of the National Association of State Boards of Education, who was also the mother of Mylan's CEO, played a significant role in encouraging states to require school boards to purchase Epi-Pens, paving the way for Mylan to develop a near monopoly in school nurses' offices, supported by state legislation and federal legislation known as the "EpiPen Law.").

23 *See, e.g.*, Chris McGreal, *Purdue Pharma Accused of 'Corrupting' WHO to Boost Global Opioid Sales*, GUARDIAN (May 22, 2019, 1:09 PM EDT), https://www.theguardian.com/us-news/2019/may/22/purdue-pharma-opioid-world-health-organization-painkiller-global-sales (discussing pharmaceutical company influence over World Health Organization guidelines to relax prescription standards for opioids).

24 *See, e.g.*, Elizabeth A. Kitsis, *The Pharmaceutical Industry's Role in Defining Illness*, 13 VIRTUAL MENTOR 906 (2011).

25 *See, e.g.*, Edward Nik-Khah, *Neoliberal Pharmaceutical Science and the Chicago School of Economics*, 44 SOC. STUD. SCI. 489 (2014) (exploring the role of the pharmaceutical industry in supporting institutions influential in policy debates about deregulation).

26 This control over the narrative can be seen in the NIST Special Publication 1234: Return on Investment Initiative to Advance the President's Management Agenda, Final Green Paper, which has led to proposed rule changes that would narrow the scope of government rights over publicly funded inventions and related technology. *See* Nat'l Inst. of Standards & Tech., *NIST Special Publication 1234: Return on Investment Initiative to Advance the President's Management Agenda, Final Green Paper*, U.S. DEP'T COM. (April 2019), https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.1234.pdf [hereinafter *NIST Green Paper*]; *see, e.g.*, Law Professors, Comment Letter on NIST Proposed Rule on Rights to Federally Funded Inventions and Licensing of Government Owned Inventions, 86 FR 35 at https://www.regulations.gov/comment/NIST-2021-0001-13026. For a broader discussion about notions of capture that encompass the narratives dominating policy debates, see, for example, Baxter, *supra* note 19 (discussing cultural and social dimensions of capture, including control over the "entire language of the policy debate" in the context of regulating the financial industry).

on its own is not enough to constitute pharmaceutical capture. Pharmaceutical capture occurs only when the magnitude and scope of corporate influence is significant enough to alter the incentive structures, and corresponding decisions, of a sufficient number of industry stakeholders (whether it be consumption choices, prescription choices, rulemaking, enforcement decisions, or other relevant decisions and actions) in ways that ensure that relevant markets yield the outcomes desired by the industry captors. The result of pharmaceutical capture is a pharmaceutical industry that generates excessive profits, often at the expense of health outcomes. The subsequent concentration of large profits in the hands of a small group of large health care companies, including among them the largest pharmaceutical companies, further increases the ability of these companies to influence regulatory design, deepening the capture.[27]

After developing the concept of pharmaceutical capture, this Article develops a case study of opioids to illustrate how pharmaceutical capture works in practice. This case study provides a detailed account of how some of the largest companies in the pharmaceutical industry exercise control over the construction and regulation of the health care markets they profit from.[28] The opioid epidemic has its roots in the over-production, over-prescription, and abuse of prescription opioids. These are drugs that have been developed through the direct and indirect use of publicly funded research, benefited from government grants of patent protection and other regulatory exclusivities, subject to government approval and oversight, prescribed by state-licensed physicians, monitored by federal agencies, and paid for by public programs and highly regulated private insurers. The evolution of the opioid epidemic reveals the pervasive influence that opioid manufacturers and distributors exerted—and continue to exert—over the design of this regulatory system and the underlying market structure to ensure profits at the expense of public health.

Although the opioid epidemic is among the most dramatic examples of

27 *See, e.g.*, Barak Richman et al., *Pharmaceutical M&A Activity: Effects on Prices, Innovation, and Competition*, 48 LOY. U. CHI. L.J. 787 (2017) (exploring consequences of unprecedented market concentration in pharmaceutical industry); *see also* Daniel Carpenter & David A. Moss, *Introduction* to PREVENTING REGULATORY CAPTURE, *supra* note 21, at 1, 11 (developing a definition of capture that distinguishes between weak and strong forms of capture).

28 For a thoughtful analysis of the political, legal and social context that contributed to the opioid epidemic and the need for systemic change as a policy response see, for example, Mariano-Florentino Cuéllar & Keith Humphreys, *The Political Economy of the Opioid Epidemic*, 38 YALE L. & POL'Y REV. 1 (2019) ("[I]nstitutional realities as well as political and economic pressures operate against the backdrop of various legal domains that can enable or exacerbate a public health crisis. Without taking those realities seriously, narrow interventions focused on a single area of law or isolated technical changes in treatment may prove largely ineffective."). For a discussion of how the design of innovation institutions contributed to the opioid epidemic, see, for example, Daniel J. Hemel & Lisa Larrimore Ouellette, *Innovation Institutions and the Opioid Crisis*, J. L. & BIOSCIENCES 1 (2020).

pharmaceutical capture, the problems it exposes are by no means unique to opioids,[29] nor are they unique to public health emergencies.[30] While the structural problems that capture creates are often most visible in emergency contexts, the influence that companies with financial interests in pharmaceutical sales exert over markets relevant to their profitability, and the resulting growth of profits at the expense of public health, is endemic in pharmaceutical markets.[31] Numerous lawsuits arising from particularly egregious misconduct have exposed myriad examples, large and small, in which pharmaceutical companies, along with other corporate actors in health care markets, exercise control over the structure and operation of their relevant markets to grow demand, control price, and extract

29 *See, e.g.*, Katy Milani & Devin Duffy, *Profit over Patients: How the Rules of Our Economy Encourage the Pharmaceutical Industry's Extractive Behavior*, ROOSEVELT INST., (Feb. 2019), https://rooseveltinstitute.org/wp-content/uploads/2020/07/RI_Profit-Over-Patients_brief_201902.pdf (discussing how the structure of pharmaceutical markets leads companies to prioritize profits at the expense of patient health).

30 *See, e.g.*, Stephen Buryani, *How Profit Makes the Fight for a Coronavirus Vaccine Harder*, GUARDIAN (Mar. 4, 2020, 7:29 AM EST), https://www.theguardian.com/commentisfree/2020/mar/04/market-coronavirus-vaccine-us-health-virus-pharmaceutical-business ("The current setup is often the worst of both worlds—too slow to pick up research on new threats because the money isn't there, and too quick to drop it if it can't be sure the money will be there in the future. It's a highly market-dependent system, and the market usually fails us."); Sarah Karlin-Smith, *How the Drug Industry Got Its Way on the Coronavirus*, POLITICO (Mar. 5, 2020, 5:28 PM EST), https://www.politico.com/news/2020/03/05/coronavirus-drug-industry-prices-122412 ("Industry lobbyists successfully blocked attempts this week to include language in the $8.3 billion emergency coronavirus spending bill that would have threatened intellectual property rights for any vaccines and treatments the government decides are priced unfairly."); Sharon Lerner, *Big Pharma Prepares to Profit from the Coronavirus*, INTERCEPT (Mar. 13, 2020, 11:46 AM), https://theintercept.com/2020/03/13/big-pharma-drug-pricing-coronavirus-profits ("The global crisis 'will potentially be a blockbuster for the industry in terms of sales and profits,' [Gerald Posner] said, adding that 'the worse the pandemic gets, the higher their eventual profit.'"); Gerald Posner, *Big Pharma May Pose an Obstacle to Vaccine Development*, N.Y. TIMES (Mar. 2, 2020), https://www.nytimes.com/2020/03/02/opinion/contributors/pharma-vaccines.html ("Pharmaceutical industry concerns about profits, as well as potential liability for adverse reactions to the inoculation, often keep them from moving quickly enough to develop or distribute effective vaccines when there emerges a novel virus, like the one that has set off the Covid-19 outbreak.").

31 The life cycle description of pharmaceutical markets provided in Section II.C shows the many ways in which pharmaceutical companies influence the formal and informal rules governing the markets they operate in. See also a discussion of the structural features of pharmaceutical markets that allow companies to make decisions with profit rather than public health in mind in Yaniv Heled, Liza Vertinsky & Cass Brewer, *Why Healthcare Companies Should (Be)come Benefit Corporations*, 60 B.C. L. REV. 1 (2019). While the focus of this Article is on pharmaceutical companies, they are by no means the only participants in industry capture. Other industry players, such as HMOs and other private insurers, pharmacy benefit managers, and pharmaceutical distributors, are also involved in shaping pharmaceutical markets with profits in mind, and stories of capture can be extended to include them all. *See, e.g.*, Robin Feldman, *Perverse Incentives: Why Everyone Prefers High Drug Prices -- Except for Those Who Pay the Bills*, 57 HARV. J. ON LEGIS. 303 (2020) (exploring ways in which the pharmacy benefit manager industry exerts systemic influence on a variety of industry stakeholders to keep prices—and profits—high).

profit.[32] The pharmaceutical industry is the biggest source of False Claims Act recoveries by the Department of Justice (DOJ), for example, and the public disclosures that result from litigation and settlements reveal the complex and expansive ways in which the corporate wrongdoers seek to influence market outcomes for their pharmaceutical products.[33] A few examples make headline news. The $3 billion settlement reached with GlaxoSmithKline to resolve fraud allegations, kickbacks, off label marketing, and failure to report safety data in the sale of well-known prescription drugs Paxil, Wellbutrin, and Avandia was widely publicized.[34] The settlements reached with manufacturers of antipsychotic drugs like Johnson & Johnson, maker of Risperdal,[35] and Eli Lilly, maker of Zyprexia,[36]

32 *See, e.g.*, ROSENTHAL, *supra* note 1 (offering a large number of examples of how different industry players exert influence on the creation and operation of markets for their products in order to increase profits); *see also* Paul D. Jorgenson, *Pharmaceuticals, Political Money, and Public Policy: A Theoretical and Empirical Agenda*, 14 J. L. MED. & ETHICS 553 (2013) (arguing that the pharmaceutical industry has influenced legislators to define policy problems in ways that advance their interests). For a historical perspective see, for example, Jean-Paul Gaudillière & Ulrike Thoms, *Pharmaceutical Firms and the Construction of Drug Markets: From Branding to Scientific Marketing*, 29 HIST. & TECH. 105 (2013).

33 *See, e.g.*, Press Release, Off. of Pub. Affs., Dep't of Just., (Jan. 9, 2020), https://www.justice.gov/opa/pr/justice-department-recovers-over-3-billion-false-claims-act-cases-fiscal-year-2019; *see also Pharma Biggest Source of DoJ False Claims Act Recoveries*, PHARMA LETTER (Jan. 15, 2021), https://www.thepharmaletter.com/article/pharma-biggest-source-of-doj-false-claims-act-recoveries (largest recoveries by U.S.DoJ in civil cases involving fraud and fraud claims against the government in the fiscal year 2020 came from settlements and judgements against drug companies).

34 In 2012, GlaxoSmithKline admitted guilt and agreed to pay $3 billion to resolve fraud allegations and failure to report safety data in the sale of prescription drugs Paxil, Wellbutrin and Avandia, with practices including unlawfully promoting drugs for treatments not approved by the FDA, publishing and distributing a misleading medical journal article misreporting clinical data about efficacy while failing to disclose the results of clinical studies with negative efficacy results, and encouraging overprescribing of its drugs in ways that caused harm. *See* Press Release, Off. of Pub. Affs., Dep't of Just., (July 2, 2012), https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report.

35 *See, e.g.*, Jonathan D. Rockoff, *J&J Is Accused of Kickbacks to Omnicare on Drug Sales*, WALL STREET J., (Jan. 16, 2010, 12:01 AM ET), https://www.wsj.com/articles/SB10001424052748703657604575004902853166786 (describing how the Department of Justice charged Johnson & Johnson with "paying 'tens of millions of dollars in kickbacks' to a nursing-home pharmacy company to boost sales of Johnson & Johnson drugs to nursing-home patients. . . . The allegations, detailed in a 34-page complaint, shed light on the workings of a lucrative marketing channel for drug makers that can help drive sales of major drugs: the middlemen like Omnicare that process prescriptions, distribute medicines and manage insurance coverage."). In 2013 Johnson & Johnson admitted to having engaged in a variety of illegal activities related to prescription drugs Risperdal, Invega and Matrecor, including promotion for uses not approved as safe and effective by the FDA and payment of kickbacks to physicians and the nation's largest long-term care pharmacy provider, with a settlement of more than $2.2 billion to resolve civil and criminal liability. *See* Press Release, Off. of Pub. Affs., Dep't of Just., (Nov. 4, 2013), https://www.justice.gov/opa/pr/johnson-johnson-pay-more-22-billion-resolve-criminal-and-civil-investigations.

36 *See, e.g.*, Eli Lily and Company Agrees to Pay $1.415 billion to resolve allegations of off label promotion of Zyprexia, DoJ Press Release, January 15, 2009 at https://www.justice.gov

for a variety of illegal activities designed to expand their markets by aggressively promoting uses of antipsychotic medications not approved as safe and effective for use in nursing homes and related markets, also received a great deal of media attention. But most corporate strategies to exert profit at the expense of health receive little attention, either remaining hidden or with details revealed only through disclosures occurring as the result of government investigations into alleged wrongdoing or through litigation.[37] Moreover, enforcement efforts reveal only illegal activity, but many forms of pharmaceutical capture do not involve conduct that is illegal. As discussed in Part II, there are extensive patterns of industry influence over pharmaceutical markets and their regulation that are perfectly legal, despite any negative impact on public health objectives.

In offering an extended approach to the capture of U.S. pharmaceutical markets, this Article also challenges longstanding approaches to deregulation and privatization in the pharmaceutical industry. Although popular explanations for the high cost and poor performance of the U.S. health care system vary, there is a growing public consensus that U.S. health care markets in general, and pharmaceutical markets in particular, are not working well for patients and public health.[38] In the context of pharmaceutical markets, public outcry has tended to focus largely on the issue of high prices, including the high price of prescription drugs.[39] Some of this public and policy discontent with the health care system has been channeled into political support for a "free market" response premised on market primacy and the need for deregulation.[40] Some has been focused on the

/archive/opa/pr/2009/January/09-civ-038.html.

37 *See, e.g.*, Sammy Almashat & Timothy Waterman, *Rapidly Increasing Criminal and Civil Monetary Penalties Against the Pharmaceutical Industry: 1991 to 2010*, PUB. CITIZENS (Dec. 16, 2010), https://www.citizen.org/wpcontent/uploads/migration/rapidlyincreasingcriminalandcivilpenalties.pdf.

38 For a reflection of public concerns, see, for example, Jim Norman, *Healthcare Once Again Tops List of Americans' Worries*, GALLUP (Apr. 1, 2019), https://news.gallup.com/poll/248159/healthcare-once-again-tops-list-americans-worries.aspx.

39 *See, e.g.*, Ezekiel J. Emanuel, *Big Pharma's Go-To Defense of Soaring Drug Prices Doesn't Add Up*, ATLANTIC (Mar. 23, 2019), https://www.theatlantic.com/health/archive/2019/03/drug-prices-high-cost-research-and-development/585253.

40 The belief in "market primacy"—that markets, if just left alone by government to operate freely, will produce efficient and effective health care outcomes—plays an important role in shaping U.S. health care policy. *See, e.g.*, Joseph White, *Markets and Medical Care: The United States 1993-2005*, 85 MILBANK Q. 395 (2007) (exploring how "the broad ideological battle over the role of markets remains a basic dividing line and dominant theme in American health policy" and how powerful these ideological arguments can be in shaping policy and public opinion regardless of actual impact on health care). Powerful political groups such as the Heritage Foundation and the America Enterprise Institute along with a variety of other political think tanks have supported market primacy as the basis for health care reform. For examples of this argument at work, see Joseph Antos, *Improve Markets, Not Government Controls, for Real Health Reform*, 42 J. AMBULATORY CARE MGMT. 173 (2019) (republished by the American Enterprise Institute, June 17, 2019) (arguing that reform should be focused on promoting consumer choice and market competition); James Capretta & Kevin

need to remove "barriers" to innovation in the form of reserved government rights over publicly funded technology and public expenditures over the resulting products.[41] This Article confronts the market primacy arguments that have been gaining prominence in political circles and among some segments of the public.[42] It argues that these efforts to change pharmaceutical regulation and to minimize the independent role of government in policing pharmaceutical markets are simply another manifestation of pharmaceutical capture. The purpose of this analysis is not to challenge the innovative power of the industry or its value as a source of technologies that reduce morbidity and mortality, but rather to expose the harms of failing to effectively regulate the industry with public health goals in mind. This Article concludes with some ideas for how to make regulations more robust to special interests and more responsive to patient and public health needs.

The rest of this Article proceeds as follows. Part II provides a brief overview of regulatory capture and the debate it has provoked over the appropriate role of regulation. It then offers a theory of pharmaceutical capture and explains why this holistic concept of capture is necessary to understand the influence that corporate actors exert over the design and operation of pharmaceutical markets. Part III uses the opioid epidemic as a case study of pharmaceutical capture at work. Part IV suggests why deregulation is not the answer to pharmaceutical industry woes and argues instead for a redesign of regulation. This Article concludes with some ideas for shifting current regulatory approaches in ways that might lead to a pharmaceutical recapture.

I. A THEORY OF PHARMACEUTICAL CAPTURE

The need to reform U.S. health care markets has been a central feature of political debate and an area of intense public interest for decades.[43] While there is

Dayratna, *Compelling Evidence Makes the Case for a Market-Driven Health Care System*, HERITAGE FOUND. (Dec. 20, 2013), https://www.heritage.org/health-care-reform/report/compelling-evidence-makes-the-case-market-driven-health-care-system ("It is primarily federal policies that are responsible for driving up costs and making health insurance unaffordable for so many Americans."); Matthew Kandrach, *To Improve Healthcare, Look to the Free Market, Not Single-Payer*, THE HILL (Feb. 9, 2018, 12:15 PM EST), https://thehill.com/opinion/healthcare/373119-to-improve-health-care-look-to-the-free-market-not-single-payer ("What's clear is that substantive health-care reform requires less government interference so that patients have more ownership and control over their health-care dollars and choices."); and Raymond March*, Deregulation is the Only Cure for High Drug Prices*, FDAREVIEW.ORG, (Jan. 3, 2019), https://www.fdareview.org/2019/01/03/deregulation-is-the-only-cure-for-high-drug-prices.

41 *See, e.g.*, *NIST Green Paper*, *supra* note 26.

42 *See also* Steven K. Vogel, *Rethinking Stigler's Theory of Regulation: Regulatory Capture or Deregulatory Capture*, PROMARKET BLOG (May 15, 2018), https://promarket.org/rethinking-stiglers-theory-regulation-regulatory-capture-deregulatory-capture (making the argument that the push for deregulation is best understood as a form of deregulatory capture).

43 *See, e.g.*, PAUL STARR, REMEDY AND REACTION: THE PECULIAR AMERICAN STRUGGLE OVER

fierce debate over what should be done to improve quality and reduce cost, political support for a private market approach towards the provision of health care has continued to dominate alternative positions. At the same time, the role of the private sector in all aspects of health care has continued to expand.[44] This leaves the current U.S. health care debate mostly confined to decisions about whether and how to regulate, and deregulate, health care markets to improve outcomes, bringing with it contested views about whether regulations can be relied upon to achieve public health goals or whether regulation is instead itself a source of market failure.

Pharmaceutical markets are heavily regulated for a variety of reasons, ranging from the need to create incentives for research and development to ensuring the quality, efficacy, and safety of pharmaceuticals.[45] Ideally, regulations are designed with the public interest in mind. But sometimes special interests come to dominate regulatory decisions, and regulations are harnessed to serve those interests instead of the public good, a phenomenon generally referred to as "regulatory capture."[46] The idea that industry members with special interests may unduly influence regulators, resulting in regulation that favors special interests at the expense of the public interest, is far from new.[47] But the extent of involvement of the private sector in every aspect of market design in a market that is both uniquely vulnerable to industry influence and critical to public health raises new challenges that go beyond simple models of regulatory capture.[48] The financialization of pharmaceutical markets further exacerbates these challenges by increasing the pressures on pharmaceutical companies to ensure revenue growth.[49] This Part II

HEALTHCARE REFORM (2011) (providing a historical examination of the political dynamics of U.S. health care reform).

44 *See, e.g.*, ROSENTHAL, *supra* note 1; David U. Himmelstein & Steffie Woolhandler, *Privatization in a Publicly Funded Health Care System: The U.S. Experience*, 38 INT'L J. HEALTH SERVICES 407 (2008); Heather Perlberg, *How Private Equity Is Ruining American Healthcare*, BLOOMBERG (May 20, 2020, 2:09 PM PDT), https://www.bloomberg.com/news/features/2020-05-20/private-equity-is-ruining-health-care-covid-is-making-it-worse.

45 *See, e.g.*, Kesselheim et al., *supra* note 17. For a broad discussion of the evolution and nature of FDA regulation over the pharmaceutical industry, and an underlying theory of regulation, see DANIEL CARPENTER, REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT THE FDA (2010).

46 For a standard definition see Prateek Agarwal, *Regulatory Capture Definition*, INTELLIGENT ECONOMIST (May 30, 2019), https://www.intelligenteconomist.com/regulatory-capture. For alternative ways of defining and understanding "regulatory capture" see PREVENTING REGULATORY CAPTURE, *supra* note 21.

47 *See, e.g.*, William J. Novak, *A Revisionist History of Regulatory Capture*, *in* PREVENTING REGULATORY CAPTURE, *supra* note 21, at 25.

48 For a description of the unique characteristics of health care markets that make relying on the profit incentive for health care production problematic, see, for example, Heled, Vertinsky & Brewer, *supra* note 31.

49 *See, e.g.*, William Lazonick et al., *US Pharma's Financialized Business Model* (Inst. for New Econ. Thinking, Working Paper No. 60, 2017), https://ssrn.com/abstract=3035529; Rosie Collington,

suggests that general understandings of regulatory capture, which focus on instances in which regulatory agencies come to be dominated by the interests that they regulate, are inadequate to capture the systemic and pervasive ways in which the pharmaceutical industry has taken on the multifaceted design of its own markets.

A. Theories of Regulatory Capture

"The true forms of government, therefore, are those in which the one, or the few, or the many, govern with a view to the common interest; but governments which rule with a view to the private interest, whether of the one, the few, or the many, are perversions." – Aristotle[50]

Theories of regulatory capture have a long history, with their roots in "the general notion that democratic and republican institutions of government were prone to the corruptions of private interest."[51] Concerns with the ability of concentrated business interests to act in ways that are harmful to the public interest have been a source of policy concern and academic debate since the earliest forms of government.[52] Indeed, concerns about the influence of powerful factions on governing bodies played a formative role in the constitutional foundations of the U.S. system of governance, with its checks and balances and separation of powers.[53] The literature on regulatory capture, which predates even this label of regulatory capture, contains a rich and varied discussion of ways in which special interests impact regulators and regulations, studies of different types and mechanisms of capture, as well as a variety of prescriptions in response to specific or general models of industry control over government decision-makers.[54] Modern discourse on regulatory capture, as further discussed below, spans a shift from a New Deal era belief in the public interest theory of regulation, with government acting in the public interest to limit capture of markets by concentrated private interests, to a post-New Deal pessimism about the ability of government to evade capture by special interests and a corresponding belief in the ability of "free"

Profits, Innovation and Financialization in the Insulin Industry, (Inst. for New Econ. Thinking, Working Paper No. 120, 2020), https://ssrn.com/abstract=3593906.

50 ARISTOTLE, THE POLITICS AND THE CONSTITUTION OF ATHENS bk. III, at 71 (Stephen Everson ed., Cambridge Univ. Press 1996) (c. 325 B.C.E.).

51 Novak, *supra* note 47, at 25.

52 *See, e.g.*, Alissa Ardito, *Regulatory Capture, Ancient and Modern*, REG. REV. (June 30, 2016), https://www.theregreview.org/2016/06/30/ardito-regulatory-capture-ancient-and-modern (examining the history of the concept of capture dating back to the classical world of Greece and Rome).

53 *See* THE FEDERALIST NO. 10 (James Madison); *see also* Novak, *supra* note 47, at 25.

54 *See, e.g.*, Ernesto Dal Bo, *Regulatory Capture: A Review*, 22 OXFORD REV. ECON. POL'Y 203 (2006) (reviewing the empirical and theoretical economics literature on regulatory capture).

markets to promote social welfare.

In the New Deal era, regulation was seen as a way of addressing the capture of markets and consumers by concentrated business interests. The New Deal was based on views of public interest or public service theories of regulation in which regulators acted to protect the public interest.[55] Progressive reformers promoting an expansion of the administrative state saw regulation itself as a way of addressing capture:

> [With regulations] designed to combat what progressives envisioned as a perennial problem in republican and democratic governance—that is, the tendency of private economic interests to capture the public political sphere. More particularly, they viewed late-nineteenth-century agglomerations of corporate wealth and power as producing a dangerous new form of the age-old threat of private interest trumping public democracy.[56]

The New Deal saw an increase in the delegation of policymaking authority to executive and independent administrative bodies, reflecting a belief in the role of experts crafting policy with the public interest in mind and acting as a safeguard on markets and a counterbalance to the power of private business interests.[57]

The public interest theory of regulation is based on the idea that if they are left unhindered, markets will often fail, and that governments—often acting through agency experts—can and will act in the public interest to correct these market failures through regulation.[58] This theory, which supported the rise in the administrative state that occurred during the New Deal era, subsequently came under attack from both progressive and conservative critics, although for different reasons. The idea that regulators will be motivated to protect the public interest was challenged in the 1960s by left-leaning scholars and activists who "suggested that agencies were captured by elite interests that used the administrative state to stifle competition and enrich themselves."[59] These groups saw the expansion of

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55 For examples of classic theories of public interest regulation see, for example, FELIX FRANKFURTER, THE PUBLIC AND ITS GOVERNMENT (Yale Univ. Press 1930); and JAMES M. LANDIS, THE ADMINISTRATIVE PROCESS (Yale Univ. Press 1938).

56 Novak, *supra* note 47, at 25, 38.

57 *See, e.g.*, Philip Wallach, *The Administrative State's Legitimacy Crisis*, BROOKINGS (Apr. 2016), https://www.brookings.edu/research/the-administrative-states-legitimacy-crisis (providing a brief historical overview of the academic debate over the rise of the administrative state).

58 *See, e.g.*, Andrei Shleifer, *Understanding Regulation*, 11 EUR. FIN. MGMT. 439, 440 (2005) (exploring some of the main theories of regulation that emerged in the twentieth century).

59 Reuel Schiller, *Regulation and the Collapse of the New Deal Order, or How I Learned to Stop Worrying and Love the Market*, *in* BEYOND THE NEW DEAL ORDER: U.S. POLITICS FROM THE GREAT DEPRESSION TO THE GREAT RECESSION 168 (Gary Gerstle, Nelson Lichtenstein & Alice O'Connor eds., 2019) [hereinafter BEYOND THE NEW DEAL ORDER].

administrative power as being in tension with, rather than in pursuit of, the public interest, focusing instead on the role of legally protected individual rights as mechanisms for protecting public interests.

> [Since] distrust of government in the 1960s extended to legislatures as well as "captured" agencies, reformers on both sides of the political spectrum searched for ways of allowing private citizens (and the "public interest" groups representing them) to wield the power of government enforcement, including by creating "private attorneys general" provisions that allowed citizens to sue to enforce the law.[60]

New environmental, health, safety, civil rights, and other social regulatory programs adopted by Congress created mechanisms for asserting these individual rights in the courts.[61]

In the 1980s, it was the turn of right-wing scholars and activists to challenge the role of agencies, and government more generally, pointing instead to the primacy of markets. "In many ways," historian Jefferson Cowie wrote, "the 1960s celebrations of the social individual made the 1980s celebration of the economic individual possible."[62] Two decades later the idea that

> [the] provision of government services should be reconceptualized as a market-driven process had . . . become commonplace . . . [and] [t]hus, the most common regulatory strategy of the new millennium was based on the presumption that fully-informed consumers would make choices in the market that punished businesses that did not meet aspirational, non-enforceable regulatory goals.[63]

Theories of regulatory capture based on a particularly pessimistic view of regulation began to gain prominence in U.S. academic and policy circles in the wake of the expansion of the administrative state in the 1950s, and were further developed through the work of George Stigler, Gary Becker, and other members of the Chicago School of Economics.[64] In 1958, in the very first volume of the *Journal of Law and Economics*, Becker raised the question of whether market

60 Wallach, *supra* note 57.

61 *See, e.g.*, Richard Stewart, *Administrative Law in the Twenty-First Century*, 78 N.Y.U. L. REV. 437 *passim* (2003).

62 JEFFERSON COWIE, THE GREAT EXCEPTION: THE NEW DEAL AND THE LIMITS OF AMERICAN POLITICS 27 (2016).

63 Schiller, *supra* note 59, at 168.

64 *See, e.g.*, Levine & Forrence, *supra* note 21.

imperfections ever justified government intervention, reflecting that in the face of pervasive imperfections in government behavior, "[i]t may be preferable not to regulate economic monopolies and to suffer their bad effects, rather than to regulate them and suffer the effects of political imperfections."[65] In an influential paper called "The Theory of Economic Regulation," Stigler rejects the "public interest theory of regulation," which portrays regulation as a mechanism for protecting the public interest in otherwise unfettered markets, and lays out the view that regulators end up representing the interests of the industries they regulate and must themselves be constrained.[66] The basic idea behind this version of regulatory capture is that the concentrated and lucrative interests of industry will inevitably have more political influence than the fragmented and diffuse interests of consumers. Industry players will seek out regulation of their industry as a tool for restricting competition and increasing their control.[67] Add asymmetry of information to this mix, with the regulated industry using its own inside information to stay a step ahead of regulators, and the scope for regulatory capture—and consequent negative impact of regulation on the operations of the market—widens and deepens. For Stigler and others of a similar ideological bent, this meant that regulation was doomed to benefit the industry it regulates at the expense of the public interest; it was destined to fail and should be thrown out.[68]

This Chicago School attack on the public interest theory of regulation can be understood as resting on three main assumptions.[69] The first is that the market, and private orderings, can resolve most market failures without any government intervention. The second is that private litigation can be used to address whatever conflicts market participants might have.[70] The third, and perhaps the most critical assumption, one emphasized by Stigler in his theory of regulatory capture, is that regardless of any limitations of the market, "government regulators are incompetent, corrupt, and captured, so regulation would make things even worse."[71] This approach to regulation and the role of government produced influential theories of regulatory capture grounded in the belief that "as a rule,

65 Gary S. Becker, *Competition and Democracy*, 1 J. L. & ECON. 105, 109 (1958).

66 George J. Stigler, *The Theory of Economic Regulation*, 2 BELL J. ECON. & MGMT. SCI. 3 (1971).

67 George J. Stigler, *The Pleasures and Pains of Modern Capitalism*, *in* EXPLORATIONS IN ECONOMIC LIBERALISM: THE WINCOTT LECTURES 126, 139 (Geoffrey E. Wood ed., 1996).

68 *See, e.g.,* Novak, *supra* note 47, at 25; Zaitchik, *supra* note 13.

69 *See, e.g.*, Shleifer, *supra* note 58 (identifying these three intellectual steps in the challenge to the public interest theory of regulation that are mostly attributed to the Chicago School of Law and Economics).

70 This assumption reflects the logic of efficient bargaining provided by Ronald Coase. In a Coasean world, the courts are seen as playing an important role in resolving disputes, providing an important enforcement mechanism for private orderings. *See, e.g.*, Ronald Coase, *The Problem of Social Cost*, 31 J. L. & ECON. 1 (1960).

71 Shleifer, *supra* note 58, at 440.

regulation is acquired by the industry and is designed and operated primarily for its benefit."[72] The natural conclusion to draw from this line of reasoning, those promoting this view of the world suggested, was that only deregulation would be in the public interest. They turned to the pharmaceutical industry as one of the prime examples of the harms of regulatory capture, and worked closely with the pharmaceutical industry to further develop these ideas into a political and economic agenda for the pharmaceutical industry.[73]

The theoretical development of this particular version of the regulatory capture thesis has become intertwined with growing political support for strengthening private enterprise as a countervailing force to an expanding regulatory state.[74] But while political and even academic discussions of regulatory capture have increasingly focused on the influence of special interests on regulators, and the need to limit the actions of regulators, it is important to keep in mind the broader view of market capture that informs regulatory strategies in the first place.[75] In the absence of government as a countervailing force, special interests will control the operation of markets, and indeed the structure of the industries in which they operate, through a variety of mechanisms that go beyond traditional forms of regulatory capture. The result will be an industry that pursues profits regardless of whether the public interest is served. The concept of pharmaceutical capture that is further described below is intended to encompass this broader view of industry influence over a particular segment—one of the most profitable segments—of health care markets and the dangers of such influence on health outcomes.

72 Stigler, *supra* note 66, at 3; *see also* Mark Green & Ralph Nader**,** *Economic Regulation vs. Competition: Uncle Sam the Monopoly Man*, 82 YALE L.J. 876 (1973) (argues that the regulatory system reflects both a failure of design and a failure of process that often results in regulatory policies that undermine competition and supports monopoly).

73 *See, e.g.*, Edward Nik-Khah, Getting Hooked on Drugs: The Chicago School, the Pharmaceutical Project, and the Construction of the Modern Medical Marketplace (Apr. 2009) (unpublished manuscript) (on file at https://www.ru.nl/publish/pages/515575/nik-khak.pdf) (discussing the influential relationship between the Chicago School of Economics and the pharmaceutical industry and its impact; with an alliance "forged for the express purpose of giving the pharmaceutical industry a voice in academic discussions about how the medical marketplace should be constructed and regulated").

74 For a discussion of the history of theories of regulatory capture see, for example, Novak, *supra* note 47, at 25. But for a competing view of the role of government in an increasingly privatized economy, see, for example, MARTHA MINOW, PARTNERS, NOT RIVALS: PRIVATIZATION AND THE PUBLIC GOOD (2002).

75 For a discussion of evolving theories of regulation and the relationship between the state and markets, see, for example, GOVERNMENTS AND MARKETS: TOWARD A NEW THEORY OF REGULATION (Edward J. Balleisen & David A. Moss eds., 2009).

B. Pharmaceutical Capture

Contemporary theories of regulatory capture continue to focus primarily on the relationships between regulators and the industries that they regulate, exploring situations in which the regulators are unduly influenced by the special interests of the entities they are regulating.[76] While theories of regulatory capture have evolved well beyond Stigler's seminal contributions, discussed above, "the essential idea that policymakers are for sale, and that regulatory policy is largely purchased by those most interested and able to buy it, remains central to the literature."[77]

In their comprehensive study of capture, Daniel Carpenter and David Moss begin their effort to build a more nuanced view of capture by providing a conceptual structure built around a view of regulatory capture as "the result or process by which regulation, in law or application, is consistently or repeatedly directed away from the public interest and towards the interests of the regulated industry, by the intent and action of the industry itself."[78] In this Article, I push the concept of capture even further within the context of the pharmaceutical industry, to encompass the systemic and pervasive nature of the influence exerted by the largest corporate actors in the industry over all material aspects of markets and their regulation. Pharmaceutical capture, as I define it, occurs when the magnitude and scope of corporate influence is significant enough to alter the incentive structures, and corresponding decisions, of a sufficient number of industry stakeholders (whether it be consumption choices, prescriptions by doctors, rulemaking by regulatory agencies, enforcement decisions, or some other form of decision-making or stakeholder action) in ways that ensure that relevant markets yield the outcomes desired by the industry captors.

While the pharmaceutical industry is certainly not the only industry susceptible to this type of systemic capture, I build on arguments made in prior work to suggest that U.S. pharmaceutical markets have distinctive features that make it particularly susceptible to capture of this scope and magnitude.[79] Five features in particular stand out: the pervasive role of regulation over the entire product life cycle; the belief in the private sector as the primary engine of (lifesaving) biomedical innovation and the socialization of costs but not benefits from this R&D; the fragmentation of the market and the treatment of patients as consumers for some purposes but not others; the pervasive role of industry in

76 *See generally* PREVENTING REGULATORY CAPTURE, *supra* note 21 (providing a collection of ideas about what regulatory capture is, how it works and how to mitigate it; arguing for more nuanced understanding of regulatory capture).

77 Daniel Carpenter & David A. Moss, *Introduction* to PREVENTING REGULATORY CAPTURE, *supra* note 21, at 1, 8.

78 *Id.* at 13.

79 *See, e.g.*, Heled, Rutschman & Vertinsky, *supra* note 15, at 1; Heled, Vertinsky & Brewer, *supra* note 31.

shaping scientific, medical, and patient knowledge about pharmaceuticals and their use; and the extreme potential for profit due in part to the inelasticity of demand for the goods involved.

The pervasive role of regulation over the entire life cycle of pharmaceuticals, combined with regulatory fragmentation on the one hand and holistic pharmaceutical strategies on the other, is one factor facilitating pharmaceutical capture. The pharmaceutical industry is subject to a number of overlapping regulatory systems at the federal level, including the patent system administered by the U.S. Patent and Trademark Office (USPTO), the funding and licensing of biomedical research by the National Institutes of Health (NIH), Biomedical Advanced Research and Development Agency (BARDA) and other government agencies, the oversight of clinical testing and the approval of new drugs and accompanying market and data exclusivities and oversight of post-approval marketing and distribution of drugs by the U.S. Food and Drug Agency (FDA), monitoring of certain classes of drugs by the Drug Enforcement Agency (DEA) under the Controlled Substances Act, government reimbursement schemes administered by the Centers for Medicare and Medicaid Services (CMS), regulation by the Federal Trade Commission (FTC) to address anticompetitive behavior and deceptive and unfair trade practices, and for some products a requirement that they be provided only through prescription by an authorized, state-licensed professional health care worker (most often a physician). Regulating and enforcing prescription drug practices, along with other forms of regulating medical practice, are primarily left to state law.[80] There are many additional federal and state laws and regulations that impact pharmaceuticals, including without limitation rules governing manufacturing and marketing practices, reimbursement schemes, product liability, insurance practices, and the types of transactions that are permissible between physicians and pharmaceutical manufacturers. This fragmented web of regulations targeting different aspects of pharmaceuticals creates myriad opportunities for corporate influence and control over pharmaceutical markets. While regulators are confined to specific areas of regulation, and limited jurisdiction within those areas, corporate actors are able to adopt a holistic, systemic approach towards their products and business strategies.

The belief in the private sector as a driving force of biomedical innovation, with particularly high stakes when it comes to life saving technologies, is a second driving factor for pharmaceutical capture in the United States. The regulatory structure in its existing form is justified largely in terms of promoting innovation on the front end, and providing access to safe and effective drugs on the back end. Regulatory exclusivities and public funding are awarded to pharmaceutical

80 *See, e.g.*, State Laws on Prescription Drug Misuse and Abuse, CTRS. FOR DISEASE CONTROL & PREVENTION (June 15, 2018), https://www.cdc.gov/phlp/publications/topic/prescription.html.

companies to encourage them to develop drugs, and their subsequent monopolies and control over pricing are justified as the necessary cost of encouraging innovation. These same pharmaceutical companies are then tasked with producing their own data to show the regulators that their products are safe and effective. Although the government finances the research and even sometimes the development of drugs, and despite the fact that the government is the largest single purchaser of drugs through programs such as Medicare and Medicaid, the ability of the government to bargain with private companies over access and price are limited through regulation.[81] The government also plays little role in product selection beyond prioritizing certain areas of research in government funding, relying instead on the private sector to drive product choice. The (questionable) rationale that supports these restrictions on government intervention into product and pricing decisions, and that constrains use of those government mechanisms for intervening that do exist, is that market forces will adequately discipline the behavior of companies without the chilling effect that government intervention might have on investment and innovation.[82] This rationale is used to support current government strategies for accelerating the development of COVID-19 treatments and vaccines, for example, where public funding and other resources are being poured into private sector R&D activities to spur private innovation with few public safeguards attached.[83]

In addition to this narrative of pharmaceutical innovation, the contours of the regulatory structure have also been influenced by shifting ideas about the rights and needs of the patient that have been shaped by the industry in ways that are conducive to commercial interests. The legal framework accords a special position to the role of the physician as expert decision maker and gatekeeper in the prescribing of drugs, limiting the liability of drug manufacturers and providing a realm of discretion to physicians. At the same time, the legal framework reflects a view of the patient as a rational, autonomous consumer of health care when it comes to determining what rights and responsibilities companies should have when marketing their products to these patient-consumers—a view that is in tension with the role of the physician as gatekeeper.[84] Industry players have been

81 *See, e.g.*, John B. Kirkwood, *Buyer Power and Healthcare Prices*, 91 WASH. L. REV. 253 *passim* (2015) (discussing the limitations on the government's ability to negotiate price for its drug purchases under Medicare, among other limitations on government ability to negotiate on price of prescription drugs).

82 *See, e.g.*, John F. Wasik, *Why Medicare Can't Get the Lowest Drug Prices*, FORBES (Aug. 10, 2018, 8:26 AM EDT), https://www.forbes.com/sites/johnwasik/2018/08/10/why-medicare-cant-get-the-lowest-drug-prices.

83 *See, e.g.*, Mariana Mazzucato & Azzi Momenghalibaf, *Drug Companies Will Make a Killing from Coronavirus*, N.Y. TIMES (Mar. 18, 2020), https://www.nytimes.com/2020/03/18/opinion/coronavirus-vaccine-cost.html.

84 For a broader discussion of this tension see, for example, Liza Vertinsky, Rethinking the

quick to utilize the protections that they argue are necessary to promote innovation, as well as the role of the physician as gatekeeper and patient as consumer, for purposes of expanding their marketing while limiting their liability.

A fourth factor that contributes to industry influence over the evolution and operation of pharmaceutical markets is the pervasive role of industry in scientific and medical research and in medical education, and indeed even in "educating" patients and policymakers.[85] Pharmaceutical companies in particular exert influence over scientific research and discussions, as well as medical training and education and professional norms.[86] They also engage in efforts to orient public policy discussions and writing on the idea of patients as consumers with the right to exercise choice over health care products, and they cultivate relationships with patients and patient advocacy groups who further this message.[87] Their interactions with regulators, health care providers, patients, and payors form part of a systematic corporate strategy to control health policy narratives in ways that support industry positions.

Finally, and in part as a result of the other factors discussed above, pharmaceutical markets offer great potential for the largest and most powerful corporate actors to profit, and thus strong incentives to invest in, and resources to support, efforts at pharmaceutical capture.[88]

Role of the Prescriber with the Patient in Mind (March 12, 2021) (unpublished manuscript) (on file with author).

85 For materials exploring the role of industry in medical research and education, see, for example, Resources, PHARMEDOUT, https://sites.google.com/georgetown.edu/pharmedout/resources (last visited July 6, 2021); *see also* INSTITUTE OF MEDICINE, *Conflicts of Interest in Biomedical Research*, *in* CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE 97 (Bernard Lo & Marilyn J. Field eds., 2009) (report examining conflicts of interest in medical education, research and practice, focuses on conflicts of interest across the spectrum of medicne). For a discussion of concerns about industry funding of clinical trials, see, for example, Sameer S. Chopra, *Industry Funding of Clinical Trials: Benefit or Bias?*, 290 JAMA 113 (2003).

86 *See, e.g.*, Charles Ornstein, *From Twitter to Treatment Guidelines, Industry Influence Permeates Medicine*, NAT'L PUB. RADIO (Jan. 17, 2017, 11:01 AM ET), https://www.npr.org/sections/health-shots/2017/01/17/510226214/from-twitter-to-treatment-guidelines-industry-influence-permeates-medicine (summarizing findings from a series of papers in JAMA on how "the long arm of the pharmaceutical industry continues to pervade practically every area of medicine")

87 *See, e.g.*, Matthew S. McCoy et al., *Conflicts of Interest for Patient Advocacy Organizations*, 376 NEW ENG. J. MED. 880 (2017) (documenting a significant level of industry funding and other forms of involvement in patient advocacy organizations); *see also* Sharon Batt et al., *Pharmaceutical Ethics and Grassroots Activism in the United States: A Social History Perspective*, 17 J. BIOETHICAL INQUIRY 49 (2020) (examining the dangers of expanded industry funding of patient advocacy groups since the 1990s and industry influence over patient advocacy discourse and agendas); Emily Kopp et al., *Patient Advocacy Groups Take in Millions from Drugmakers. Is There a Payback?*, KHN (Apr. 6, 2018), https://khn.org/news/patient-advocacy-groups-take-in-millions-from-drugmakers-is-there-a-payback/ (describing trends in pharmaceutical industry influence over patient advocacy organizations and providing a database that tracks industry donations to these organizations).

88 *See, e.g.*, Heled, Vertinsky & Brewer, *supra* note 31 (discussing private incentives to

C. Capture Across the Product Life Cycle

Pharmaceutical companies, along with other large corporate actors in the industry, adopt a holistic approach to their regulatory strategies, both across different products and across product life cycles, thinking systemically about how different regulations interact in ways that may ultimately impact product sales, and profits. Direct efforts at regulatory capture are combined with efforts to influence other aspects of market design, including the types and nature of research relevant to pharmaceutical markets, the guidelines and standards of care used by physicians, and the agendas and activities of patient advocacy groups. Pharmaceutical capture occurs when this influence is significant enough to alter the incentive structures, and corresponding decisions, of a sufficient number and range of key industry stakeholders (including patients, doctors, health care payors and regulators) in ways that systematically produce market outcomes desired by the pharmaceutical industry—often at the expense of the public interest.

Examining the opportunities for regulatory capture across the life cycle of biomedical products provides a picture of how pharmaceutical companies, as well as other powerful industry players, seek to influence every aspect of the regulatory process that might touch upon their market opportunities, ranging from before the idea for the product even emerges to post-sale liability for product harms. The following discussion offers a brief—and by no means complete—overview of capture opportunities across the product life cycle, beginning with the research preceding product discovery and development and ending in post-sale product liability.

Early Stage Biomedical Research and Development Pharmaceutical company involvement in market design begins in processes of knowledge production and in the legal structures that govern access to and control over any resulting discoveries.[89] Pharmaceutical companies play a range of different roles in the generation of scientific knowledge, as well as decisions to not generate certain kinds of scientific evidence.[90] They have some influence over the flow of government funding to support biomedical research, along with the legal structures

maximize profits and resulting impact on pharmaceutical markets).

89 *See, e.g.*, SERGIO SISMONDO, GHOST-MANAGED MEDICINE: BIG PHARMA'S INVISIBLE HANDS, (2018) (exploring the role of pharmaceutical companies in the production of medical knowledge); Kitsis, *supra* note 24 (exploring the role of pharmaceutical companies in the construction of disease, offering a case of fibromyalgia and how the search for new treatments might have influenced the definition of the illness); Marc A. Rodwin, *Five Un-Easy Pieces of Pharmaceutical Policy Reform*, 41 J. L. MED. & ETHICS 581 (2013) (exploring the improper role of drug firms in setting R&D priorities).

90 *See, e.g.*, Elie A. Akl & Assem M. Khamis, *The Intersection of Industry with the Health Research Enterprise*, 17 HEALTH RSCH. POL'Y & SYS. 53 (2019) (providing a framework that identifies different types of relationships between industry and researchers, particularly in pharmaceuticals).

that govern receipt of the funds and access to the results. While some funding takes the form of public-private partnerships or direct grants to the private sector, many of the drugs that pharmaceutical companies develop are based at least in part on early publicly funded research performed at universities and government labs.[91]

Pharmaceutical companies cultivate close relationships with the academy, often providing financial support to universities and their researchers through sponsored research and public-private collaborations, seeking in return control over publications and the option to obtain intellectual property rights to the results.[92] As public funding for academic research has become harder to secure, financial support from pharmaceutical companies has become increasingly attractive, allowing companies to expand their influence over research activities and researchers. Despite the growing use of conflict-of-interest policies and other efforts to ensure independence of academic research, the industry's influence over research continues to grow.[93]

Securing Rights to Publicly Funded Inventions Where promising drug candidates emerge from collaborations between public research entities and pharmaceutical companies, the companies are often able to secure rights to any inventions that emerge through the use of contracts that favor private intellectual property ownership. Where promising drug candidates arise from academic research or labs, the process for acquiring rights to commercialize publicly funded research, along with the legal strings attached to the use of such research, become the target of pharmaceutical interest. The Bayh-Dole Act (for inventions developed using federal government funding) and Stevenson-Wydler Technology Innovation Act (for inventions from federal labs) provide legal frameworks for licensing patents covering publicly funded inventions to private companies, and public-

91 *See, e.g.*, Pierre Azoulay et al., *Public R&D Investments and Private-Sector Patenting: Evidence from NIH Funding Rules*, 86 REV. ECON. STUD. 117 (2019) (measuring the impact of NIH funding on patenting by biotech and pharmaceutical companies); Ekaterina Galkina Cleary et al., *Contribution of NIH Funding to New Drug Approvals 2010-2016*, 115 PROC. NAT'L ACAD. SCIS. 2329 (2018)
(examining the contributions that NIH funding has made to published research associated with 210 new molecular entities that the FDA approved during the period 2010-2016); Marcela Vieira, *Research Synthesis: Public Funding of Pharmaceutical R&D*, KNOWLEDGE PORTAL (Apr. 2019), https://www.knowledgeportalia.org/public-funding-of-r-d (providing a comprehensive review of public funding on pharmaceutical R&D). For a critique of public-private partnerships and multistakeholder initiatives in health, see, for example, JONATHAN H. MARKS, THE PERILS OF PARTNERSHIP: INDUSTRY INFLUENCE, INSTITUTIONAL INTEGRITY, AND PUBLIC HEALTH (2019).

92 For a collection of papers exploring different aspects of the relationship between industry and the academic and medical community, see Publications, PHARMEDOUT, https://sites.google.com/georgetown.edu/pharmedout/resources/publications (last visited July 6, 2021).

93 *See, e.g.*, Peter Whoriskey, *As Drug Industry's Influence Over Research Grows, So Does the Potential for Bias*, WASH. POST, (Nov. 24, 2012), https://www.washingtonpost.com/business/economy/as-drug-industrys-influence-over-research-grows-so-does-the-potential-for-bias/2012/11/24/bb64d596-1264-11e2-be82-c3411b7680a9_story.html.

private partnerships facilitate further utilization of publicly funded facilities and discoveries by private companies.[94] While this technology transfer framework provides only modest government rights and protections of the public interest, even those rights are rarely if ever exercised, compliance remains limited,[95] and efforts are now being made to weaken even these limited rights.[96] Even in the midst of a pandemic, efforts to attach reasonable pricing and access terms to federal funding of pandemic therapies and vaccines have proven unsuccessful. Indeed, the federal government has recently expanded its use of "other contracting authority" to allow funding agreements with pharmaceutical companies that are not subject even to the limited federal protections of the public interest found in traditional funding agreements.[97]

Medical and Scientific Education and Discourse In addition to funding and collaborating on R&D, pharmaceutical companies also exercise considerable influence over medical and scientific discourse through relationships with academics and academic journals, publications, and educational programs.[98] A particularly insidious form of industry influence involves the practice of medical ghostwriting.[99] Pharmaceutical companies either directly or indirectly, through the use of medical education companies, hire medical writers to produce works that serve a corporate purpose and seek doctors or academics to sign on as authors or co-authors to lend legitimacy to the work, which is then published in a medical or scientific journal. "Reported examples of ghost-writing have covered up problems

94 *See, e.g.*, PAUL W. HEISEY ET AL., *Technology Transfer by Federal Agencies*, *in* GOVERNMENT PATENTING AND TECHNOLOGY TRANSFER 11 (2006); *see also* Act to Amend the Patent and Trademark Laws (Bayh-Dole Act), Pub. L. No. 96-517, 94 Stat. 3015 (1980) (federal legislation dealing with inventions arising from federally funded research); Stevenson-Wydler Technology Innovation Act of 1980, Pub. L. No. 96-480, 94 Stat. 2311 (federal technology transfer law encouraging federal labs to engage in technology transfer).

95 *See, e.g.*, Arti K. Rai & Bhaven N. Sampat, *Accountability in Patenting of Federally Funded Research*, 30 NATURE BIOTECHNOLOGY 953 (2012).

96 See, for example, recent proposals to "streamline" the technology transfer process and remove "barriers" to private-sector development such as those summarized in *NIST Green Paper*, supra note 26.

97 *See, e.g.*, KEI Staff, *KEI Letter to Speaker Pelosi Regarding Use of "Other Transactions Authority" (OTA) in Coronavirus Bill to Escape Bayh-Dole Public Interest Safeguards, Press Release*, KNOWLEDGE ECOLOGY INT'L (Mar. 23, 2020), https://www.keionline.org/32530.

98 *See supra* note 92.

99 *See, e.g.*, Chung-Lin Chen, *Assessing Potential Legal Responses to Medical Ghostwriting: Effectiveness and Constitutionality*, 5 J. LAW & BIOSCIENCES 84 (2018) (examining the extensive practices of ghostwriting by pharmaceutical companies and the challenges of legal regulation); Susan Gaidos, *Ghostwriters in the Medical Literature*, SCIENCE (Nov. 12, 2010), https://www.sciencemag.org/careers/2010/11/ghostwriters-medical-literature (examining the role that ghostwriters, and the medical education companies that employ them and pharmaceutical companies that fund them play in shaping medical-scientific discourse and literature); Nicola Jones, *Ghosts Still Present in the Medical Machine*, 461 NATURE 325 (2009) (discussing surveys indicating continuing problem of medical ghostwriting by pharmaceutical companies).

with drugs, sought to circumvent the Federal Food and Drug Agency's prohibition on advertising off-label indications and endeavored to create a market for a drug."[100] A widely publicized example of industry influence over the production and dissemination of "scientific" knowledge came to light in the extensive litigation against Merck, a well-known pharmaceutical company, after it was forced to withdraw its painkiller Vioxx from the market because of the known cardiovascular risks associated with its use.[101] Merck's practices included the use of ghostwriters and carefully selected data in publications supporting the use of Vioxx, raising questions not just about the authorship of the studies but also about the underlying validity of the clinical trials on which the research was based.[102] The Merck documents suggested that practices of this sort are widespread in the industry.[103]

Using Regulatory Exclusivities to Restrict Competition Pharmaceutical companies rely upon the patent system to exclude competitors during their development and sale of a new drug.[104] Sometimes patents are a necessary part of the development process, given the high costs of drug discovery and development and the long period from discovery to sale. For startup biotech companies, patents secure rights to promising discoveries and make them attractive for investment and/or acquisition. Universities and government labs rely on the technology transfer provisions included in the Bayh-Dole Act and Stevenson-Wydler Technology Innovation Act to license patents to pharmaceutical companies.[105] Yet patents can also be used strategically by pharmaceutical companies in a wide variety of potentially anticompetitive ways to delay entry into a market well after the initial patents on a new drug have expired and well beyond the legitimate confines of their monopoly rights.[106] Patents work in combination with a variety

100 *See, e.g.*, Elise Langdon-Neuner, *Medical Ghost-Writing*, 6 MENS SANA MONOGRAPH 257 (2008).

101 *See, e.g.*, Harlan Krumholz et al., *What Have We Learnt from Vioxx*? 334 BRIT. MED. J. 120 (2007).

102 *See, e.g.*, Janice Hopkins Tanne, *Merck Used Selective Data in Vioxx Publications,* JAMA *Says*, 336 BRIT. MED. J. 849 (2008).

103 *See, e.g.*, Joseph S. Ross, Kevin P. Hill, David S. Egilman & Harlan M. Krumholz, *Guest Authorship and Ghostwriting in Publications Relating to Rofecoxib: A Case Study of Industry Documents from Rofecoxib Litigation*, 299 JAMA 1800 (2008); Stephanie Saul, *Ghostwriters Used in Vioxx Studies, Article Says*, N.Y. TIMES (Apr. 15, 2008), https://www.nytimes.com /2008/04/15/business/15cnd-vioxx.html.

104 *See, e.g.*, Jonathan J. Darrow, *Pharmaceutical Gatekeepers*, 47 IND. L. REV. 363 (2014).

105 *See, e.g.*, Maria Freire, *Statement of National Institutes of Health Before Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies*, NAT'L INST. OF HEALTH (Aug. 1, 2001), https://stemcells.nih.gov/policy/ statements/080101freire.htm.

106 *See, e.g.*, KEVIN T. RICHARDS, KEVIN J. HICKEY & ERIN H. WARD, CONG. RSCH. SERV., R46221, DRUG PRICING AND PHARMACEUTICAL PATENTING PRACTICES (2020) (providing an overview of pharmaceutical company gaming of the patent system, including evergreening, patent thickets,

of other regulatory exclusivities, or what have been described as regulatory shelters, to significantly limit competition in pharmaceutical markets.[107] The pharmaceutical industry not only exploits the existing patent law framework to limit competition, but also exerts influence over patent legislation and other aspects of patent policy in order to preserve and enhance patent rights.[108] Anticompetitive practices such as creating patent thickets, product hopping, evergreening, and "pay for delay" arrangements, all involving the use of patents as mechanisms for restricting competition, are well documented.[109]

Despite the fact that much of the R&D that contributes to new pharmaceuticals is not performed by pharmaceutical companies, they rely heavily on a narrative of exclusive rights fueling innovation to justify strong patent protection and resulting high prices for the products they ultimately sell.[110] With little cost transparency, and the ready availability of data generated by an industry-funded think tank to support their arguments, this narrative is hard to attack.[111] Pharmaceutical companies are influential stakeholders in patent policy, although their power is counterbalanced by equally large and influential companies in the high tech sectors. While they tend to concentrate their lobbying and other pressures on Congress as the source of patent legislation, pharmaceutical companies also seek to influence the USPTO.[112] While the USPTO has limited ability to make rules, its practices can impact the availability and scope of patents as well as the costs associated with them, and the USPTO is not devoid of incentives to favor some

product hopping and pay for delay); Erin Fox, *How Pharma Companies Game the System to Keep Drugs Expensive*, HARV. BUS. REV. (Apr. 6, 2017), https://hbr.org/2017/04/how-pharma-companies-game-the-system-to-keep-drugs-expensive (providing examples of how pharma uses patent strategies to delay competition). As examples of these strategies in use, see Katherine Ellen Foley, *Big Pharma Is Taking Advantage of Patent Law to Keep OxyContin from Ever Dying*, QUARTZ (Nov. 18, 2017), https://qz.com/1125690/big-pharma-is-taking-advantage-of-patent-law-to-keep-oxycontin-from-ever-dying; and Cynthia Koons, *This Shield of Patents Protects the World's Best-Selling Drug*, BLOOMBERG (Sep. 7, 2017, 3:00 AM PDT), https://www.bloomberg.com/news/articles/2017-09-07/this-shield-of-patents-protects-the-world-s-best-selling-drug (discussing the example of AbbVie's strategy of patenting multiple aspects of the research, development, and manufacturing of blockbuster drug Humira as illustrating increasing trend in biologics to find more "patentable" steps in their invention).

107 *See, e.g.*, Yaniv Heled, *Regulatory Competitive Shelters*, 76 OHIO STATE L.J. 299 (2015).

108 *See, e.g.*, Jay P. Kesan & Andres A. Gallo, *The Political Economy of the Patent System*, 87 N.C. L. REV. 1341 (2009).

109 For a description of these different practices see, for example, RICHARDS, HICKEY & WARD, *supra* note 106. For the impact of patent practices in the context of biologics, see Greg Girvan & Avik Roy, *The Growing Power of Biotech Monopolies Threatens Affordable Care*, FOUND. FOR RSCH. ON EQUAL OPPORTUNITY (Sept. 15, 2020), https://freopp.org/the-growing-power-of-biotech-monopolies-threatens-affordable-care-e75e36fa1529 (exploring how patents are used in anticompetitive ways to limit or even prevent competition in biologics).

110 *See, e.g.*, Heled, Rutschman & Vertinsky, *supra* note 15.

111 *See, e.g.*, Nik-Khah, *supra* note 73.

112 *See, e.g.*, Kesan & Gallo, *supra* note 108.

groups, particularly large-scale patent holders and large players in pro-patent industries like the pharmaceutical industry, over others.[113] While the question of whether Federal Circuit rulings are influenced by special interests is a subject of debate, pharmaceutical companies nonetheless do their best to support positions that strengthen their patent rights.[114]

Drug Approval and Industry Relationships with the FDA Regulations surrounding clinical testing and the drug approval process are of critical importance to pharmaceutical companies, and therefore also a target for industry influence. The FDA is charged with ensuring the safety, efficacy, and security of drugs, biologics, and medical devices, while also being responsible for helping to speed innovations to market where they might advance public health.[115] This dual mandate to ensure safety and efficacy while also promoting speedy innovation brings with it conflicting pressures even before the influence of special interests is taken into account.[116] Industry relations with the FDA remain complicated, as do determinations of the degree to which FDA decisions remain independent of these interests.[117] FDA regulators work closely with pharmaceutical companies, and the FDA receives almost half its budget from fees paid by private industry.[118] The FDA plays an important role in establishing guidelines and providing oversight of the design and implementation of clinical trials. The FDA then reviews applications for approvals of new drugs using evidence that pharmaceutical companies submit, including three phases of clinical trials, to determine whether the products are safe and offer some benefit over existing drugs. Pharmaceutical companies are in charge of designing and funding the generation of evidence designed to show that their products are safe and effective, and asymmetries of information and conflicts

113 *See, e.g.*, Melissa F. Wasserman, *Deference Asymmetries: Distortions in the Evolution of Regulatory Law*, 93 TEX. L. REV. 625 (2013).

114 *See, e.g.*, Stuart Minor Benjamin & Arti K. Rai, *Fixing Innovation Policy: A Structural Perspective*, 77 GEO. WASH. L. REV. 1 (2008).

115 *See* Douglas C. Throckmorton, *The Public Health Role of Drug Regulation in the U.S.*, FOOD & DRUG ADMIN. (Mar. 20, 2017), https://www.fda.gov/media/104374/download.

116 *See, e.g.*, CARPENTER, *supra* note 45 (examining how the FDA has cultivated a reputation that has conferred power to regulate and the interplay between the FDA and powerful industry stakeholders).

117 *See, e.g.*, Daniel Carpenter, *The Political Economy of FDA Drug Review: Processing, Politics and Lessons for Policy*, 23 HEALTH AFFS. 52 (2004) (arguing that the FDA drug review process involves institutional learning driven by reputational concerns but is also shaped by organized interests).

118 *See, e.g.*, John LaMattina, *The Biopharmaceutical Industry Provides 75% of the FDA's Drug Review Budget. Is This a Problem?*, FORBES (June 28, 2018, 7:42 AM EDT), https://www.forbes.com/sites/johnlamattina/2018/06/28/the-biopharmaceutical-industry-provides-75-of-the-fdas-drug-review-budget-is-this-a-problem; Charles Piller & Jia You, *Hidden Conflicts? Pharma Payments to FDA Advisers After Drug Approvals Spark Ethical Concerns*, SCIENCE (July 5, 2018, 2:00 PM), https://www.sciencemag.org/news/2018/07/hidden-conflicts-pharma-payments-fda-advisers-after-drug-approvals-spark-ethical.

of interest abound.[119] The FDA also reviews applications for generic versions of these drugs, based again on data provided by the applicants as well as prior data from the non-generic version of the drugs. In addition to approvals of new drugs and generic versions, the FDA can approve existing drugs for new uses. Along with approvals, the FDA provides valuable market and/or data exclusivities that augment the exclusivity conferred by existing patent protection. Pharmaceutical lobbies are constantly at work to encourage a faster, more streamlined, and less demanding review process, while also generally seeking to expand data and market exclusivities.[120]

Direct and Indirect Product Marketing Marketing is a key part of the pharmaceutical business model, and pharmaceutical companies are eager to avoid rules that restrict how this marketing can take place. The product label, which is regulated by the FDA, is incredibly important to pharmaceutical marketing, since this determines the scope of what it is legally allowed to market the product as a treatment for. While physicians are able to use the drug for off-label use, direct marketing of off-label uses is illegal. Many of the lawsuits brought against pharmaceutical companies involve variations in efforts to expand off-label use of their drugs. One of the "darker side[s] of pharma marketing," for example, "involves creating clinical trials aimed at influencing doctors and educational courses to showcase expensive drugs from non-FDA approved uses—even when there is no scientific proof of safety or efficacy."[121]

Cultivating Relationships With Prescribers Building relationships between pharmaceutical companies and the physicians who prescribe their products is a key part of marketing efforts.[122] In addition to rules against off-label marketing, there are a variety of rules governing relationships between pharmaceutical companies and physicians designed to protect against conflicts of interest, such as anti-kickback statutes that prohibit payments to physicians for prescribing drugs.[123] But these rules leave open substantial opportunities for pharmaceutical companies to engage in a variety of different promotional efforts that have been shown to

119 *See, e.g.*, Light, Lexchin & Darrow, *supra* note 20.

120 *See, e.g.*, Daniel Carpenter, *Corrosive Capture? The Dueling Forces of Autonomy and Industry Influence in FDA Pharmaceutical Regulation*, *in* PREVENTING REGULATORY CAPTURE, *supra* note 21, at 152 (exploring tensions between independence of the FDA and industry influence).

121 Michelle Llamas, *Selling Side Effects: Big Pharma's Marketing Machine*, DRUGWATCH (July 17, 2016), https://www.drugwatch.com/featured/big-pharma-marketing.

122 *See, e.g.*, Marc A. Rodwin, C*onflicts of Interest, Institutional Corruption, and Pharma: An Agenda for Reform*, 40 J. L. MED. & ETHICS 511 (2012) (examining improper dependencies of physicians on pharmaceutical companies and the conflicts of interest that arise). For an exhaustive look at conflicts of interest between physicians and pharmaceutical companies see, for example, MARC A. RODWIN, MEDICINE, MONEY, AND MORALS: PHYSICIANS' CONFLICTS OF INTEREST (1993).

123 *See, e.g.*, *A Roadmap for New Physicians: Fraud and Abuse Laws*, U.S. DEP'T OF HEALTH & HUM. SERVS., https://oig.hhs.gov/compliance/physician-education/01laws.asp (last visited July 6, 2021).

increase prescription rates, varying from free lunches and free samples to large consulting fees and expense-paid trips to resorts. Industry influence starts early, through activities that establish relationships with medical students, and continues to build as these students leave residency and enter medical practice.[124] Much of the continuing medical education provided to physicians and other health care providers is funded, and even designed, by industry.[125] Pharmaceutical companies cultivate physicians as "key opinion leaders" to engage in speaking tours designed to augment their influence over physician education.[126] It is estimated that the pharmaceutical industry spends more than $11 billion annually on promotion and marketing, of which approximately $5 billion is spent on sales representatives who develop relationships with prescribers, while spending per physician is estimated to be over $8,000.[127] Despite increasing concerns about the extent of industry influence over physician education as a pharmaceutical marketing tool, the practice continues.[128]

Generating Demand From the "Consumer" Patient In addition to marketing their products to physicians, pharmaceutical companies have increasingly been marketing prescription drugs directly to patients, treating patients as consumers. Before the 1980s, pharmaceutical marketing efforts were largely focused on doctors and pharmacists. But in the 1980s, marketing strategies shifted to include, and even focus on, marketing to patients, increasingly viewed and portrayed as consumers who should be able to make their own product choices. Regulations surrounding the ability to advertise to consumers, requirements about what information industry must provide to consumers, and the role of physicians as intermediaries in that process, remain an area ripe for industry capture.[129] Direct-to-consumer (DTC) advertising is regulated by the FDA, although the FTC is charged with overseeing unfair advertising practices. The volume of DTC

124 *See, e.g.*, Kirsten E. Austad, Jerry Avorn & Aaron S. Kesselheim, *Medical Students' Exposure to and Attitudes About the Pharmaceutical Industry: A Systematic Review*, 8 PLOS MED. 1 (2011).

125 *See, e.g.*, Adriane Fugh-Berman & Sharon Batt, *"This May Sting a Bit": Cutting CME's Ties to Pharma*, 8 VIRTUAL MENTOR 412 (2006).

126 *See, e.g.*, Adriane Fugh-Berman, *Not in My Name: How I Was Asked to "Author" a Ghostwritten Research Paper*, GUARDIAN (Apr. 20, 2005, 9:19 PM EDT), https://www.theguardian.com/science/2005/apr/21/science.research.

127 *See, e.g.*, Paul A. Komesaroff & Ian H. Kerridge, *Ethical Issues Concerning the Relationships Between Medial Practitioners and the Pharmaceutical Industry*, 176 MED. J. AUSTL. 118 (2002); Teri Randall, *Kennedy Hearings Say No More Free Lunch—Or Much Else—From Drug Firms*, 265 JAMA 440 (1991).

128 *See, e.g.*, Anna Wilde Mathews, *At Medical Journals, Writers Paid by Industry Play Big Role*, WALL ST. J. (Dec. 13, 2005, 12:01 AM ET), https://www.wsj.com/articles/SB113443606745420770.

129 *See, e.g.*, Michelle Llamas, *Selling Side Effects: Big Pharma's Marketing Machine*, DRUGWATCH (July 17, 2016), https://www.drugwatch.com/featured/big-pharma-marketing.

pharmaceutical advertising remained fairly low until the 1980s, when a shift towards patient-centered decision-making accompanied by a political climate that was favorable to corporate interests led to greater use of consumer advertising by pharmaceutical companies. By the 1990s, earlier FDA regulations had been relaxed to accommodate the new media used for DTC advertising, and the regulations were relaxed again in 2004, each time reducing the amount and detail of the information that pharmaceutical companies were required to disclose in their advertisements. Spending on DTC advertising jumped from $12 million in 1980 to $47 million in 1990, $340 million in 1995, $1.2 billion in 1998, and more than $5 billion in 2006 and 2007, dropping to $4.5 billion in 2009 in response to the financial slowdown.[130] While the volume of DTC advertising has increased, the FDA's capacity to monitor the advertising has remained constant, leaving the FDA with the impossible task of monitoring a huge volume of advertising with a small team of people.[131]

Once patients are viewed as consumers, with the right to make choices about their health care needs, marketing becomes a form of providing consumers with information that they need to make those choices, and restrictions on advertising can be portrayed as harming consumer autonomy. The role of the physician as the gatekeeper of information about prescription drugs is inverted by this "consumerist model of health information."[132] In a twist of the law, pharmaceutical companies are able to market directly to consumers while at the same time relying on the learned intermediary doctrine in case law, which assumes that physicians are playing a gatekeeper role, to limit (although not remove) their duty to warn consumers of the harms attached to the products they are selling. A number of commentators have called for restrictions or even a prohibition on DTC advertising of prescription drugs to consumers, but efforts to increase restrictions on pharmaceutical advertising have been met with increasingly successful First Amendment challenges.[133]

Limiting Legal Liabilities Pharmaceutical companies often find themselves in court in a defensive mode, defending against claims of fraud, false claims, misrepresentation, failure to warn, and—as in the case of the opioid litigation—general nuisance claims. They are among the many corporate actors seeking tort

130 C. Lee Ventola, *Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic*?, 36 PHARMACY & THERAPEUTICS 681 (2011) (describing changes in FDA regulation and changes in direct-to-consumer spending over time).

131 *See, e.g.*, Jeremy Greene & David Herzberg, *Hidden in Plain Sight: Marketing Prescription Drugs to Consumers in the Twentieth Century*, 100 AM. J. PUB. HEALTH 793 (2010); Meredith Wadman, *Drug Ads Move Online, Creating a Web of Regulatory Challenges*, 16 NATURE MED. 22 (2010).

132 *See, e.g.*, Greene & Herzberg, *supra* note 131.

133 *See, e.g.*, Miriam Schuchman, *Drug Risks and Free Speech—Can Congress Ban Consumer Drug Ads?*, 356 NEW ENG. J. MED. 2236 (2007).

reform and encouraging other restrictions on consumer access to the courts. But they also come to court to challenge regulations that impact their sales. Recent challenges include litigation against the Centers for Disease Control (CDC) challenging the process by which they adopted opioid guidelines, litigation against the Department of Health and Human Services (HHS) for requiring drug companies to disclose their prices, and litigation against states that engage in efforts such as ensuring emergency access to insulin stockpiles.

Pricing and Distribution The pricing and distribution systems for pharmaceuticals are complex and opaque, involving a variety of intermediaries, such as pharmacy benefit managers, and a variety of both public payors (including CMS, the Veterans Association, Tricare for military families, state Medicaid, and federal and state health insurance for its employees) and private payors (through employers or private insurers). A number of quasi-governmental actors also play a role in shaping reimbursement systems for prescription drugs, such as the compendia that influence drug use and reimbursement and formularies.[134] The fragmentation and opacity of the system, and the number of intermediaries existing between the manufacturer of drugs and the patient, makes it difficult to regulate drug pricing.

Influencing Legislators While much of the pharmaceutical capture involves industry influence outside of lawmaking, pharmaceutical companies also spend a great deal of time and money on efforts to influence legislators.[135] Industry influence on lawmaking occurs both through direct mechanisms, such as lobbying, and indirect mechanisms, such as making campaign contributions to lawmakers seeking re-election, supporting patient advocacy groups that can attract policy attention, and providing lucrative job opportunities for government actors when they retire from political roles. Beginning with direct efforts at lobbying, the pharmaceutical industry has by some accounts contributed almost $2.5 billion to lobbying and funding members of Congress over the past decade,[136] and it remains

134 *See, e.g.*, *Policy Primers: Prescription Drug Pricing and Consumer Costs*, HEALTH AFFS. (Sept. 14, 2017), https://www.healthaffairs.org/do/10.1377/hblog20170914.061983/full ("Formularies are tools used by purchasers to limit drug coverage based on favorable clinical performance and relative costs.").

135 *See, e.g.*, Olivier J. Wouters, *Lobbying Expenditures and Campaign Contributions by the Pharmaceutical and Health Product Industry in the United States, 1999-2018*, 180 JAMA INTERNAL MED. 688 (2020) (examining the magnitude of industry spending on campaign contributions and lobbying over time; identifying industry influence as a concern); Karl Evers-Hillstrom, *Big Pharma Continues to Top Lobbying Spending*, OPENSECRETS (Oct. 25, 2019, 3:42 PM), https://www.opensecrets.org/news/2019/10/big-pharma-continues-to-top-lobbying-spending; Lev Facher, *Pharma Is Showering Congress with Cash, Even as Drug Makers Race to Fight the Coronavirus*, STAT (August 10, 2020), https://www.statnews.com/feature/prescription-politics/prescription-politics ("[P]harma's giving underscores the breadth of its influence and its efforts to curry favor through lobbying and donations to the lawmakers who regulate health care.").

136 *See, e.g.*, Chris McGreal, *How Big Pharma's Money—And Its Politicians—Feed the U.S.*

the top lobbying force in Washington.[137] The pharmaceutical lobby has about two lobbyists for each member of Congress,[138] many of whom are former members of government.[139] The pattern of giving generally aligns with the power that legislators have or are likely to have, including greater giving to the party in power, greater giving to those in leadership roles, and greater attention to those with jurisdiction over issues relevant to the pharmaceutical industry.[140] Lobbying efforts are often successful in watering down or even preventing the passage of legislation that goes against industry interests, as can be seen by the pattern of industry pressure followed by industry-friendly modifications to legislation and even by the absence of meaningful legislation on hot-button issues such as drug pricing.[141] The tightly organized and aligned coalitions of industry interests stand in stark contrast to a fractured and fragmented Congress, where there are many different opinions about what aspects of health care are problematic and about how best to respond to these problems. [142]

Utilizing Patient Groups to Influence Regulation In addition to direct

Opioid Crisis, GUARDIAN (October 19, 2017, 6:00 AM EDT), https://www.theguardian.com/us-news/2017/oct/19/big-pharma-money-lobbying-us-opioid-crisis ("Nine out of 10 members of the House of Representatives and all but three of the US's 100 senators have taken campaign contributions from pharmaceutical companies seeking to affect legislation on everything from the cost of drugs to how new medicines are approved.").

137 *See, e.g.*, Evers-Hillstrom, *supra* note 135; *see also* Elizabeth Lucas & Sydney Lupkin, *Pharma Cash to Congress*, KAISER HEALTH NEWS (May 22, 2020), https://khn.org/news/campaign (tracking how much pharmaceutical companies contribute to members of Congress).

138 McGreal, *supra* note 136.

139 *See* Sydney Lupkin, *Big Pharma Greets Hundreds of Ex-Federal Workers at the "Revolving Door*," GUARDIAN (Jan. 25, 2018), https://khn.org/news/big-pharma-greets-hundreds-of-ex-federal-workers-at-the-revolving-door/.

140 *See, e.g.*, Emmarie Huetteman & Sydney Lupkin, *Drugmakers Funnel Millions to Lawmakers; A Few Dozen Get $100,000-Plus*, KAISER HEALTH NEWS (Oct. 16, 2018), https://khn.org/news/drugmakers-funnel-millions-to-lawmakers-a-few-dozen-get-100000-plus.

141 *See, e.g.*, Jonathan H. Marks, *Lessons from Corporate Influence in the Opioid Epidemic: Toward a Norm of Separation*, 17 J. BIOETHICAL INQUIRY 173 (2020) (discussing corporate influence over legislators and policymakers); Michelle M. Mello, Sara Abiola & James Colgrove, *Pharmaceutical Companies' Role in State Vaccination Policymaking: The Case of Human Papillomavirus Vaccination*, 102 AM. J. PUB. HEALTH 893 (2012) (documenting industry influence over legislation to support uptake of new vaccines); John Morgan, *A Bitter Pill: How Big Pharma Lobbies to Keep Prescription Drug Prices High*, CITIZENS FOR RESP. & ETHICS IN WASH. (June 18, 2018), https://www.citizensforethics.org/reports-investigations/crew-reports/a-bitter-pill-how-big-pharma-lobbies-to-keep-prescription-drug-prices-high (report documenting industry influence over legislation targeting prescription drug prices, includes case studies such as legislation limiting ability of government to negotiate price for drugs purchased under Medicare Part D and industry efforts to extend orphan drug designations and exclusivities); *see also* sources cited *supra* note 135 (exploring financial influence of pharmaceutical industry over legislators).

142 *See, e.g.*, Florko & Facher, *supra* note 18 ("Pharma's savvy lobbying and campaign contributions don't account for everything—by pure luck, industry has benefited from a fractured Congress and often-chaotic White House.").

contributions and lobbying, pharmaceutical companies engage in indirect efforts to influence legislation through charitable donations and other support for patient advocacy groups.[143] Patient advocacy organizations, nonprofit organizations that focus on combating a particular disease or disability or improving the life of a particular patient group, can and do play influential roles in health policy. The agendas of the patient advocacy organizations are often heavily influenced by their industry funders.[144] Some pharmaceutical companies provide millions of dollars to patient advocacy groups, many of which are comprised of patients who depend upon the products made by these companies.[145] In some cases pharmaceutical companies provide resources to encourage and train patients to participate in legislative advocacy, including providing testimony and exerting political pressure.[146] One study found that 83% of the 104 largest patient advocacy organizations receive financial support from the pharmaceutical industry, and suggested that smaller patient advocacy organizations are likely to be even more dependent on pharmaceutical funding.[147]

Political Expenditures The pharmaceutical industry also makes often secretive contributions to organizations that themselves engage in efforts to sway legislation through carefully crafted campaigns.[148] This allows companies and industry groups to take a neutral policy position publicly while advancing a private agenda. As one example, the Pharmaceutical Research and Manufacturers of America (PhRMA) publicly adopted a neutral position on the Affordable Care Act

143 *See, e.g.*, Emily Kopp et al., *Pre$cription for Power: Investigating the Relationships Between Patient Advocacy Groups and Big Pharma*, KAISER HEALTH NETWORK, https://khn.org/patient-advocacy ("[P]atient advocacy groups [are] IRS-registered nonprofits devoted to assisting patient populations with a particular disease, disability or condition beyond simply providing services or care." This includes groups that provide financial assistance with co-pays.).

144 *See, e.g.*, Sarah Jane Tribble, *Drugmakers Help Turn Patients with Rare Diseases into D.C. Lobbyists*, KAISER HEALTH NEWS (Apr. 10, 2017) hts://khn.org/news/drugmakers-help-turn-patients-with-rare-diseases-into-d-c-lobbyists (exploring conflicts of interest inherent in industry-supported patient advocacy groups that lobby for legislation that is desired by their industry supporters).

145 *See, e.g.*, Rick Claypool, *Patients' Groups and Big Pharma*, PUB. CITIZEN (Aug. 4, 2016) https://www.citizen.org/wp-content/uploads/patients-groups-and-big-pharma-money-report.pdf; Kopp et al., *supra* note 143.

146 *See, e.g.*, Tribble, *supra* note 144.

147 *See, e.g.*, Matthew S. McCoy et al., *Conflicts of Interest for Patient-Advocacy Organizations*, 376 NEW ENG. J. MED. 880 (2017) (seeking to quantify industry financial support for patient advocacy groups and to identify conflicts of interest)

148 *See, e.g.*, Jay Hancock, *Drug Trade Group Quietly Spends "Dark Money" to Sway Policy and Voters*, KAISER HEALTH NEWS (July 30, 2018), https://khn.org/news/drug-trade-group-quietly-spends-dark-money-to-sway-policy-and-voters (discussing the role of dark money, money funneled in non-transparent ways to non-profits focused on a particular agenda designed to influence politics; arguing that such groups have thrived since the Supreme Court's decision in Citizens United, which loosened rules for corporate political spending, along with limited enforcement of the remaining rules by the IRS).

while at the same time providing more than $6 million to the American Action Network to support its efforts to put an end to the Affordable Care Act through ad campaigns and other measures.[149]

The Revolving Door The impact of the "revolving door," in which government employees subsequently find well-paid private employment in the industries they used to regulate, sometimes moving back and forth between the two sectors, is important but difficult to quantify.[150] The practice of hiring federal employees directly from agencies, particularly those involved in regulating the industry, is widespread. Although there are limitations in place designed to reduce conflicts of interest, such as a lifetime restriction on working on matters handled while in government, and a two-year ban on switching sides on a broader range of matters, in reality the practice reduces the manpower of regulators and increases industry access to the regulators still in power.[151] Knowing this opportunity exists may impact the regulators, and once they enter private practice they bring their knowledge of enforcement strategies and their pre-existing relationships with coworkers to enhance industry-regulator relationships.

Limiting Enforcement Other parts of the regulatory strategy over the product life cycle involve capture of enforcers, such as the DEA (for controlled substances), the FTC for consumer protection and antitrust issues, and federal and state attorneys general seeking to protect consumers and the public health. The FTC is charged with protecting consumers by stopping unfair, deceptive, or fraudulent practices, such as misleading pharmaceutical advertising. The DEA is charged with enforcing U.S. controlled substance laws and regulations, including rules pertaining to the manufacture, distribution, and dispensing of legally produced controlled substances such as opioids. Federal and state attorneys general play an enforcement role through their ability to take measures such as litigating to protect the public health.

In Sum: Capture Over the Product (and Profit) Lifecycle While this product life cycle framework of pharmaceutical company influence over market structure is incomplete, it provides the outline of what a systemic view of regulation needs to encompass. As soon as a pharmaceutical company contemplates a new product,

149 *Id.*

150 *See, e.g.*, Karen Hobert Flynn, *For Big Pharma, The Revolving Door Keeps Spinning*, HILL (July 11, 2019, 2:30 PM EDT), https://thehill.com/blogs/congress-blog/politics/452654-for-big-pharma-the-revolving-door-keeps-spinning; Sheila Kaplan, *From FDA Expert to Biotech Insider: The Drug Industry Thrives on the Revolving Door*, STAT (Sept. 27, 2016), https://www.statnews.com/2016/09/27/fda-biopharama-revolving-door-study (discussing implications of the revolving door between FDA and the biopharma industry); Morgan, *supra* note 141 (discussing how the pharmaceutical industry leverages the revolving door between government agencies and lobbying firms and the appointment of former pharmaceutical lobbyists to key government positions to influence policy and provides examples).

151 *See supra* note 150 and accompanying text.

or even before, all stages of the product life cycle become opportunities for influencing the future profit trajectory of not only the new product, but also existing and future related products and services. The sale of opioids, for example, ended up creating new opportunities for the companies selling opioids to later market drugs to treat overdosing and addiction.[152] The following case study provides a concrete illustration of pharmaceutical capture across the product and market life cycle at work, highlighting the ways in which pharmaceutical companies have sought to harness every part of this framework in their pursuit of profitable drug opportunities.

II. A CASE STUDY OF CAPTURE: OPIOIDS AND THE BUSINESS OF PAIN

"It is a story of how the most ancient painkiller known to humanity has emerged to numb the agonies of the world's most highly evolved liberal democracy . . . . And to meet that pain, America's uniquely market-driven health-care system was more than ready." – Andrew Sullivan[153]

"There's no question that Covid-19 is a deadly plague, with more than 90,000 deaths in the U.S. since January 2020. [But] [o]pioids are equally deadly, with approximately 450,000 lives lost to taking opioids between 1999 and 2017. In 2018 alone, there were 67,367 deaths involving opioids . . . ." – David A. Patterson Silver Wolf[154]

Although attention has now been diverted to the pandemic caused by the rapid spread of COVID-19, the United States remains in the midst of a public health epidemic of its own creation, an opioid epidemic with its roots in the over-production, over-prescription, and abuse of prescription opioids.[155] These are drugs that have been developed through the direct and indirect use of publicly funded research, incentivized by government grants of patents, data and market

152 *See, e.g.*, David Armstrong, *Facing Blame for Seeding the Opioid Crisis, Purdue Explored Its Next Profit Opportunity—Treating Addition*, STAT (Jan. 30, 2019), https://www.statnews.com/2019/01/30/purdue-pharma-oxycontin-maker-explored-addiction-treatment.

153 Andrew Sullivan, *The Poison We Pick*, N.Y. MAG. (Feb 20, 2018), http://nymag.com/daily/intelligencer/2018/02/americas-opioid-epidemic.html.

154 David A. Patterson Silver Wolf, *Real-Time Data Are Essential for Covid-19. They're Just as Important for the Opioid Overdose Crisis*, STAT (May 20, 2020), https://www.statnews.com/2020/05/20/real-time-data-essential-for-opioid-overdose-crisis-as-for-covid-19 (arguing for the importance of making real time data about the opioid epidemic available).

155 *See, e.g.*, Tanya Albert Henry, *How to Reignite the Fight Against the Nation's Opioid Epidemic*, AMA (June 23, 2020), https://www.ama-assn.org/delivering-care/opioids/how-reignite-fight-against-nation-s-opioid-epidemic (discussing the AMA's concern that the already-growing opioid epidemic will be worsened by Covid-19).

exclusivities, subject to government approval and oversight, prescribed by state-licensed physicians, monitored by federal agencies, and paid for by public programs and highly regulated private insurers. The consequences of the broad availability and professionally sanctioned use of prescription opioids are widespread and the economic and social costs immense.[156]

Although the opioid epidemic has only recently been declared a public health emergency, the epidemic is not new, and this is not even the first time that the United States has experienced a crisis of opioid overuse.[157] After a brief look at the earlier epidemic, this Part shows how the modern opioid epidemic emerged as the result of an intertwined evolution of medical approaches to treating pain, growth of the business of treating pain, and patient beliefs about the appropriate treatment of pain, an evolution that has been largely influenced by those with the largest financial stakes in opioid prescriptions and sales. Painkillers are one of the most widely prescribed groups of medications in the United States and a big business for industry, with opioid sales reaching $9.6 billion in 2015.[158] While the profits generated by the largest distributors and manufacturers of opioids over the past few decades have been staggering, the social, economic, and human costs of the epidemic have been even more staggering. The CDC estimates "that the total 'economic burden' of prescription opioid misuse alone in the United States is $78.5 billion a year,"[159] and studies continue to emerge documenting the devastating and far-reaching effects of the epidemic on individual lives, public health, and economic and social welfare.[160]

Part III uses the opioid epidemic as a case study to illustrate the theory of pharmaceutical capture at work in part because of its salience and the sheer magnitude of the harms resulting from capture, and in part because of the depth of information that has been made public as a result of subsequent litigation. While the details and nuances of this story may be unique to opioids, the patterns of

156 *See, e.g.*, Chris Christie et al., *The President's Commission on Combatting Drug Addiction and the Opioid Crisis* (Nov. 1 2017), https://www.doh.wa.gov/Portals/1/Documents/2300/2017/PresidentsCommissionOnCombatingDrugAddictionOpioidCrisis.pdf.

157 *See, e.g.*, Jessica Glenza, *America's Opioid Epidemic Began More than a Century Ago—With the Civil War*, GUARDIAN (Dec. 30, 2017, 7:00 AM EST), https://www.theguardian.com/science/2017/dec/30/americas-opioid-epidemic-began-more-than-a-century-ago-with-the-civil-war; Sullivan, *supra* note 153.

158 *See, e.g.*, Matthew Perone & Ben Wieder, *Pro-Painkiller Echo Chamber Shaped Policy Amid Drug Epidemic*, ASSOCIATED PRESS NEWS (Sept. 19, 2016), https://apnews.com/3d257452c24a410f98e8e5a4d9d448a7.

159 Opioid Overdose Crisis, NAT'L INSTITUTION ON DRUG ABUSE (Mar. 11, 2021), https://www.drugabuse.gov/drug-topics/opioids/opioid-overdose-crisis.

160 *See, e.g.*, *Deaths, Dollars, and Diverted Resources: Examining the Heavy Price of the Opioid Epidemic*, AM. J. MANAGED CARE (July 30, 2019), https://www.ajmc.com/publications/supplement/deaths-dollars-diverted-resources-opioid-epidemic (supplement that includes studies of a variety of ways in which the opioid epidemic has caused harm).

relationships, influence, and control that result in capture are far from unique, reflecting a level of industry influence and control that is endemic in the pharmaceutical industry.[161] The following case study thus serves as a stark but useful illustration of pharmaceutical capture and its consequences.

A. Overwriting the Lessons of America's Earlier Opioid Epidemic

"*Three respectable London druggists, in widely remote quarters of London, from whom I happened lately to be purchasing small quantities of opium, assured me that the number of amateur opium-eaters (as I may term them) was at this time immense; and that the difficulty of distinguishing those persons to whom habit had rendered opium necessary from such as were purchasing it with a view to suicide, occasioned them daily trouble and disputes*." – Thomas de Quincy, *Confessions of an English Opium-Eater* (1871)[162]

"Opioids reach every part of society: blue collar, white collar, everybody. It's nonstop. It's every day. And it doesn't seem like it's getting any better." – The Opioid Diaries (2018)[163]

The United States experienced an opioid epidemic in the nineteenth century that left us with a well-documented historical record of the dangers created by the over-prescription and over-use of opioids.[164] This earlier epidemic also prompted a variety of government measures to restrict opioid use, including not only regulations that restricted distribution and increased liability for unauthorized sales and inappropriate prescriptions, but also efforts to alter professional education and training to discourage prescription and efforts to change public norms to discourage use. The effects of these measures persisted well into the twentieth

161 For support of this proposition, see *supra* notes 29-37 and accompanying text and *infra* notes 299-300. *See also* ROSENTHAL, *supra* note 1 (exploring the myriad of ways in which health care has been transformed into a business focused largely on profits, and how this focus has in turn transformed U.S. health care); Marks, *supra* note 141, at 173-74 ("Previous analyses of corporate influence in the pharmaceutical sector make clear that the opioid companies' strategies are not entirely novel . . . These strategies are both extensive and comprehensive, involving webs or networks of relationships with government, the academy, and civil society.").

162 Thomas de Quincy, *Confessions of an English Opium Eater*, LONDON MAG. (Sept. 1821), https://www.gutenberg.org/files/2040/2040-h/2040-h.htm.

163 James Nachtwey, *The Opioid Diaries*, TIME (Feb. 22, 2018), https://time.com/james-nachtwey-opioid-addiction-america (quoting Walter Bender, Deputy Sheriff, Montgomery County, Ohio).

164 *See, e.g.*, Erick Trickey, *Inside the Story of America's 19th-Century Opiate Addiction*, SMITHSONIAN MAG (Jan. 4, 2018), https://www.smithsonianmag.com/history/inside-story-americas-19th-century-opiate-addiction-180967673.

century. While the earlier epidemic shares some commonalities with the modern epidemic, however, the nineteenth century "wave of medical opioid addiction" has been described as more accidental than the current epidemic, which according to historian David Courtwright has "a more sinister commercial element to it."[165] Understanding how the modern opioid epidemic emerged despite the lessons of the earlier one is an important part of the story of capture.

Opioids have been used by humans for thousands of years, with early drugs such as opium providing the foundation for later derivatives such as morphine, followed by heroin, and later prescription painkillers such as Vicodin, Percocet, and OxyContin, and finally synthetic drugs like fentanyl and methadone.[166] America's first opioid epidemic dates back more than a century.[167] Physicians then, as now, played a central role by liberally prescribing opioids to their patients, often without a sufficient understanding and appreciation of the risks associated with their use.[168]

Physicians first started providing morphine to their patients as a treatment for pain in the early nineteenth century, a time in which there was no criminal regulation of morphine, heroin, or opium, and opiates could be prescribed by physicians and sold by pharmacists in a largely unregulated market place.[169] Since physicians had few cures available they began to prescribe morphine to treat a wide variety of conditions, ranging from diarrhea to toothaches, and pharmacists were ready and waiting with a variety of morphine and other opioid-based drugs to sell over the counter to any interested customers.[170] While state medical licensing laws gave physicians the authority to write prescriptions, prescriptions were not required and almost any drug could be obtained without one. Two classes of drugs emerged, the first known as "patent medicines" with typically undisclosed ingredients sold under trade names and marketed heavily to consumers for self-medication, and the second group, later referred to as "ethical" drugs by the

165 *Id.*

166 Josh Katz, *Short Answers to Hard Questions About the Opioid Crisis*, N.Y. TIMES (Aug. 10, 2017) https://www.nytimes.com/interactive/2017/08/03/upshot/opioid-drug-overdose-epidemic.html.

167 For a broad discussion of the history of the opioid epidemic see DAVID T. COURTWRIGHT, DARK PARADISE: A HISTORY OF OPIATE ADDICTION IN AMERICA (2001).

168 *Id.*.

169 *See, e.g.*, Jon Kelvey, *How Advertising Shaped the First Opioid Epidemic*, SMITHSONIAN MAG. (Apr. 3, 2018), https://www.smithsonianmag.com/science-nature/how-advertising-shaped-first-opioid-epidemic-180968444.

170 *See, e.g.*, Andrew Kolodny et al., *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, 36 ANN. REV. PUB. HEALTH 559, 561 (2015) ("Nineteenth-century physicians addicted patients—and, not infrequently, themselves—because they had few alternatives to symptomatic treatment."); Kelvey, *supra* note 169; Trickey, *supra* note 164 ("Doctors then, as now, overprescribed the painkiller to patients in need, and then, as now, government policy had a distinct bias . . . .").

American Medical Association, listed in the United States Pharmacopoeia and marketed almost solely to physicians.[171] Morphine, opium, and heroin were often used as secret ingredients in "patent medicines" marketed directly by pharmacists to consumers as solutions to common ailments, even for children.[172] While no prescriptions were necessary for the more potent "ethical" opioid-based drugs, physicians nonetheless played an important role by prescribing these more potent drugs to their patients. Companies ran aggressive advertising campaigns with physicians as their target, including tactics such as placing ads for morphine in medical journals and distributing pamphlets advertising their opioid wares to physicians.[173]

The commonplace, medically accepted use of morphine and opium powders by physicians in quantities sufficient to create risks of addiction, along with heavy use of opioids by the large number of veterans returning from the Civil War, contributed to an opioid epidemic in the late nineteenth century that impacted an estimated 1 in every 200 Americans.[174] In the wake of this epidemic, efforts were taken to change how medical providers and the public viewed the medical use of narcotics, physicians were trained to limit their use of opiates, states passed laws restricting the sale of opiates without a valid prescription, and federal legislation was enacted regulating the marketing and later pre-market approval of these drugs.

Although there was pushback from drug companies that profited from wholesale trade in narcotics and although the use of narcotics as part of medical practice persisted, a more restrictive narcotics policy and professional practice ultimately took root. Federal legislation designed to control the availability and use of opioids was passed in 1906, 1909, 1914, and 1924.[175] In 1908, President Roosevelt appointed as the first U.S. opium commissioner a physician, Dr. Hamilton Wright, who viewed opium and morphine as a "national curse" and saw little room for opioids as a part of legitimate medical practice.[176] The Harrison Narcotic Control Act was passed in 1914 as a complex compromise among competing interests, requiring anyone engaged in the sale or distribution of narcotics to register with the government, pay a tax, and keep detailed records of

171 *See* Julie Donohue, *A History of Drug Advertising: The Evolving Roles of Consumers and Consumer Protection*, 84 MILBANK Q. 659, 664-665 (2006).

172 *See, e.g.*, Kelvey, *supra* note 169.

173 *See, e.g.*, David T. Courtwright, *Preventing and Treating Narcotic Addiction—A Century of Federal Drug Control*, 373 NEW ENG. J. MED. 2095 (2015).

174 *See, e.g.*, Trickey, *supra* note 164.

175 *See, e.g.*, Richard D. deShazo et al., *Backstories on the U.S. Opioid Epidemic. Good Intentions Gone Bad, an Industry Gone Rogue, and Watch Dogs Gone to Sleep*, 131 AM. J. MED. 595 (2018).

176 *See, e.g.*, Chris McGreal, *The Making of an Opioid Epidemic*, GUARDIAN (Nov. 8, 2018, 1:00 AM EST) https://www.theguardian.com/news/2018/nov/08/the-making-of-an-opioid-epidemic.

transactions in narcotics open to government inspection.[177] Among other things, this Act made narcotics available only by prescription, turning physicians into gatekeepers of medical access to these drugs.[178] These changes in federal policy towards narcotics, along with efforts to change social and medical norms, acted as deterrents to opioid prescription and use.[179]

These efforts proved successful in addressing the epidemic and curtailing opioid use for quite some time, the effects persisting well into the 1960s. But then things began to change. "American narcotic policy from the early 1920s until the middle 1960s had two key objectives: the quashing of legal maintenance and the suppression of illicit narcotic transactions through vigorous police enforcement. What has happened since then has been a qualified abandonment of the first goal, but not of the second." [180] This shift in narcotic policy has its roots in the entrepreneurial efforts of companies who glimpsed the market potential for using opioids to treat pain.

B. The Co-Evolution of the Treatment of Pain and the Business of Pain

"It is hard to fathom, and bitterly ironic: the depth of the suffering caused by drugs whose ostensible purpose is to alleviate pain." – The Opioid Diaries[181]

The market for all kinds of prescription drugs expanded in the 1950s as a combined result of new pharmaceutical products, a rise in health care consumption, and federal legislation requiring a prescription for the sale of pharmaceuticals.[182] The market for prescription opioids as a treatment for acute pain also expanded, as the idea of pain as a legitimate medical condition in need of treatment became more widely accepted.[183] By 1980, acute pain was treated with opioids so often that the opioid propoxyphene was the second-most dispensed drug in the United States.[184] But even then, the use of prescription opioids remained limited primarily to the treatment of acute pain and to patients suffering from advanced cancer and

177 *See, e.g.*, David T. Courtwright, *A Century of American Narcotics Policy*, *in* 2 TREATING DRUG PROBLEMS: COMMISSIONED PAPERS ON HISTORICAL, INSTITUTIONAL, AND ECONOMIC CONTEXTS OF DRUG TREATMENT (Dean R. Gerstein & Henrick J. Harwood eds., 1992).

178 *See, e.g.*, Chris Elkins, *The Opioid Epidemic: What Caused the Heroin Epidemic*, DRUGREHAB (Jan. 3, 2017) https://www.drugrehab.com/featured/opioid-epidemic-causes.

179 *See, e.g.*, Mark R. Jones et al., *A Brief History of the Opioid Epidemic and Strategies for Pain Medicine*, 7 PAIN THERAPY 13 (2018).

180 *See, e.g.*, Courtwright, *supra* note 177.

181 Nachtwey, *supra* note 163.

182 *See, e.g.*, Greene & Herzberg, *supra* note 131.

183 *See, e.g.*, Jones et al., *supra* note 179.

184 *See, e.g.*, Nabarun Dasgupta et al., *Opioid Crisis: No Easy Fix to Its Social and Economic Determinants*, 108 AM. J. PUB. HEALTH 182 (2018) (emphasizing the need to look to structural and social determinants of health framework to shape effective interventions).

other terminal conditions. Concerns about the addictive properties of opioids and fear of liability attached to overprescribing continued to limit more expansive prescribing of opioids. It took the efforts of some entrepreneurial businessmen targeting their efforts at every part of the life cycle of opioid products—from ideas about how to treat pain all the way through to post-sale strategies for limiting enforcement efforts and product liability—to overcome these concerns and fuel the market for opioid products that they were ready to provide.

1. Commercial Construction of the Science of Pain and Addiction

"What is the purpose of publications? . . . [The] purpose of data is to support, directly or indirectly, the marketing of our product." – taken from a Pfizer sales document[185]

Beginning in the 1980s, the ways in which doctors were trained and expected to treat pain and general public perceptions about what kinds of pain necessitated treatment began to shift. While the shift may have begun at least in part as a response to concerns about the undertreatment of pain, it was magnified by a small but growing number of companies that saw the opportunity to make money from the treatment of pain.[186] Leading the charge in this effort to transform the treatment of pain, and therefore the market for opioids, was a now infamous company called Purdue Pharma.[187]

Purdue Pharma began a campaign to implant two ideas into the medical marketplace—the idea that health care providers were not adequately addressing the pain suffered by their patients, and the idea that opioids could be used to treat pain without causing addiction.[188] The claim that opioids were not that addictive was introduced into medical discourse in 1980 with the publication of a five-sentence letter to the editor in the *New England Journal of Medicine* that suggested low rates of addiction among a sample of hospitalized patients who received at least one dose of narcotics.[189] The letter provided no evidence to back up its claims

185 Barton Moffatt & Carl Elliott, *Ghost Marketing: Pharmaceutical Companies and Ghostwritten Journal Articles*, 50 PERSPS. BIOLOGY & MED. 18 (2007) (examining the harmful effects of ghostwriting medical articles as a pharmaceutical marketing tool).

186 *See, e.g.*, Sarah DeWeerdt, *Tracing the U.S. Opioid Crisis to Its Roots*, NATURE (Sept. 11, 2019), https://www.nature.com/articles/d41586-019-02686-2.

187 *See, e.g.*, Sari Horwitz et al., , *Inside the Opioid Industry's Marketing Machine*, WASH. POST (Dec. 6, 2019), https://www.washingtonpost.com/graphics/2019/investigations/opioid-marketing (using evidence from unsealed court documents to show the role of Purdue Pharma in using aggressive and often misleading marketing to grow the market for opioids as a treatment for pain).

188 *See, e.g.*, *Ed. Bd.*, *An Opioid Crisis Foretold*, N.Y. TIMES (Apr. 21, 2018), https://www.nytimes.com/2018/04/21/opinion/an-opioid-crisis-foretold.html.

189 Jane Porter & Hershel Jick, *Addiction Rare in Patients Treated with Narcotics*, 302 NEW ENG. J. MED. 123, 123 (1980) (letter to the editor that reported that only 4 out of 11,882 hospitalized people given opioids became addicted, offered without supporting evidence, concluded that "despite

and, indeed, did not purport to be a controlled study, yet through the promotional efforts of companies like Purdue Pharma it became the basis for subsequent widespread industry claims that opioids were safe if properly managed. A bibliometric study of this letter mapped the subsequent pattern of heavy citing of the letter as "scientific" support for the broad claim that the long-term use of opioids was rarely associated with addiction.[190] A later paper describing the treatment of thirty-eight patients with chronic pain, also anecdotal in nature, published in the medical journal *Pain* in 1986 concluded that opioids could be safely prescribed even on a long-term basis.[191] This study also became widely relied upon. "The scientific background for the use of opioids for non-malignant pain was therefore not based upon any demonstrable outcomes or safety studies."[192] The 1986 paper was co-authored by a leading pain authority, Dr. Russell Portenoy, who soon became one of the pharmaceutical industry's highly compensated key "thought leaders" on the use of opioids to treat nonacute pain. Despite the lack of solid scientific foundation, these early papers became the basis for a marketing campaign by opioid producers designed to convince physicians that prescription opioids were safe and effective to treat chronic pain.

Building on this frail and faulty "scientific" foundation, companies with vested interests in growing the market for opioids played an active role in establishing additional "studies" and papers to bolster the belief among many physicians that there was little risk of addiction or even abuse associated with the use of prescription opioids to treat pain.[193] The pharmaceutical industry role in shaping medical discourse on opioids continued to evolve well beyond the use of these existing early "studies." Pharmaceutical companies used practices such as medical ghostwriting, in which they would hire a medical writer or medical communications company to write a paper favorable to their product and then secure doctors or academics as "authors" of the articles, which would then be published in medical journals.[194] Ghostwriting was used to proliferate the

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widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction").

190 Pamela T.M. Leung, Erin M. Macdonald, Irfan A. Dhalla & David N. Juurlink, *A 1980 Letter on the Risk of Opioid Addition*, 376 NEW ENG. J. MED. 2194 (2017).

191 *See, e.g.*, Kolodny et al., *supra* note 170. The paper cited was Russell K. Portenoy & Kathleen M. Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases*, 25 PAIN 171 (1986).

192 *See, e.g.*, Jones, Viswanath, Peck, Kaye, Gill & Simopoulos, *supra* note 179.

193 *See, e.g.*, William C. Becker & David A. Fiellin, *Limited Evidence, Faulty Reasoning, and Potential for a Global Opioid Crisis*, 358 BRIT. MED. J. 3115 (2017); Sonia Moghe, *Opioid History: From 'Wonder Drug' to Abuse Epidemic*, CNN (Oct. 14, 2016, 6:41 AM EDT), https://www.cnn.com/2016/05/12/health/opioid-addiction-history/index.html.

194 *See, e.g.*, Adriane Fugh-Berman, *The Corporate Coauthor*, 20 J. GEN. INTERNAL MED. 546 (2005); Sergio Sismondo, *Ghost Management: How Much of the Medical Literature Is Shaped Behind the Scenes by the Pharmaceutical Industry?*, 4 PLOS MED. 1429 (2007).

publication of studies dismissing the addictive nature of opioids and promoting their benefits. In addition to ghostwriting, pharmaceutical companies used their control over unpublished information relevant to opioids to control medical and public understandings about opioids. This selective disclosure of information extended to clinical testing, influencing the design of clinical studies, and the selective disclosure of results.[195]

The message that opioids were not addictive was accompanied by the promotion of work emphasizing the undertreatment of pain. By 1990, medical attention had focused on the undertreatment of chronic pain, which remains among the most common reasons for seeking medical attention.[196] The Institute of Medicine noted an increased prevalence of reported chronic pain, attributing it to factors such as greater patient expectations for pain relief, obesity, musculoskeletal disorders in an aging population, increased frequency and complexity of surgery, and greater survivor rates after injury and cancer.[197] Instead of expanding access to time-consuming and often expensive behavioral pain therapy approaches, the health care response was largely to increase the prescription of opioids for chronic pain.[198]

The national shift towards broad prescribing of opioids thus began with the systematic marketing of the idea that opioids might be safer and less addictive than previously thought. This marketing campaign, which was driven by opioid manufacturers and distributors, involved the financial support and use of questionable research and the misinterpretation and misstatement of results to influence physician attitudes towards the prescription and use of opioids.[199]

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195 Regulatory failures by the FDA, including inadequate oversight of the approval process for opioids, have been exposed in subsequent government reports. In 2017 the President's Commission on Combatting Addiction and the Opioid Crisis found that the epidemic was caused in part by inadequate FDA oversight, including failures to obtain adequate evidence of effectiveness before approving new opioids. Christie et al., *supra* note 156; *see, e.g.*, Andrew Kolodny, *How FDA Failures Contributed to the Opioid Crisis*, 22 AMA J. ETHICS 743 (2020).

196 *See, e.g.*, Gery P. Guy et al., *Vital Signs: Changes in Opioid Prescribing in the United States, 2006-2015*, CTRS. FOR DISEASE CONTROL & PREVENTION (July 7, 2017), https://www.cdc.gov/mmwr/volumes/66/wr/mm6626a4.htm.

197 *See, e.g.*, Dasgupta et al., *supra* note 184.

198 For a discussion of why alternative non-opioid treatments may have failed to emerge, see, for example, Hemel & Ouellette, *supra* note 28 (explaining how the IP incentive structures in place may have failed to facilitate investments in non-addictive treatments, and how these disincentives were compounded by other regulatory shortcomings). For suggestions of how industry may have influenced this shift away from the development of non-addictive alternative treatments, see, for example, Marks, *supra* note 141.

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

2. Pain Associations as Corporate Partners

"Our goal is to bind these organizations more closely to us than heretofore, but also to align them with our expanded mission and to see that the fate of our product(s) are inextricably bound up with the trajectory of the pain movement." – Purdue President Richard Sackler, in a 2001 internal email conversation about meeting with patient-advocacy groups[200]

As part of their campaign to encourage the use of opioids for long-term chronic pain, pharmaceutical companies funded and sometimes even created professional and patient pain advocacy groups, such as the American Pain Foundation and American Pain Society (APS), to serve as "fronts" for pharmaceutical lobbying and promotional efforts.[201] As documented in a recent report by former Missouri Senator Claire McCaskill, these groups became involved in issuing guidelines that minimized the risks of addiction, lobbying against laws aimed at curbing opioid abuse, and even protecting doctors sued for overprescribing painkillers.[202]

Professional organizations such as the APS, formed in 1977, became actively involved in encouraging more aggressive treatment of pain in the 1990s with a campaign to reduce what was seen by some physicians as the underassessment and undertreatment of pain.[203] APS published guidelines that encouraged doctors to expand their use of narcotics to treat pain in 1995, and in 1996 it established the pain as the "Fifth Vital Sign" campaign to publicize its guidelines.[204] Throughout the 1990s, APS aggressively promoted the concept of pain as a "vital sign" requiring assessment and treatment at the physician's office or after treatment in a hospital.[205] The Joint Commission on Accreditation of Healthcare Organizations (Joint Commission), which controls accreditation of health facilities, followed in 2001 with pain management standards requiring hospitals to measure pain, and the Federation of State Medical Boards not only supplied prescribing guidelines, but also called on the medical boards to penalize physicians for the undertreatment of

200 *See* Julia Lurie, *Unsealed Documents Show How Purdue Created a "Pain Movement,"* MOTHER JONES (Aug. 29, 2019), https://www.motherjones.com/crime-justice/2019/08/unsealed-documents-show-how-purdue-pharma-created-a-pain-movement (quoting Richard Sackler in email obtained as part of Massachusetts litigation against Purdue).

201 *Id.*

202 *See Fueling an Epidemic: A Flood of 1.6 Billion Doses of Opioids into Missouri and the Need for Stronger DEA Enforcement*, U.S. SENATE HOMELAND SEC. & GOVERNMENTAL AFFS. COMM. (2018).

203 *See* N. Levy et al., *"Pain as the Fifth Vital Sign" and Dependence on the "Numerical Pain Scale" Is Being Abandoned in the U.S.: Why?*, 120 BRIT. J. ANAESTHESIA 425 (2018).

204 *Id.*

205 *See, e.g.*, Brian F. Mandell, *The Fifth Vital Sign: A Complex Story of Politics and Patient Car*e, 83 CLEVELAND CLINIC J. MED. 400 (2016).

pain. The Joint Commission adopted standards that required health care organizations under its jurisdiction to "recognize the right of patients to appropriate assessment and management of pain." [206]

The efforts of the APS to encourage the treatment of pain were closely aligned with the aggressive marketing of opioids by companies such as Purdue Pharma, Johnson & Johnson, and Endo Pharmaceuticals, and it received significant funding from opioid manufacturers to support its activities.[207] The now-defunct American Pain Foundation received 90% of its funding in 2010 from the drug and medical device industry, and its board members included those with extensive financial relationships to drug makers.[208] The Joint Commission received financial support for the publication of its pain guidelines, and the Federation of State Medical Boards allegedly accepted money from pharmaceutical companies to produce and distribute aggressive prescribing guidelines for narcotics.[209]

The relationships between professional organizations and industry in this process of establishing guidelines for the treatment of pain have been the subject of increasing public scrutiny as the extensive financial ties between these organizations and opioid manufacturers and distributors have been uncovered.[210] But although many of these pain associations have been discredited and even dissolved, the changes in standards of care that resulted from the activities of these associations have persisted.

3. Recruiting Prescribers

"My viewpoint is that I can have these relationships [and] they would benefit my research mission and to some extent they can benefit my own pocketbook, without producing in me any tendency to engage in undue influence or misinformation."

206 *See, e.g.*, Holcomb B. Noble, *A Shift in the Treatment of Chronic Pain*, N.Y. TIMES (Aug. 9, 1999), https://www.nytimes.com/1999/08/09/us/a-shift-in-the-treatment-of-chronic-pain.html.

207 *See, e.g.*, Gounder, *supra* note 199; *see also* Francie Diep, *Did Researchers Who Seek to Relieve Pain Contribute to the Opioid Epidemic?*, PACIFIC STANDARD (May 2, 2019), https://psmag.com/social-justice/did-researchers-who-seek-to-relieve-pain-contribute-to-the-opioid-epidemic ("A congressional investigation has found that, between 2012 and 2017, the society received more than $960,000 from America's top five opioid manufacturers.")

208 *See, e.g.*, Charles Ornstein & Tracy Weber, *American Pain Foundation Shuts Down as Senators Launch Investigation of Prescription Narcotics*, PROPUBLICA (May 8, 2012, 8:57 PM EDT), https://www.propublica.org/article/senate-panel-investigates-drug-company-ties-to-pain-groups.

209 *See, e.g.*, John Fauber, *Follow the Money: Pain, Policy, and Profit*, MEDPAGE TODAY (February 19, 2012), https://www.medpagetoday.com/Neurology/PainManagement/31256.

210 *See, e.g.*, *HSGAC Minority Staff Report, Fueling an Epidemic, Report 3 (referred to as the* Mckaskill report) at https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20EpidemicA%20Flood%20of%201.6%20Billion%20Doses%20of%20Opioids%20into%20Missouri%20and%20the%20Need%20for%20Stronger%20DEA%20Enforcement.pdf; Ornstein & Weber, *supra* note 208.

– Dr. Russell Portenoy[211]

A sharp increase in the overall number of medical prescriptions for prescription drugs written and dispensed occurred in the mid- to late-1990s, and this increase can be attributed at least in part to aggressive marketing campaigns pursued by pharmaceutical companies with physicians and others with influence over prescription decisions as their target.[212] The relationships between physicians, professional associations representing physicians, and pharmaceutical companies that led to increased prescribing of prescription drugs in general, and of opioids in particular, are elaborate and, by now, well-documented. Looking specifically at opioids, pharmaceutical companies worked with physicians, medical researchers, medical associations, and patient groups to establish pain as a problem that required adequate treatment and opioids as safe and effective treatments.[213] Pharmaceutical companies responded to the business opportunities created by the chronic pain market with a proliferation of both new opioid-based therapies and marketing strategies that included downplaying addiction risks, promoting off-label use, physician kickback schemes to encourage prescriptions in high volumes, and other more indirect forms of encouraging physicians to prescribe opioids.[214]

Direct marketing by pharmaceutical companies to physicians in the United States is not only widespread, but also effective: prescribing rates have been shown to increase in response to even small-scale marketing efforts such as free meals.[215] Opioid manufacturers engaged in particularly aggressive large-scale marketing of opioid products to physicians, first to overcome inhibitions about prescribing opioids outside of cancer and acute pain, and then to encourage larger volumes of prescriptions. Large staffs of sales representatives trained to carry messages about the nonaddictive nature of opioids made thousands of sales calls to physicians and were compensated based on resulting prescription volumes. Compiled data on prescribing behaviors by physicians was used to focus marketing efforts on the highest prescribers, and extra marketing efforts were targeted at states with less stringent prescription controls in place.[216] Recent research has shown that at least

211 *See* Arthur H. Gale, *Drug Company Compensated Physicians Role in Causing America's Deadly Opioid Epidemic: When Will We Learn?*, 113 MO. MED. 244, 248 (2016).

212 Nora D. Volkow, *America's Addiction to Opioids: Heroin and Prescription Drug Abuse*, NAT'L INST. ON DRUG Abuse (May 14, 2014), https://archives.drugabuse.gov/testimonies/2014/americas-addiction-to-opioids-heroin-prescription-drug-abuse.

213 *See, e.g.*, DeWeerdt, *supra* note 186.

214 *See, e.g.*, Dasgupta et al., *supra* note 184 (emphasizing the need to look to structural and social determinants of health framework to shape effective interventions).

215 *See, e.g.*, Colette DeJong et al., *Pharmaceutical Industry-Sponsored Meals and Physician Prescribing Patterns for Medicare Beneficiaries*, 176 JAMA INTERNAL MED. 1114 (2016).

216 *See, e.g.*, Austin Frakt, *Damage from OxyContin Continues to Be Revealed*, N.Y. TIMES (Apr. 13, 2020), https://www.nytimes.com/2020/04/13/upshot/opioids-oxycontin-purdue-pharma.html; Abby E. Alpert et al., *Origins of the Opioid Epidemic and Its Enduring Impacts* (Nat'l Bureau

one in twelve U.S. physicians, and one in five family physicians, received some form of direct marketing for opioids, and that increased industry marketing of opioid products to physicians, ranging from consulting fees and speaker fees to free meals and travel, is associated with higher rates of prescribing opioids and also elevated overdose deaths.[217]

In order to encourage physicians to use opioids widely to treat pain, the pharmaceutical companies had to address concerns about the addictive nature of opioids and questions about their effectiveness as a treatment for long term chronic pain. They also had to ingrain ideas of pain as requiring treatment and opioids as a viable, indeed as the preferred, option into physician standards of patient care. One of the many ways in which they did this was to design and fund medical education for physicians and other health care providers likely to influence prescription volumes. Purdue Pharma alone provided financial support for more than 20,000 pain related educational programs between 1996 and 2002.[218] In roughly the same time period it conducted over forty national pain-management and speaker-training conferences in luxury resorts, all expenses paid, for more than 5,000 physicians, pharmacists, and nurses. From these conferences, Purdue selected and trained "thought leaders" for its speaker bureau. Part of the pharmaceutical marketing strategy involved selecting amenable medical experts as "thought leaders" to provide highly compensated presentations and articles designed to encourage expanded use of prescription opioids to treat pain. The neurologist and pain specialist Dr. Portenoy, once widely respected and known as the "King of Pain," was one of the leading proponents in encouraging the prescription of opioids, providing other physicians with assurances that the risks of addiction were minimal and that the inadequate treatment of pain bordered on medical negligence.[219] As a young doctor, Portenoy had co-authored one of the early papers mentioned, suggesting that opioids could be used more broadly for patients not suffering from cancer. This paper, based on observations from just thirty-eight cases, opened up the door for broader opioid use. Later, Portenoy and his followers were involved in writing articles and giving lectures to the medical community about the safety and effectiveness of narcotics. Portenoy was a director of the American Pain Foundation and President of the APS, and both he and the pain associations he was involved with received millions of dollars from opioid manufacturers and distributors for the promotion of opioids to the medical

of Econ. Rsch., Working Paper No. 26500, 2019).

217 *See, e.g.*, Scott E. Hadland et al., *Association of Pharmaceutical Industry Marketing of Opioid Products with Mortality from Opioid-Related Overdoses*, 2 JAMA NETWORK OPEN 1 (2019).

218 *See, e.g.*, Kolodny et al., *supra* note 170.

219 *See, e.g.*, Gale, *supra* note 211 (describing the relationships between Dr. Portenoy and the pharmaceutical industry and the role he was compensated to play as a thought leader in encouraging opioid use).

community. Many other physicians had similar relationships with opioid manufacturers, receiving various forms of compensation for providing lectures and participating in "pain education" programs. Portenoy, now discredited, admits that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true."[220]

In response to assurances from pharmaceutical companies and their "thought leaders" that patients would not become addicted to opioid pain relievers, and in reaction to the industry-wide adoption of pain as a "fifth vital sign" requiring greater attention, doctors began prescribing opioids at greater rates. It is estimated that the volume of opioids prescribed increased by more than 400% from 1999 to 2010, an increase matched by the increasing number of prescription-drug-related deaths over the same period. This increase occurred despite the fact that there was little change in the pain reported by patients, and was largely attributed to an increase in the use of opioids to treat non-cancer-related chronic pain.[221] By 2013, health care providers were writing nearly a quarter of a billion opioid prescriptions, enough for every American adult to have their own bottle of pills.[222]

Marketing efforts by pharmaceutical companies have been creative, pervasive, constantly changing, and effective. New technologies, such as novel ways of automating health records, have continued to offer the industry opportunities to further its messages. Take, for example, the case of Practice Fusion, a software company offering free ad-supported health records software, which created a health records tool at the request of opioid manufacturers as a way of increasing prescriptions of opioids. The tool, used by physicians, created a pop-up alert upon opening a health record that would ask about a patient's level of pain, followed by a drop-down menu listing a variety of options for treating pain including prescribing opioids, followed by a treatment plan designed to encourage opioid prescriptions.[223]

4. Patents and FDA Approval as Tools to Secure the Market for "Innovative" Opioid Products

In 1987, the FDA approved MS Contin, a morphine-based drug, as the first

220 *See, e.g.*, Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, WALL ST. J. (Dec. 17, 2012, 11:36 AM ET), https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

221 *See* Guy et al., *supra* note 196.

222 Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, CTRS. FOR DISEASE CONTROL & PREVENTION (Mar. 18, 2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

223 *See, e.g.*, Bloomberg, *In Secret Deal with Drugmaker, Health-Records Tool Pushed Opioids to Doctors*, L.A. TIMES (Jan. 30, 2020), https://www.latimes.com/business/story/2020-01-30/health-records-company-pushed-opioids-to-doctors-in-secret-deal.

formulation of an opioid pain medicine that could be dosed every twelve hours instead of more frequently.[224] This was followed by FDA approval of OxyContin, the first formulation of oxycodone that could be dosed every twelve hours, in 1995. OxyContin was billed as an innovation that would offer the benefits of pain relief without the risks of addiction, with its slow-timed release designed to moderate the effects of the drug. The drug was marketed as nonaddictive based on support from Portenoy's study of thirty-eight subjects, with heavy reliance placed on this study to support the message that most patients would not develop addiction from even long-term treatment of pain using this and other opioid medications. Purdue emphasized this innovation of a timed release of oxycodone when securing FDA approval for OxyContin as a new and "safer" drug, an approval based on its claim that the timed release made the drug effective for 12 hours and reduced chances of abuse.[225] Purdue managed to obtain FDA approval for the drug despite the absence of studies showing that the drug was an improvement over existing treatments for pain.[226] The FDA's failure to obtain adequate evidence of safety and effectiveness was not limited to Oxycodone or OxyContin. Indeed, while the full role of the FDA in contributing to the opioid epidemic is still under investigation, evidence of failures in oversight includes a failure to properly enforce marketing regulations, a failure to obtain adequate evidence of long-term safety and effectiveness of opioids, and a failure to manage conflicts of interest. [227]

The new formulation of the drug was also used to obtain patent protection, which could then be used to limit competition.[228] Purdue introduced another new (patented) formulation of the drug that allegedly reduced the risk of abuse in 2010.[229] It has made a number of other slight adjustments to the drug over time, many of the changes directed at extending patent protection for the drug. Through small changes to the chemical structure of the drug to create a slow-release pill,

224 *See Timeline of Selected FDA Activities and Significant Events Addressing Opioid Misuse and Abuse*, FOOD & DRUG ADMIN. (Mar. 30, 2021), https://www.fda.gov/drugs/information-drug-class/timeline-selected-fda-activities-and-significant-events-addressing-opioid-misuse-and-abuse [hereinafter *FDA Opioid Timeline*].

225 *See, e.g.*, Frakt, *supra* note 216.

226 *See, e.g.*, Kolodny, *supra* note 195 (explaining how the FDA failed to require adequate safety and effectiveness data).

227 *See, e.g.*, *id.*; Christie et al., *supra* note 156; *60 Minutes: Did the FDA Ignite the Opioid Epidemic?* (CBS television broadcast Feb. 24, 2019).

228 For a broader discussion of how the opioid crisis is intertwined with intellectual property law, see, for example, Hemel & Ouellette, *supra* note 28.

229 See, e.g., Associated Press, *Revamped OxyContin Was Supposed to Reduce Abuse, But Has It?*, STAT (July 22, 2019), https://www.statnews.com/2019/07/22/revamped-oxycontin-was-supposed-to-reduce-abuse-but-has-it (questioning whether reformulation reduced health risks, although marketing it as such helped sales, and the patent provided additional exclusivity); Amanda D'Ambrosio, *FDA Panel: Reformulated OxyContin Did not Reduce Overall Abuse*, MEDPAGE TODAY (Sept. 11, 2020), https://www.medpagetoday.com/publichealthpolicy/opioids/88583.

Purdue has been able to file new patents for OxyContin thirteen times with the USPTO, extending exclusive rights on the drug all the way to 2030.[230]

Opioid use accelerated rapidly starting with the introduction and heavy marketing of OxyContin.[231] After just a few years, and one of the most aggressive pharmaceutical marketing campaigns ever undertaken for a narcotic pain killer, annual sales of OxyContin reached $1 billion.[232] When approving OxyContin, the FDA believed that this drug would be less susceptible to abuse than prior drugs because of its slow-release properties, but this proved not to be the case. Starting in the 2000s, efforts were made by the FDA and other federal agencies to engage in intra-agency coordination to address the harms from opioid abuse, but these efforts were largely ineffectual. They focused largely on patient education, stronger warnings, and public-private partnerships with pharmaceutical companies designed to establish risk management programs and consumer education programs. Public-private partnerships such as the Analgesic, Anesthetic, and Addiction Clinical Trial Translations, Innovations, Opportunities, and Networks (ACTTION) Initiative, designed to improve clinical studies of pain medicines and promote the development of safer pain medicines, included the very pharmaceutical companies that were marketing (and mismarketing) existing opioids.[233]

5. Corporate Influence Over Standards of Care and Liability

The standard of patient care both influences and is influenced by general medical practices, scientific and medical understandings, legal proceedings and laws that establish or shield doctors from liability, and reimbursement guidelines. Prior to the 1990s, standards of care for the treatment of patients experiencing pain did not include the use of opioids outside of the care of terminally ill cancer patients or use for the treatment of acute pain.[234] Physicians who deviated from these practices risked legal liability.

In the 1990s, as discussed above, physicians and pain advocacy groups,

230 *See, e.g.*, Katherine Ellen-Foley, *Big Pharma Is Taking Advantage of Patent Law to Keep OxyContin from Ever Dying*, QUARTZ (Nov. 18, 2017), https://qz.com/1125690/big-pharma-is-taking-advantage-of-patent-law-to-keep-oxycontin-from-ever-dying.

231 *See, e.g.*, Kolodny et al., *supra* note 170.

232 *See, e.g.*, Barry Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million*, N.Y. TIMES (May 10, 2007), https://www.nytimes.com/2007/05/10/business/11drug-web.html.

233 *See, e.g.*, NAT'L ACADS. OF SCIS., ENG'G & MED., *Public-Private Partnerships to Advance Pain and Opioid Use Disorders Research and Development*, *in* ADVANCING THERAPEUTIC DEVELOPMENT FOR PAIN AND OPIOID USE DISORDERS THROUGH PUBLIC-PRIVATE PARTNERSHIPS: PROCEEDINGS OF A WORKSHOP (2018).

234 *See, e.g.*, Andrew Rosenblum et al., *Opioids and the Treatment of Chronic Pain: Controversies, Current Status, and Future Directions*, 16 EXPERIMENTAL & CLINICAL PSYCHOPHARMACOLOGY 405 (2008).

working closely with and often financed by pharmaceutical companies, began advocating for broader and more aggressive use of pain and pushed for the removal of barriers to the use of opioids to treat pain.[235] These efforts were targeted at getting professional organizations and regulators to change the standard of care for patients experiencing pain. In 1996, the American Academy of Pain Medicine and the APS issued a joint statement that opioids should have a role in the treatment of nonacute pain. According to this statement

> [t]he trend is to adopt laws or guidelines that specifically recognize the use of opioids to treat intractable pain. These statements serve as indicators of increased public awareness of the sequelae of undertreated pain and help clarify that the use of opioids for the relief of chronic pain is a legitimate medical practice.[236]

The HHS responded with Clinical Practice Guidelines for the management of acute pain and cancer pain that included statements that opioids are an essential part of pain management. While opioids had long been classified as controlled substances and liability attached to misuse, states began to pass intractable pain treatment acts that removed the threat of prosecution for physicians who aggressively treated pain with controlled substances.[237]

Thus, "[a]fter 40 years of debate among doctors, medical review boards and law-enforcement officials, state legislatures begun passing laws to shield doctors from being prosecuted for prescribing powerful medications against intractable pain."[238] This change in the law was prompted by changes in medical consensus about the appropriate use of opioids, a consensus that was formed by pharmaceutical companies working closely with pain advocacy groups and physicians who believed that opioids were the appropriate treatment for nonacute pain.[239] In 1998, the Federation of State Medical Boards, also a recipient of

235 *See, e.g.*, deShazo et al, *supra* note 175 (discussing changes in state laws to reduce liability for prescribing opioids in the 1990s).

236 *See* Am. Acad. of Pain Med. and the Am. Pain Soc'y, *The Use of Opioids for the Treatment of Chronic Pain, Consensus Statement*, 6 J. PHARM. CARE PAIN & SYMPTOM CONTROL 97 (1998) ("Our objective is for state policies to recognize but not interfere with the medical use of opioids for pain relief . . . .").

237 *See e.g.*, deShazo et al., *supra* note 175; DeWeerdt, *supra* note 186.

238 *See, e.g.*, Noble, *supra* note 206.

239 *See, e.g.*, Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 AM. J. PUB. HEALTH 221 (2009). For an overview of the ways in which the pharmaceutical companies developed and used relationships with doctors and various professional associations to alter the standard of care in ways that promoted opioid use, see, for example, Elaine Silvestrini, *Profiting from Pain*, DRUGWATCH (Dec. 15, 2017), https://www.drugwatch.com/featured/opioid-crisis-big-pharma.

industry funds, announced a recommended policy reassuring doctors that they would not face regulatory action for their opioid prescriptions provided it was in the course of medical treatment.[240] In 2001, the Joint Commission on the Accreditation of Healthcare Organizations charged with accrediting U.S. hospitals issued new standards requiring hospitals to make the treatment of pain a priority. Going even further, in 2004, the Federation of State Medical Boards, with the support of the Joint Commission, proposed to reverse liability, suggesting that for the first time, state medical boards make undertreatment of pain punishable.[241] Interestingly, by 2004, OxyContin had already become one of the leading drugs of abuse in the United States.[242]

The campaign by pharmaceutical companies and their commercial allies to ingrain the idea of pain as a fifth vital sign and to shift accountability from the over-prescription of opioids to the undertreatment of pain was aimed not just at medical providers, but also at patients. The idea was to make the treatment of pain a part of patient care, to foster patient expectations that pain would be treated, and to evaluate the quality of care based on patient satisfaction with pain treatment. In 2001, the Institute of Medicine issued a report called *Crossing the Quality Chasm: A New Health System for the 21st Century*, which identified six ways in which the quality of medical care, and therefore the patient's experience, needed to improve, using patient satisfaction as a proxy for measuring gains in these areas.[243] This was followed by the creation of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey by the CMS and the Agency for Healthcare Research and Quality, which incorporated patient satisfaction data and functioned as a measure of quality care.[244] Hospitals were required to participate in the HCAHPS under the Deficit Reduction Act of 2005, and "the Patient Protection and Affordable Care Act of 2010 expanded the role of patient satisfaction as a payment incentive by including the HCAHPS Survey scores as a part of the Hospital Value Based Purchasing program."[245] Given the way the scores were calculated, patient perception of pain control had a large impact on

240 *See, e.g.*, Catan & Perez, *supra* note 220.

241 *See, e.g.*, Silvestrini, *supra* note 239.

242 *See, e.g.*, Zee, *supra* note 239; *see also* Theodore J. Cicero et al., *Trends in Abuse of OxyContin and Other Opioid Analgesics in the United States: 2002-2004*, 6 J. PAIN 662 (2005) (study of prevalence and magnitude of abuse of OxyContin and other prescription).

243 *See* INST. OF MED. (U.S.) COMM. ON QUALITY OF HEALTH CARE IN AM., CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY (Nat'l Acads. Press 2001) [hereinafter CROSSING THE QUALITY CHASM].

244 *See, e.g.*, HCAHPS Fact Sheet, CTRS. FOR MEDICARE & MEDICAID SERVS. (Nov. 2, 2017), https://www.hcahpsonline.org/globalassets/hcahps/facts/hcahps_fact_sheet_november_2017.pdf.

245 *See T. Rummans et al., How Good Intentions Contributed to Bad Outcomes, 93 Mayo Clinic Proceedings 344, 347 (2018); see also* HCAHPS: Patient's Perspectives of Care Survey, CMS Fact Sheet at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalHCAHPS.

reimbursement under this purchasing program, and there is evidence that physicians who denied patient requests for opioids received lower scores.[246]

6. Patients as Consumers and The Marketing of Pain

"Convincing people they are sick and need a drug is a multi-billion dollar industry."[247]

The notion that pain needed to be regularly assessed in all patients, and the idea that pain was subjective and thus treatment should be based on self-reporting by the patient, became accepted as part of both the provision and the administration of health care.[248] From there, the treatment of pain became a measure of patient satisfaction, and patient satisfaction became a measure of physician and hospital performance, and that in turn became a determinant of funding.[249] This made the patient, and the patient's expectations about how pain should be treated, a focal point for pharmaceutical companies interested in expanding opioid sales. While early marketing efforts by opioid manufacturers had focused largely (although not exclusively) on physicians or others with prescribing authority and pharmacists, later efforts included substantial investments in marketing to patients, portrayed by the industry as "consumers," a shift discussed at length in Part II in the context of DTC advertising and related marketing by pharmaceutical companies to patients.

C. Legislative Capture

The co-evolution of the treatment of pain and the business of pain described above has been facilitated by pharmaceutical industry influence over legislative and enforcement efforts. According to a study by the Center for Public Integrity and *Associated Press*, participants in the Pain Care Forum, a coalition of industry, professional, and patient advocacy groups that is financed largely by drug companies, spent more than $740 million lobbying federal and state lawmakers on a variety of issues that included opioid-related measures between 2006 and 2015, with an additional $140 million spent on political campaign contributions.[250] "Nine out of 10 members of the House of Representatives and all but three of the US's 100 senators have taken campaign contributions from pharmaceutical companies seeking to affect legislation on everything from the cost of drugs to how new

246 *See, e.g.*, Anthony Jerant et al., *Association of Clinician Denial of Patient Requests with Patient Satisfaction*, 178 JAMA INTERNAL MED. 85 (2018).

247 Llamas, *supra* note 129.

248 *See, e.g.*, Mandell, *supra* note 205.

249 *Id.*; *see also* Levy et al., *supra* note 203 (discusses strategies to encourage treatment of pain through measures such as a campaign to include pain as a fifth vital sign).

250 *See, e.g.*, Perone & Wieder, *supra* note 158.

medicines are approved."[251] The opioid industry, along with its allies, have provided support to as many as 7,100 candidates for state level offices.[252] In addition to campaign contributions, pharmaceutical companies and their industry organization PhRMA funded patient advocacy groups and professional pain advocacy groups that, as described above, acted as powerful advocates for legislation that would enhance the business of pain. There is evidence of states passing laws favorable to opioids based on almost identical legislative language that some legislators said was supplied by the pharmaceutical lobbyists.[253] While this kind of lobbying influences medical and drug policy across the board, the effects of these efforts were particularly stark, and costly, in the case of opioids. Efforts to pass laws to curb the mass prescribing of opioids repeatedly failed over a number of years as drugmakers successfully shifted blame for the rising number of opioid deaths onto the millions who became addicted.[254]

This level of legislative capture became evident in the organized industry response to increased enforcement actions by the DEA. The following story of how the DEA's enforcement efforts were thwarted provides a good illustration of legislative capture at work.

D. Going After the Enforcers

"If there was a terrorist that showed up in Montgomery County today and shot 50 people or 25 or 10 for that matter, this community would be in an uproar. There would be an army here trying to stop it. That's exactly where we are with opioids. But who's showing up to stop it?" – The Opioid Diaries [255]

One of the DEA's tasks is to ensure that legally produced narcotics that are subject to controls on use are not diverted for improper use or illegal purposes.[256] The DEA also has the authority to approve the total amounts of opioids produced each year. Federal law requires manufacturers, distributors, and pharmacies to report each narcotics transaction to the DEA, and this information is stored by the DEA in a database called the Automation of Reports and Consolidated Order

251 *See* McGreal, *supra* note 136.

252 *See Pharma Lobbying Held Deep Influence Over Opioid Policies*, CTR. FOR PUB. INTEGRITY (Sept. 18, 2016), https://publicintegrity.org/politics/state-politics/pharma-lobbying-held-deep-influence-over-opioid-policies.

253 *Id.*

254 *See* McGreal, *supra* note 136.

255 Nachtwey, *supra* note 163 (quoting Bruce Langos, Executive Director, Criminal Intelligence Center, Dayton, Ohio).

256 For an overview of the legal foundation for drug diversion laws and the role of the DEA, see, for example, John J. Mulrooney II & Katherine E. Legel, *Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters*, 101 MARQ. L. REV. 333 (2017).

System (ARCOS). The ARCOS database is designed to track the path of every prescription opioid pill sold in the United States and this database documented the sale of over 76 billion oxycodone and hydrocodone pills between 2006 and 2012[257] and more than 100 billion pills between 2006 and 2014.[258] The manufacture and distribution channels for prescription opioids remained largely concentrated in a small number of companies—with just six companies responsible for distributing three quarters of the pills sold during 2006 to 2012 and just three companies responsible for manufacturing 88% of the pills sold during that period.[259]

In the face of suspicious patterns of wholesale distribution of opioids in the early 2000s, the DEA began to target the largest wholesale companies that were distributing massive amounts of prescription opioids. Among the powers granted to the DEA is the ability to suspend or revoke the licenses of pharmaceutical companies, pharmacies, and doctors permitted to dispense opioids if they fail to comply with federal law. While there were thousands of distributors holding DEA licenses to dispense drugs, the three large distributors—McKesson, AmerisourceBergen, and Cardinal Health—controlled a lion's share of the market, collecting an annual revenue of about $400 billion.[260]

The DEA's Office of Diversion Control responded to evidence of abusive wholesaler practices by pursuing aggressive civil enforcement actions backed by threats of immediate injunctions and financial penalties against wholesalers suspected of over-supplying corrupt pharmacies known as "pill mills" located across the country.[261] This approach was formalized with the launch of the "Distributor Initiative" by the Office of Diversion Control in 2005, a campaign that "pitted the DEA against an industry with close ties to lobbyists, lawyers and politicians." [262] Once this initiative started to raise its sites to the largest three pharmaceutical distributors, the industry response became aggressive. The large

257 Scott Higham et al., *76 Billion Opioid Pills: Newly Released Federal Data Unmasks the Epidemic*, WASH. POST (July 16, 2019, 5:19 PM PDT), https://www.washingtonpost.com/investigations/76-billion-opioid-pills-newly-released-federal-data-unmasks-the-epidemic/2019/07/16/5f29fd62-a73e-11e9-86dd-d7f0e60391e9_story.html.

258 Steven Rich et al., *More Than 100 Billion Pain Pills Saturated the Nation Over Nine Year*s, WASH. POST (Jan. 14, 2020, 4:13 PM PST), https://www.washingtonpost.com/investigations/more-than-100-billion-pain-pills-saturated-the-nation-over-nine-years/2020/01/14/fde320ba-db13-11e9-a688-303693fb4b0b_story.html.

259 *See, e.g.*, Higham et al., *supra* note 257.

260 *See, e.g.*, Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, WASH. POST (Oct. 22, 2016), https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html.

261 *See, e.g.*, Ed. Bd., *Locating Blame in the Opioid Epidemic*, WASH. POST (Oct. 30, 2016), https://www.washingtonpost.com/opinions/is-the-dea-partly-to-blame-for-the-opioid-epidemic/2016/10/30/2fd5dc30-9c78-11e6-b3c9-f662adaa0048_story.html.

262 *See, e.g.*, Bernstein & Higham, *supra* note 260.

distributors and their pharmaceutical manufacturer allies increased their lobbying pressure on the DEA, the DOJ, and members of Congress, urging them to take a softer approach towards enforcement. Many of the lobbyists were former attorneys general, politicians, and even former members of the DEA. Indeed, as DEA enforcement activity increased, so did pharmaceutical industry efforts to hire some of the top DEA officials, particularly those involved in regulating the industry.[263]

The Deputy Attorney General pressured the DEA's diversion chief to limit actions against the industry after a case involving two large drug companies in 2012. Subsequently some DEA officials at the DEA headquarters began delaying and blocking enforcement actions, requiring higher standards of proof to move cases forward. As a result, the number of civil cases filed against wholesalers declined and the pace of enforcement actions slowed. [264] In fiscal year 2011, civil case filings against distributors, manufacturers, pharmacies and doctors had reached 131. By 2014, they had fallen to just forty.[265]

The pharmaceutical industry also engaged in efforts to secure more industry-friendly regulation through support for a bill to limit DEA's enforcement ability by increasing the legal standard for initiating enforcement.[266] Pharmaceutical companies were involved in every step of the legislative process, with evidence to suggest that a drug lobbyist was involved in ghostwriting the original bill, and patients' rights groups that lobbied for support for the legislation were later revealed to have extensive ties to the drug industry.[267] Political action committees funded by the pharmaceutical industry provided the twenty-three lawmakers who supported various versions of this bill with $1.5 million, and the industry spent $102 million to lobby Congress to support this bill and other industry-friendly bills between 2012 and 2014.[268]

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263 *See, e.g.*, Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Cure Opioid Abuse*, WASH. POST (Dec. 22, 2016), https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html (explaining how subsequent to DEA efforts to crack down on opioid distributors in 2005, pharmaceutical companies and their law firms hired at least forty-two DEA officials, of which thirty-one were directly responsible for regulating the industry.)

264 *See, e.g.*, Bernstein & Higham, *supra* note 260.

265 *See, e.g.*, Higham et al., *supra* note 263.

266 *See, e.g.*, Lee Fang, *Opioid Lobbyist Left a Digital Fingerprint on Campaign by "Patient Advocates*," INTERCEPT (Oct. 22, 2017, 5:10 AM), https://theintercept.com/2017/10/22/opioid-lobbyist-left-a-digital-fingerprint-on-a-campaign-by-patient-advocates (describing industry influence over the drafting of the legislation and their strong ties to patient advocacy groups that pressured lawmakers to adopt the legislation).

267 *See, e.g.*, Scott Higham & Lenny Bernstein, *The Drug Industry's Triumph Over the DEA*, WASH. POST (Oct. 15, 2017), https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress; *see also* Fang, *supra* note 266 (describing political influence exerted by the pharmaceutical industry).

268 *See, e.g.*, Higham & Bernstein, *supra* note 267.

Congress ultimately enacted a law, the Ensuring Patient Access and Effective Drug Enforcement Act of 2016, that increased the legal standard for the DEA to initiate civil enforcement actions, further limiting the ability of the DEA to address abuses by opioid wholesalers.[269] This Act modified the Controlled Substances Act to require that the DEA identify "imminent danger to the public health and safety" before suspending registration of a manufacturer, distributor, or dispenser for controlled substances privileges. The law was billed as a way of improving "efforts to fight prescription drug abuse without impeding legitimate patients' access to medication."[270]

Efforts to influence enforcers have not been limited to the DEA. Industry was quick to oppose new more conservative guidelines issued by the CDC in 2016 for prescribing opioids to treat chronic pain, for example, an attack which has continued to take various forms since the issuance of the guidelines.[271] Pharmaceutical companies have also been actively involved in managing the fallout from the state and federal litigation that has gathered steam since the early 2000s, as described below. Efforts such as this to influence legislation and enforcement activity form a core part of the pharmaceutical business model. This idea of legislation as a variable that could be altered when it interfered with sales is illustrated by a 2013 McKinsey & Company consulting report prepared for Purdue Pharma and unearthed during litigation.[272] In this report, McKinsey recommended that "Purdue fight back against efforts by a major pharmacy chain, the Drug Enforcement Agency, and the Department of Justice to stop illegal opioid prescribing . . . . These new rules were cutting into sales of the highest doses, which were also the most profitable . . . ."[273]

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269 Ensuring Patient Access and Effective Drug Enforcement Act of 2016, Pub. L. No. 114-145, 130 Stat. 353 (to be codified at 21 U.S.C. §§ 823(j), 824(c), (d)).

270 For an example of the industry spin on the "Ensuring Patient Access and Effective Drug Enforcement Act" see, for example, *Prescription Drug Abuse Bill Ready to Be Signed into Law*, CHAIN DRUG REV. (Apr. 13, 2016), http://www.chaindrugreview.com/prescription-drug-abuse-bill-ready-to-be-signed-into-law.

271 *See, e.g.*, Ben Goodwin, Judy Butler & Adriane Fugh-Berman, *Industry-Funded Attacks on the CDC's Prescribing Guidelines Are Eroding Public Health*, STAT (June 11, 2019), https://www.statnews.com/2019/06/11/attacks-cdc-opioids-prescribing-guideline.

272 See e.g. M. Forsythe and W. Bogdanich, McKinsey Advised Purdue on How to "Turbocharge" Opioid Sales, Lawsuit Says, New York Times, Feb. 1, 2019 (discusses role of McKinsey in working with Purdue Pharma to promote opioid sales and profits); First Amended Complaint, Commonwealth of Massachusetts vs. Purdue at https://s3.documentcloud.org /documents/5715954/Massachusetts-AGO-Amended-Complaint-2019-01-31.pdf (includes description of McKiney's role in aggressive efforts to expand sales of opioids).

273 Armstrong, *supra* note 152 (describes Purdue's strategies for expanding opioid sales as revealed in court documents, including role of McKinsey in helping Purdue to shape its misleading message for marketing opioids). See also M. Forsythe and W.Bogdanish, McKinsey Settles for Nearly $600 Million Over Role in Opioids Crisis, New York Times, Feb. 3, 2021 at https://www.nytimes.com/2021/02/03/business/mckinsey-opioids-settlement.html (describes

E. Limiting Liability and Profiting from Addiction

"Company documents recommended becoming an 'end-to-end pain provider.'"[274]

Efforts by state and local governments to hold pharmaceutical companies accountable through litigation began as early as 2001, when West Virginia filed a lawsuit against Purdue for its marketing and sales taxes, but Purdue simply paid $10 million to settle the case and moved on.[275] Facing growing controversy as the harms of opioid abuse became evident, Purdue enlisted the help of former New York mayor Rudy Giuliani and his consulting firm in 2002 to help manage these concerns.[276] The FDA issued a warning letter to Purdue for misleading advertising in 2003, but sales of OxyContin continued and a new formulation was approved by the FDA in 2010.[277] Purdue was charged in federal court in 2007 for failing to disclose the risks of addiction that OxyContin posed, and in what would become a string of settlements by opioid manufacturers and distributors, Purdue Pharma and three of its top executives admitted that they had misled the FDA clinicians and patients about the risks of OxyContin by aggressively marketing the drug as a safe alternative to short-acting narcotics to physicians and to patients.[278] This time the company paid $600 million and added warning labels, but sales of opioids continued unabated.[279] Around the same time, a twenty-six-state lawsuit against Purdue led to a settlement of $19.5 million and an agreement by Purdue to limit some of its more controversial sales practices, like paying bonuses to sales representatives based on the volume of OxyContin prescribed. While the total dollar amount may seem high, the penalties are small in comparison to the profits that the companies generated from opioid sales, and can thus be regarded almost like licenses to break the law. It is estimated, for example, that by 2016 Purdue had

McKinsey role in advising Purdue Pharma on how to increase opioid sales and profits). Details of McKinsey's role are included in a complaint filed by the Commonwealth of Massachuetts against Mckinsey at https://www.mass.gov/doc/massachusetts-mckinsey-complaint/download

274 Armstrong, *supra* note 152.

275 *See, e.g.*, Sam Dekin, *The Maker of OxyContin Has a New Way to Profit from the Opioid Crisis*, MISSION HARBOR BEHAV. HEALTH (Oct. 24, 2019), https://sbtreatment.com/blog/oxycontin-maker-update.

276 *See, e.g.*, Erik Ofgang, *Purdue Pharma and OxyContin: A Timeline*, CONN. MAG. (Oct. 24, 2019), https://www.connecticutmag.com/health-and-science/purdue-pharma-and-oxycontin-a-timeline/article_e140534a-f50f-11e9-96ab-8bb2725250e0.html.

277 *See FDA Opioid Timeline*, *supra* note 224.

278 *See, e.g.*, Gounder, *supra* note 199.

279 *See* Rebecca L. Haffajee & Michelle M. Mello, *Drug Companies' Liability for the Opioid Epidemic*, 377 NEW ENG. J. MED. 2301, 2305 (2017) ("Notwithstanding the $600 million federal settlement with Purdue in 2007—one of the largest in history with a drug company—opioid litigation has yet to financially dent the $13-billion-a-year opioid industry. Moreover, opioid litigation victories have all taken the form of settlements, in which companies usually have not admitted any fault.").

earned more than $36 billion in revenue from OxyContin.[280]

Since that time there has been a growing volume of lawsuits brought against pharmaceutical manufacturers like Purdue Pharma and pharmaceutical distributors like McKesson by local and state governments, as well as by the federal government. Hundreds of lawsuits have been filed, with almost every state and many local governments following suit.[281] As the lawsuits accumulated, many were consolidated into one massive multidistrict litigation in the U.S. District Court for the Northern District of Ohio, the largest U.S. civil case in history.[282] Many of these lawsuits continue to wind their way through court in varying forms of consolidation and with varying impact. These cases have demonstrated that the largest distributors of opioids were aware of the volume and distribution patterns of the pills they were selling and that they allowed sales to continue despite persistent indications that the pills were being sold in apparent violation of federal laws and diverted to the black market. [283] Apart from Purdue Pharma, which filed for bankruptcy in 2019 and emerged as a new company promising to devote its profits to addiction treatments and settlement payouts, the pharmaceutical companies and distributors implicated in opioid lawsuits continue to operate.[284]

In addition to limiting their losses and (for the most part) preserving the right to continue to operate, the industry defendants have been able to exercise control over the proceedings in ways that limit public access to important information. One of the key battles that has taken place in civil suits filed by state and local governments against opioid manufacturers and distributors has been the fight over public access to distribution and sales data.[285] The pharmaceutical company defendants, along with the DEA and the DOJ, argued against the public release of

280 *See, e.g.*, Ofgang, *supra* note 276.

281 *See, e.g.*, Higham et al., *supra* note 257 ("America's largest drug companies saturated the country with 76 billion oxycodone and hydrocodone pills from 2006 through 2012 as the nation's deadliest drug epidemic spun out of control, according to previously undisclosed company data released as part of the largest civil action in U.S. history.")

282 *See, e.g.*, Lenny Bernstein & Christopher Rowland, *As Lawyers Zero in on Drug Companies, a Reckoning May Be Coming*, WASH. POST (July 17, 2019, 4:45 PM PDT), https://www.washingtonpost.com/health/as-lawyers-zero-in-on-drug-companies-a-reckoning-may-be-coming/2019/07/17/c634a1bc-a89a-11e9-86dd-d7f0e60391e9_story.html; Scott Higham & Lenny Bernstein, *Drug Makers and Distributors Face Barrage of Lawsuits Over Opioid Epidemic*, WASH. POST (July 4, 2017), https://www.washingtonpost.com/investigations/drugmakers-and-distributors-face-barrage-of-lawsuits-over-opioid-epidemic/2017/07/04/3fc33c64-5794-11e7-b38e-35fd8e0c288f_story.html (stating how dozens of state, county and city governments have brought or have contemplated bringing legal actions against the small number of firms responsible for the largest distributions and sales of opioids.).

283 *See, e.g.*, Higham et al., *supra* note 257 (describing a consolidated civil action that includes nearly 2,000 cities, towns, and counties arguing that approximately twenty drug companies saturated their communities with opioids).

284 *See, e.g.*, Ofgang, *supra* note 276.

285 *See, e.g.*, Rich et al. *supra* note 258.

the DEA database ARCOS, based on company rationales of unfair competitive advantage and DOJ rationales of protecting DEA investigations.[286] The ARCOS database provides what some have characterized as a "virtual road map to the nation's opioid epidemic," with detailed information about every transaction, raising the question of why the DEA and DOJ did not act sooner to intervene.

At the same time that companies involved in the manufacture and distribution of opioids were starting to face liability for the harms arising from the opioid epidemic, some were already exploring new profit opportunities both abroad and in markets to treat addiction. Purdue, for example, began in earnest to pursue the market for addiction in 2014, creating a secret program with the codename Project Tango to explore the business opportunities in the growing market for addiction treatments that the company had helped to create.[287] Starting with one product, Suboxone, Purdue quickly turned its attention to the overdose-reversing agent Narcan as another possible strategic fit. Ultimately, Purdue decided not to acquire the rights to sell either product, although an international affiliate did. In 2018, Richard Sackler, the former chairman and president of Purdue, received a patent for another drug to treat addiction.[288]

Purdue filed for bankruptcy in September 2019, likely at least in part to freeze the thousands of lawsuits filed against the company and to shift the resolution of claims, as well as discussions about limiting future liability, into bankruptcy court.[289] The bankruptcy plan that has emerged more than a year later includes a $10 billion plan to transform the company into a new company with its profits devoted to combatting the opioid crisis, including the creation of trusts to disburse funds to state and local governments and a division to produce treatments for both addiction and overdosing.[290] The proposed plan also includes sweeping releases of the company and Sackler family members from future liability, and while the

286 *See, e.g.*, Higham, Horwitz & Rich, *supra* note 257 ("America's largest drug companies saturated the country with 76 billion oxycodone and hydrocodone pills from 2006 through 2012 as the nation's deadliest drug epidemic spun out of control, according to previously undisclosed company data released as part of the largest civil action in U.S. history.")

287 *See, e.g.*, Armstrong, *supra* note 152.

288 *See, e.g.*, Andrew Joseph, *Richard Sackler, Member of Family Behind OxyContin, Was Granted Patent for Addition Treatment*, STAT (Sept. 7, 2018), https://www.statnews.com /2018/09/07/richard-sackler-member-of-family-behind-oxycontin-was-granted-patent-for-addiction-treatment.

289 *See, e.g.*, Andrew Joseph, *Purdue Pharma Filed for Bankruptcy*, STAT (Sept. 16, 2019), https://www.statnews.com/2019/09/16/if-purdue-pharma-declares-bankruptcy-what-would-it-mean-for-lawsuits-against-the-opioid-manufacturer.

290 See e.g. A. Katersky and M. Deliso, Purdue Pharma Bankruptcy Plan, Which Would Give Sackler Family Immunity, Moves Ahead as Planned, ABC News, June 3, 2021 at https://abcnews.go.com/Business/purdue-pharma-bankruptcy-plan-give-sackler-family-immunity/story?id=78072454. A copy of the Disclosure Statement for the Chapter 11 Plan for Purdue Pharma filed with the bankruptcy court on March 15, 2021 can be found here: https://www.statnews.com/wp-content/uploads/2021/03/purdue-reorg-plan-full-version.pdf

Sackler family has provided almost half of the funds for the new company, they retain billions derived from opioid sales by Purdue and are still faced with the risk of individual civil and criminal liability.[291] The story playing out in the bankruptcy courts for Purdue reflects broader concerns with the ways in which bankruptcy courts have become ways to resolve mass tort liability in a manner favorable to the corporate wrongdoers.[292] Although Purdue, along with two other opioid companies—Mallinkrodt and Insys—are no longer in the business of manufacturing opioids, many other companies continue to engage in the manufacture and sale of opioids. While the settlement amounts that many of these companies have paid to settle opioid litigation may seem large, the amounts pale in comparison with the profits earned, and some of the largest opioid companies have subsequently sought tax breaks for the legal costs they incurred to further soften the financial hit.[293]

F. In Sum: Opioids as An Illustration of Pharmaceutical Capture

When the full extent of corporate influence over all of the key stakeholder groups involved in opioid markets is exposed, it will be hard to understand the evolution of the opioid epidemic as anything other than the result of pharmaceutical capture by companies who saw an opportunity to profit from cultivating the business of pain and growing the market for opioids to treat pain. Companies operating with patent, market, and other forms of regulatory exclusivities over the marketing, distribution and/or sale of opioid products approved by the FDA found ways to ensure the sale of millions of pills via prescriptions from licensed physicians, building their sales pitches upon medical and scientific records they helped to create and satisfying a demand for pain treatment that they helped to grow. Rules governing the use of opioids were either

291 *See, e.g.*, Renae Merle & Lenny Bernstein, *Purdue Pharma's Bankruptcy Plan Includes Special Protection for the Sackler Family Fortune*, WASH. POST (Sept. 18, 2019, 1:38 PM PDT) (detailing the diversion of funds from Purdue to Sackler family accounts and the implications for the bankruptcy plan).

292 Libby Lewis, *The Sackler Family's Bankruptcy Scheme*, AM. PROSPECT (Mar. 31, 2021), https://prospect.org/justice/sackler-familys-bankruptcy-scheme (arguing that the Sacklers are using the bankruptcy plan as a way to evade personal liability, and that this signals a bigger problem with the bankruptcy system—"a sign of how bankruptcy has become the haven for dispensing with the mass torts that come out of mass corporate wrongdoing"); *see also* Jason Mast, *Drowning in Litigation: Mallinkrodt Becomes Third Opioid Producer to File for Bankruptcy*, ENDPOINTS NEWS (Oct. 12, 2020, 8:56 AM EDT), https://endpts.com/drowning-in-litigation-mallinckrodt-becomes-third-opioid-producer-to-file-for-bankruptcy (discusses use of bankruptcy by companies that profited from the opioid epidemic as a tactic to freeze litigation and leave litigants competing with creditors for payouts).

293 *See, e.g.*, Douglas MacMillan & Kevin Schaul, *Drug Companies Seek Billion-Dollar Tax Deductions from Opioid Settlement*, N.Y. TIMES (Feb. 12, 2021), https://www.washingtonpost.com/business/2021/02/12/opioid-settlement-tax-refund.

attacked or turned to advantage, with efforts to transform legal standards and professional guidelines limiting opioid prescriptions into de facto rules to prescribe opioids. Standards of care evolved in response to industry prodding to encourage opioid use, and overuse. Legislative capture was used to tone down enforcement efforts and ramp up prescriptions. The pharmaceutical companies that had helped to create the opioid epidemic were even invited to the table by the NIH to discuss new ideas for public-private partnerships to address the epidemic and develop new treatments for addiction. Companies in the wake of legal battles investigated opportunities to turn their settlement liabilities into tax breaks.

While the case study described above features now infamous actors like Purdue Pharma, many pharmaceutical manufacturers—including not just well-known companies like Johnson & Johnson but also some relatively unknown generic manufacturers, played (and continue to play) active roles in fueling the opioid epidemic.[294] Moreover, pharmaceutical manufacturers were by no means the only actors in this process of pharmaceutical capture—many other corporate actors standing to benefit from growing sales of opioids, either directly or indirectly, also played important roles in fueling opioid prescriptions.[295] These actors, including but not limited to large wholesalers, distributors, and retailers of opioids, also exerted an extensive web of influence over decision makers in the industry in order to obtain their desired outcomes.[296] Professional advisors, such as the management consulting firm McKinsey & Company, recently implicated in the Purdue litigation, assisted with strategies for obtaining desired regulatory environments.[297] Over time the web of stakeholders with commercial interests in growing the opioid market expanded, as described in the case study, to include professional medical associations, patient advocacy groups, and physicians. As lawsuits began to proliferate, the defense bar also benefited.[298]

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294 *See, e.g.*, Aaron C. Davis et al., *Little Known Makers of Generic Drugs Played Central Role in Opioid Crisis, Records Show*, WASH. POST (July 27, 2019, 9:25 AM PDT), https://www.washingtonpost.com/investigations/little-known-generic-drug-companies-played-central-role-in-opioid-crisis-documents-reveal/2019/07/26/95e08b46-ac5c-11e9-a0c9-6d2d7818f3da_story.html ("[R]ecords show that by 2006, as the death rate accelerated, a handful of obscure generic-drug manufacturers were selling the bulk of opioid pills flooding the country.").

295 *See, e.g.*, Marks, *supra* note 141 (describing the multiple industry players implicated in the opioid epidemic).

296 For a discussion of the lawsuits brought against opioid distributors, see, for example, German Lopez, *The Thousands of Lawsuits Against Opioid Companies, Explained*, Vox (Oct. 17, 2019, 6:10 PM EDT), https://www.vox.com/policy-and-politics/2017/6/7/15724054/opioid-epidemic-lawsuits-purdue-oxycontin.

297 *See, e.g.*, Michael Forsythe & Walt Bogdanich, *McKinsey Settles for Nearly $600 Million Over Role in Opioid Crisis*, N.Y. TIMES (Feb. 3, 2021), https://www.nytimes.com/2021/02/03/business/mckinsey-opioids-settlement.html (explaining how McKinsey reached settlement agreements with forty-nine states over its role in providing sales advice to Purdue and other drug makers, including advice about how to avoid "strict treatment" by the FDA.).

298 *See, e.g.*, H. Nelson, The Opioid Litgation: Settlements, Winners and Losers, Forbes

In addition, while there are features of this case study that are unique to opioids, and to companies like Purdue Pharma that were the initial drivers of the epidemic, the general patterns of industry influence and control that are deployed in pharmaceutical capture are far from unique.[299] As described in Part I, and as further illustrated by other compelling case studies of corporate power in markets for other drugs, the holistic and systemic control that companies with the largest financial interests in pharmaceutical sales exert over markets relevant to their profitability, and the resulting growth of profits at the expense of public health, is endemic in pharmaceutical markets.[300]

Indeed, pharmaceutical capture, along with other forms of industry capture, have extended to include the policy narratives used to characterize the very problems they have helped to create.[301] The solution to problems of high prices and harmful products, they suggest, is to reduce the burden of regulation and the

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Magazine, July 26, 2019 (describes the massive litigation costs and the large fees generated for lawyers from the opioid litigation).

299 For support of this proposition, see *supra* notes 29-37 and 177 and infra note 300, providing support for the claim that pharmaceutical capture is widespread and not limited to opioids. *See also* Marks, *supra* note 141 (arguing that previous analysis of the pharmaceutical industry reveal similar strategies, and that the strategies employed by opioid companies were not entirely novel). For broad discussions of how corporate actors in the pharmaceutical industry create a web of influence over a wide variety of stakeholders in order to secure desired industry outcomes, see, for example, MARKS, *supra* note 91. For industry-wide examples of how business interests impact health care quality and price, with examples that include and go beyond the pharmaceutical industry to other health care markets, see, for example, STEVEN BRILL, AMERICA'S BITTER PILL: MONEY, POLITICS, BACKROOM DEALS, AND THE FIGHT TO FIX OUR BROKEN HEALTHCARE SYSTEM (Random House 2015); ROSENTHAL, *supra* note 1.

300 For case studies of corporate power in different markets, see, for example, Kalman Applbaum, *Getting to Yes: Corporate Power and the Creation of a Psychopharmaceutical Blockbuster*, 33 CULTURE, MED. & PSYCHIATRY 185 (2009) (case study analyzing documentary evidence of Eli Lilly's far reaching strategy of influence over the distribution chain to expand the sale of its antipsychotic medication Zyprexia beyond its conventional market, showing how this is typical of contemporary pharmaceutical marketing strategies); Ross et al., *supra* note 103 (illustrating Merk's role in ghostwriting clinical trial manuscripts and other materials relevant to approval and sale of its product Rofecoxib); Michael A. Steinman et al., *Narrative Review: The Promotion of Gabapentin: An Analysis of Internal Industry Documents*, 145 ANNALS INTERNAL MED. 284 (2006) (discussing how litigation and congressional inquiry have exposed expansive marketing practices used to promote drugs, including for unauthorized uses; provides case study exposing overall structure of promotion of gabapentin). For other case studies of industry influence over pharmaceutical markets, particularly through influence over medical and scientific research and medical education, see journal articles and whitepapers at Publications, PHARMEDOUT, https://sites.google.com/georgetown.edu/pharmedout/resources/publications.

301 *See, e.g.*, *2019 Profile: Biopharmaceutical Research Industry*, PHRMA (2019), https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/0-9/2019-Profile-Booklet_FINAL_NoBleeds.pdf (pharmaceutical industry organization reports framing narrative of pharmaceutical industry role in promoting innovation and improving patient health); *2020 Profile: Biopharmaceutical Research Industry*, PHRMA (2020), https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/G-I/Industry-Profile-2020.pdf (same).

inefficiencies of government oversight, while at the same time protecting the incentives (including patent and market exclusivities) that allow them to innovate. These industry narratives, and the support they lend to arguments for at least selective deregulation—in the form of restrictions on the exercise of government rights—have gained public and policy traction in the wake of a rapid industry roll out of vaccines for COVID-19.[302] Part IV begins by responding to these politically popular arguments in support of deregulation,[303] and then advocates for an alternative approach based on regulatory redesign as the best way to reorient the industry around public health goals.

III. PHARMACEUTICAL RECAPTURE

"[W]hat other and more effective [instrument] is there within the reach of the American people?"- Charles Francis Adams, Jr. (1871)[304]

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302 *See, e.g.*, Drew Armstrong, *The World's Most Loathed Industry Gave Us a Vaccine in Record Time*, BLOOMBERG (Dec. 23, 2020, 2:00 AM PST), https://www.bloomberg.com/news/features/2020-12-23/covid-vaccine-how-big-pharma-saved-the-world-in-2020; Alexandra Bruell, *Pharma Giants Market Their Value as Pandemic Bolsters Reputation*, WALL ST. J. (Nov. 9, 2020, 5:30 AM ET), https://www.wsj.com/articles/pharma-giants-market-their-value-as-pandemic-bolsters-reputation-11604917802; Ed. Bd., *Watch Out for a Vaccine Patent Heist*, WALL ST. J. (Mar. 28, 2021, 3:29 PM ET), https://www.wsj.com/articles/watch-out-for-a-vaccine-patent-heist-11616959785; Jared S. Hopkins, *How Pfizer Developed a Covid Vaccine in Record Time: Crazy Deadlines, a Pushy CEO*, WALL ST. J. (Dec. 11, 2020, 9:34 PM ET), https://www.wsj.com/articles/how-pfizer-delivered-a-covid-vaccine-in-record-time-crazy-deadlines-a-pushy-ceo-11607740483.

303 For a sampling of different approaches to market-based health care policy, see, for example, Joseph R. Antos et al., *Improving Health and Health Care: An Agenda for Reform*, HEALTH AFFS. (Dec. 9, 2015), https://www.healthaffairs.org/do/10.1377/hblog20151209.052181/full (arguing for a reorienting of health care away from government regulation and towards the preferences of consumers and patients); *Improving Health Care: A Dose of Competition*, FED. TRADE COMM'N & DEP'T OF JUST. (July 2004), https://www.ftc.gov/sites/default/files/documents/reports/improving-health-care-dose-competition-report-federal-trade-commission-and-department-justice/040723healthcarerpt.pdf (suggesting the importance of competition as a mechanism for addressing health care costs); and Michael E. Porter & Thomas H. Lee, *The Strategy That Will Fix Healthcare*, HARV. BUS. REV. (Oct. 2013), https://hbr.org/2013/10/the-strategy-that-will-fix-healthcare (offering a market driven "value based" approach to health care reform). For a discussion of the pharmaceutical policy positions that emphasize the importance of protecting incentives for the private sector to innovate, see, for example, Henry G. Grabowski et al., *The Roles of Patents and Research and Development Incentives in Biopharmaceutical Innovation*, 34 HEALTH AFFS. 302 (Feb. 1, 2015) (summarizing the role of patent and other exclusivities in promoting pharmaceutical R&D); and Lazonick et al., *supra* note 49 (providing a critique of the pharma arguments that they require stronger incentives to engage in drug R&D).

304 CHARLES FRANCIS ADAMS, *The Railroad System*, *in* *CHAPTERS* OF ERIE AND OTHER ESSAYS 333, 414 (Applewood Books 1956) (1871); *see also* Novak, *supra* note 47, at 25 (discusses how Charles Frances Adams approached the problem of railroad monopolies, dismissing prior efforts at competition and legislation and arguing for an alternative approach that would address the problem of capture).

"The regulation of these various and interfering interests forms the principal task of modern legislation . . . ." – James Madison (1787)[305]

The opioid case study provides a powerful illustration of pharmaceutical capture and its costs. A new story of the effects of pharmaceutical capture on pandemic preparedness and response is playing out before our eyes in response to COVID-19.[306] But the effects of pharmaceutical capture extend far beyond opioids, and far beyond the rush to develop COVID-19 treatments and vaccines. The effects of capture can be seen in the high price of EpiPens and insulin, the over-prescribing of drugs to treat attention deficit disorders, the promotion of aspirin as a way of preventing heart disease, unaddressed promotion of off-label use of risky anti-psychotic drugs—the list could go on.[307] This final Part begins to tackle the question of what regulators can do to "recapture" the pharmaceutical industry with the goal of reorienting the industry around public health goals. It begins by challenging one of the largest hurdles to improved regulatory design—the political dominance of beliefs in market primacy and an accompanying, albeit selective, deregulatory agenda, and then provides guidelines for regulatory change designed to "recapture" pharmaceuticals.

A. The Limits of Deregulation

"[T]he capture thesis has so pervaded recent assessments of regulation that it has assumed something of the status of a ground norm—a taken-for-granted term of art and an all-purpose social-scientific explanation—that itself frequently escapes critical scrutiny or serious scholarly interrogation." - William Novak[308]

"Market economies need clear rules to function efficiently. Without a legal framework establishing and enforcing property rights and the 'rules of the game,' our free enterprise system could not exist."[309]

In early arguments for deregulation, such as those fueled by the influential ideas of Stigler and other members of the Chicago School of Economics in the 1970s and 1980s, regulation writ large is seen as unavoidably compromised by

305 THE FEDERALIST NO. 10 (James Madison).

306 *See, e.g.*, Heled, Rutschman & Vertinsky, *supra* note 15.

307 *See supra* notes 29-37, 177, 299-300 and accompanying text.

308 Novak, *supra* note 47, at 25.

309 *Regulation & the Economy: The Relationship and How to Improve It: A Policy Statement*, COMM. FOR ECON. DEV. OF THE CONF. BD. (Sept. 27, 2017), https://www.ced.org/reports/regulation-and-the-economy.

special interests, something that will simply interfere with the competitive discipline and consumer protections that emerge from an idealized laissez-faire market system. Markets, not government, will be best at protecting the public interest, according to this view, and therefore the role of government should be curtailed and its interference with the operation of the market limited.[310]

Since that time, arguments in support of deregulation have become more nuanced, reflecting a focus on market primacy rather than deregulation per se.[311] Market primacy, in general terms, is the idea that public needs can be best satisfied through the operation of free markets, and that private market competition is the best engine for innovation.[312] Industry incumbents focus their arguments for market primacy on the importance of preserving private sector incentives to innovate through strong intellectual property rights and limited government rights over publicly funded technology.[313] Broader arguments for deregulation focus on the need to increase market competition by addressing regulatory barriers that restrict competition, some of which are—it is argued—the result of regulatory capture. [314]

While these different approaches to deregulation—one favoring entry and competition, one more focused on incentives to encourage innovation by incumbents—are in tension, they reflect a shared pessimism about the ability of government regulation to improve market outcomes.[315] Instead, the role of the

310 *See supra* Part I.

311 *See* Carpenter & Moss, *supra* note 77, at 1, 4 n.4, 8 (exploring relationship between evolving notions of and argument for deregulation and understandings of regulatory capture, includes references in footnote 4 to recent work on regulation and deregulation). For an example of approaches that move beyond traditional arguments for deregulation see, for example, IAN AYERS & JOHN BRAITHWAITE, RESPONSIVE REGULATION: TRANSCENDING THE DEREGULATION DEBATE (1992) (emphasizing the importance of industry self-regulation and the use of persuasion in addition to sanctions to guide private decision making).

312 *See, e.g.*, Fiona Scott Morton & Lysle T. Boller, *Enabling Competition in Pharmaceutical Markets* (Brookings Hutchings Ctr. Working Paper No. 30, 2017), https://www.brookings.edu/wp-content/uploads/2017/05/wp30_scottmorton_competitioninpharma1.pdf (reflecting the view that private sector competition will yield the best outcomes in the pharmaceutical industry and skepticism about the ability of government regulation to improve market outcomes).

313 See, for example, the arguments for limiting government rights over publicly funded technology to encourage private sector innovation in *NIST Green Paper*, supra note 26.

314 *See, e.g.*, Morton & Boller, *supra* note 312 (arguing that industry incumbents such as pharmaceutical manufacturers have influenced regulators and stymied regulations with the goal of limiting competition).

315 To illustrate the variety of arguments in support of a market-based approach to pharmaceutical innovation, with government regulation limited to strengthening private market incentives and/or increasing competition, see, for example Henry G. Grabowski, *Public Policy and Pharmaceutical Innovation*, 4 HEALTH CARE FIN. REV. 75 (1982) (arguing that regulation is impeding pharmaceutical innovation); David R. Henderson & Charles L. Hooper, *To Increase Innovation and Make Drugs More Affordable, Deregulate*, 2 J. CLINICAL PATHWAYS 23 (2016); Morton & Boller, *supra* note 312 (arguing that it is difficult to design regulations that encourage innovation; arguing

government is largely relegated to one of subsidizing the costs of R&D, protecting intellectual property, and procuring resulting health care products, all to a varying degree, leaving the private sector to control the development, distribution, and pricing of products. Markets, not government, will be best at serving the public interest, according to this view, and therefore the role of government should be curtailed and its interference with the operation of the market limited.

Pharmaceutical industry groups interested in removing those forms of government interference that are likely to impede the interests of their most powerful members have played an active role in the policy debate.[316] They are quick to point to the need for strong incentives in the form of patent and market exclusivity to promote costly and risky pharmaceutical R&D, even when this lies in tension with increasing market competition.[317] Their form of deregulation focuses on limiting government rights over government-funded technologies and limiting government power over the terms of product sales. Health care has also been a site of particular focus for a variety of different special-interest groups who coalesce around the idea that private sector innovation and the power of "free markets" will address the inefficiencies that characterize current U.S. health care markets.[318] The narrative of market primacy, with the private sector as an engine of innovation, is a powerful one in U.S. political circles.[319] The power of this

for policies that remove barriers to competition as the best way to promote pharmaceutical innovation and reduce drug cost); Tom Coburn, *Free Market, Better Medicine: The Solution to Our Drug Pricing Problem Involves Less Government, More Transparency*, U.S. NEWS (Feb. 15, 2018, 3:31 PM), https://www.usnews.com/opinion/articles/2018-02-15/rely-on-the-free-market-to-address-drug-prices-and-foster-innovation; and Daniel Hempel & Lisa Larrimore Ouellette, *Pharmaceutical Profits and Public Health are Not Incompatible*, N.Y. TIMES (Apr. 8, 2020), https://www.nytimes.com/2020/04/08/opinion/coronavirus-drug-company-profits.html (arguing for government policy focusing on strengthening private sector incentives to promote innovation).

316 *See, e.g.*, Wouters, *supra* note 135; Morgan, *supra* note 141; *Pharma Lobbying Held Deep Influence Over Policies on Opioids*, ASSOCIATED PRESS (Sept. 17, 2016) https://apnews.com/article/9b72ea1408f845eaa26638a652df2912.

317 *See, e.g.*, PhRMA Report, 2020 Profile Biopharmaceutical Research Industry at https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/G-I/Industry-Profile-2020_1.pdf; PhRMA, IP Incentives Fuel Biopharmaceutical Innovation and Competition at https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/0-9/6--67416-Intellectual.pdf.

318 *See, e.g.*, Antos, *supra* note 40; John C. Goodman, *Why Not Try Free Market Healthcare?*, FORBES (Oct. 17, 2019, 7:51 AM EDT), https://www.forbes.com/sites/johngoodman/2019/10/17/why-not-try-free-market-health-care; Max Gulker, *Are We Really Ready for Free-Market Healthcare?*, AM. INST. FOR ECON. RSCH. (Nov. 20, 2019), https://www.aier.org/article/are-we-really-ready-for-free-market-healthcare; *Issue: Health Care Reform*, HERITAGE FOUND., https://www.heritage.org/health-care-reform ("Health care reform should be a patient-centered, market-based alternative . . . .").

319 *See, e.g.*, Mike Hennessy, Sr., *How Pharmaceutical Innovation Is Saving the World*, PHARMTECH (Feb. 2, 2021), https://www.pharmtech.com/view/how-pharmaceutical-innovation-is-saving-the-world; John Stanford, Price Controls Would Throttle Biomedical Innovation, WALL ST. J. (July 1, 2020, 1:51 PM ET), https://www.wsj.com/articles/price-controls-would-throttle-

market-based approach is evident even now, in the midst of a pandemic, as U.S. government policies focus largely on increasing the incentives of the private sector to produce therapies and vaccines to combat COVID-19.[320]

But what many of these views neglect is the fact that markets are themselves legal, political, and social constructs that are highly dependent upon regulation. Markets rely on regulation to operate; they are institutions constructed out of rules, and so the choice is never regulation versus the absence of regulation, but rather the trading of one governance structure for another.[321] This idea has been taken one step further in recent work on "deregulatory capture," a situation in which regulators are captured by special interest groups bent on deregulation.[322] The debate over deregulation is really a debate over alternative governance models, and the question of regulatory capture becomes one of how different governance models may favor different actors.[323]

Moreover, the arguments for deregulation that are being advanced by a powerful coalition of free enterprise groups, many of which are backed by corporate interests, often adopt an overly simplified and idealized view of the laissez-faire market.[324] Yet the pharmaceutical market is anything but a free market—it is heavily regulated and includes a variety of government-created incentives and subsidies that support private enterprise.[325] And the market is anything but competitive, with large barriers to entry and restrictions on competition. In addition, health care markets have unique features that do not lend themselves to the model of perfect competition upon which many of the

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biomedical-innovation-11593625880; Thomas Sullivan, *Pharmaceutical Companies Need Longer Patents to Fund Innovation*, POL'Y & MED. (May 6, 2018), https://www.policymed.com/2012/04/pharmaceutical-companies-need-longer-patents-to-fund-innovation.html.

320 See, for example, a discussion of current reliance on private sector to produce pandemic drugs in Heled, Rutschman & Vertinsky, *supra* note 15.

321 *See, e.g.*, Robert I. Field, *Government as the Crucible for Free Market Health Care: Regulation, Reimbursement, and Reform*, 159 U. PA. L. REV. 1669 (2011) (arguing that government regulation is essential in creating markets and helping them to function).

322 *See, e.g.*, STEVEN K. VOGEL, MARKETCRAFT: HOW GOVERNMENTS MAKE MARKETS WORK (2018).

323 *See* Vogel, *supra* note 42.

324 See e.g. Nicholas Skala, *Right-Wing "Think" Tanks and Health Policy*, PHYSICIANS FOR A NAT'L HEALTH PROGRAM (July 2010), https://pnhp.org/news/right-wing-think-tanks-and-health-policy. See also E. Lipton and B. Williams, How Think Tanks Amplify Corporate America's Influence, New York Times, August 7, 2016 (describes the role of industry funding and influence on think tanks); J. Judis, The Credible Think Tank is Dead, The New Republic, Sept. 15, 2017 at (describes the politication and expansion of corporate influence over think tanks) at https://newrepublic.com/article/144818/credible-think-tank-dead. For a description of the role of corporate funding in different think tanks see Source Watch, run by the Center for Media and Democracy, at https://www.sourcewatch.org/index.php?title=SourceWatch.

325 *See, e.g.*, Field, *supra* note 321 (arguing that government programs have created the health care system that the private sector operates in).

deregulatory arguments rest.[326] When more carefully scrutinized, the arguments for deregulation generally reduce to arguments for the unencumbered pursuit of profits by industry incumbents, an agenda that relies on certain forms of regulation while attacking others.

The advocates for deregulation as a response to regulatory capture also invariably ignore an important alternative response to regulatory capture, one focused on striving to make the regulatory process more robust to capture.[327]

B. A Starting Point for Regulatory Redesign

"*All health care organizations, professional groups, and private and public purchasers should adopt as their explicit purpose to continually reduce the burden of illness, injury, and disability, and to improve the health and functioning of the people of the United States."* – Institute of Medicine[328]

Drawing lessons from the industry strategies that have resulted in pharmaceutical capture, this concluding section offers three guiding principles for redesigning the regulatory approach to pharmaceuticals. The first is the need for a holistic, systemic approach to regulation. The second is the need to recalibrate key underlying policy assumptions about pharmaceutical markets and their appropriate regulation. The third is the need to make regulation more robust to corporate interests through strategies that narrow the divergence of private interests from the public interest, make capture more costly, and/or provide greater resources and rewards for regulating in the public interest.

1. The Need for a Holistic, Systemic Approach to Regulation

As a first step in addressing pharmaceutical capture, we need a regulatory system that is more holistic and systemic in approach, one that can respond in a comprehensive and flexible way to the complex and changing strategies of the most sophisticated companies in the pharmaceutical industry.

The opioid case study provides a detailed description of the multifaceted approach that the opioid manufacturers and distributors took towards influencing the design and operation of opioid markets. These large and sophisticated companies think in systemic terms about the entire commercial life cycle of their

326 *See, e.g.*, Heled, Vertinsky & Brewer, *supra* note 31.

327 In this Article, I take it as a given that the United States will at least for the foreseeable future continue to rely on a market-driven approach to health care in general and pharmaceuticals in particular, and I focus proposals for reform on ways of shifting the regulatory approach towards these markets. An alternative approach, one that is beyond the scope of this Article, would be to expand the role of the government as a more active participant in health care markets.

328 *See, e.g.*, CROSSING THE QUALITY CHASM, *supra* note 243.

products and services, including not just current, but also future product and service opportunities. They also think comprehensively about all of the stakeholders that will influence product development, approval, and terms of sale now and in the future. They seek to incorporate all of the factors that will or may contribute to total revenues over the life cycle of the product, including sales volume and pricing and ways of limiting competition. Regulators and regulations become variables in a system of industry influence that can be used to advantage in some cases, and the negative effects on industry interests neutralized in others.

As illustrated at length in the case study, pharmaceutical companies, along with other industry stakeholders, influence professional association guidelines, treatment protocols, physician norms, "scientific" understandings of the risks and benefits of drugs, consumer expectations and understandings, regulatory approaches towards the marketing and control of drugs, and the standards of care used to assign liability for product harm. In the context of opioids, it was the combined impact of articles in medical journals, lectures by thought leaders, physician education, professional guidelines, insurance reimbursement procedures, and changes in hard and soft law surrounding standards of care and liability for treatment of pain, for example, that made the strategy of encouraging opioid prescription and use so successful. The fact that physicians heard consistent messages from multiple sources impacted their beliefs, and their prescribing behavior, much more than the effects of more fragmented messaging.[329] Influence over enforcers, such as the DEA, allowed the strategy to continue for decades.

While the most profitable companies in the pharmaceutical industry rely not on any one individual intervention, but rather on the systemic use of multiple different strategies and their interaction, regulators are generally confined in their operations to fragmented and often unconnected parts of the pharmaceutical market. Their approach to the regulation of pharmaceutical markets is siloed, dictated by the scope of their regulatory authority and jurisdiction, and limited by the resources and information they have available. Rather than working together on a common objective, such as improving health outcomes, regulators are divided by law and institutional structure into a variety of different enclaves, and assigned pieces of the market system, such as monitoring the distribution of controlled substances or approving a new drug for the stated approved use. Often the regulators are dependent on industry members for data about industry practices, and they may end up working closely with their industry counterparts—a prime example being the relationship between the FDA and pharmaceutical companies seeking drug approval.

When thinking about regulatory reform, we too often think about regulations within a narrow context, and without a system-wide analysis of the role of the

329 *See, e.g.*, Cuéllar & Humphreys, *supra* note 28.

regulations, the ways they are formulated, applied, revised, and enforced. We think about a specific regulatory problem without taking time to consider whether the individuals making the enforcement decisions are compensated adequately for their work, whether they are likely to work for industry in the future, whether their decisions are based on information that is industry generated, and/or whether the proposed regulations are tested and evaluated by industry-funded studies.[330] We often fail to think about the ways in which alternative regulations intersect, compounding the impact of each individually (such as with cumulative regulatory exclusivities), or alternatively neglecting important aspects of a multifaceted problem.[331] And we do not invest the resources in regulatory design and implementation needed to combat well-funded and sophisticated corporate strategies designed to counteract any reform efforts that might privilege the public interest over their own corporate interests.

In sum, pharmaceutical companies are interested in how the entire set of relevant existing and potential regulations, taken as a whole, along with other formal and informal rules governing relevant stakeholders, impacts their business models, and ultimately their ability to ensure stock price and revenue growth. They invest time and money in a holistic and systemic strategy that they continue to update and refine in response to shifting economic, legal and institutional constraints. They have large budgets and significant resources devoted to their systems of industry influence. Regulators, in contrast, are focused largely on their particular fragmented piece of the regulatory system—be it product approval, monitoring sales of controlled substances, assessing liability for illegal behavior, whatever piece of the regulatory process falls within their particular jurisdiction. Layer on top of this other constraints—limited resources, revolving doors, hostility of the administration towards enforcement actions, and regulators operate at a tremendous disadvantage in comparison to the entities they must regulate. Thus, as a first step in addressing pharmaceutical capture, regulatory strategies need to be holistic and systemic in the same way that corporate strategies are—with a comprehensive view of the roles that different stakeholders play and the ways in which one realm of regulation impacts others.[332]

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330 Take, for instance, the widely cited numbers provided by the Tufts Center as estimates of the astronomical cost of developing new drugs. These numbers play important roles in debates over the need for longer patent terms and other forms of pharmaceutical protection to incentivize R&D. This Center was formed with industry money, in partnership with industry, and continues to be funded by industry, and it is hard to argue that this is anything other than a way of creating its own data for policy purposes. *See, e.g.*, Nik-Khah, *supra* note 25.

331 *See, e.g.*, Erin C. Fuse Brown, *Resurrecting Health Care Regulation*, 67 HASTINGS L.J. 85 (2015) (providing a framework for mapping policy solutions onto the health care market failure they are designed to address, shows the limitations of current à la carte policy options in attacking the problem of high drug prices).

332 *See, e.g.*, Benjamin & Rai, *supra* note 114 (arguing for the creation of an entity with a trans-

2. Challenging Key Assumptions About Pharmaceutical Markets and Their Regulation

A combination of features unique to U.S. health care and to the process of discovering and manufacturing pharmaceutical products makes the pharmaceutical industry particularly vulnerable to capture by the interests of pharmaceutical companies.[333] As discussed in Part I, the factors most relevant to understanding pharmaceutical markets include: (a) the pervasive role of regulation over the entire product life cycle, including restrictions on competition intended to promote innovation at the expense of competition; (b) the belief in the private sector as the primary engine of biomedical innovation, and the asymmetric role of government as funder of R&D and purchaser of end products but with limited control over product and pricing decisions; (c) the fragmentation of the market, including but not limited to the separation between the parties who make the products, pay for the products, select the products (prescribing physicians), and consume the products (patients); (d) the pervasive role of industry in shaping scientific, medical, and patient knowledge about pharmaceuticals and their use; and the extreme potential for profit due in part to the inelasticity of demand for the goods involved.[334] This approach to pharmaceutical markets is justified and sustained by certain key assumptions about the relevant stakeholders and what their roles should be, and those assumptions in turn limit the reach of regulators and regulations. A second step in the redesign of regulation involves challenging some of these key assumptions and the ways in which they are used to limit the reach of regulation and support capture.

These key assumptions about pharmaceutical markets include the following: (a) that patients should be treated as consumers, pharmaceuticals as products, and "informed consent" as assumption of the risk; (b) that doctors are "independent" learned intermediaries and not subject to industry influence; (c) that the private sector is the driver of innovation, and that limiting the role (or at least the rights) of government is essential to promote innovation; and (d) that the combination of disclosure and informed consent coupled with the operation of market forces is adequate to discipline pharmaceutical companies.

One of the most foundational of these assumptions, one that informs the others, is the industry-cultivated idea that we can treat patients as consumers for purposes of fashioning pharmaceutical regulation. Once patients are seen as consumers, the idea of facilitating product choice through reductions in regulation

agency focus to support innovation).

333 For an in depth discussion of what makes healthcare markets unique, and particularly vulnerable to corporate influence, see, for example, Heled, Rutschman & Vertinsky, *supra* note 15; and Heled, Vertinsky & Brewer, *supra* note 31.

334 *See supra* note 333 and accompanying text.

becomes more compelling. Consumers can be provided with information about products and given choice, and when they make their product selections with ample disclosure, and through use of the concept of informed consent, they have assumed the risk of any negative consequences. This was the argument that pervaded industry defenses to tobacco litigation claims. The market can be relied upon, or so the story goes, to ensure product quality and to limit price to reflect consumer demand. To push this story further, information about products can and should be generated through consumer use rather than relying too heavily on pre-market testing and approvals. Finally, the pharmaceutical industry argues, any efforts to restrict their marketing are restrictions on commercial speech that violate the First Amendment rights of the pharmaceutical companies.[335]

There are many reasons that patients should not be treated simply as consumers, and that pharmaceutical markets—at least in their current form—do not adequately protect patients when they are allowed to rest on models of consumer choice and informed consent. Any system of regulation that is going to prioritize patient and public health needs to address the limitations of a simple consumer model of health care. Once we stop seeing patients simply as consumers and the purchase of health care as equivalent to the purchase of a television, the demands on regulators and regulations and the available avenues for regulation change. Reinvigorating the regulatory position that patients are not simply consumers, and need additional protection, could fuel more expansive regulation of a variety of corporate practices, such as DTC marketing and requirements to fully investigate and disclose the potential harms of any product.

A second fundamental, and also problematic, assumption underpinning current regulatory approaches is the independence of doctors from industry influence. Doctors are treated as gatekeepers under the law. They have the expertise to determine the needs of the patient and to evaluate treatment options, and they have a professional obligation and a code of ethics that—in an ideal world—ensure that the interests of the patients come first. This gatekeeper role includes the ability to prescribe drugs, and under the learned intermediary doctrine it shields pharmaceutical companies from certain duties to warn patients about potential harms from their drugs. Given the importance of physician decision-making for prescription drug sales, and even those offered without prescription, it is no surprise that pharmaceutical marketing has for decades focused heavily on promotional strategies targeted at physicians. A cornerstone of pharmaceutical strategy is devoted to industry influence over physician decision-making and over the standards of care that guide physician choice. The opioid epidemic illustrates the dangers of relying on this gatekeeper model without adequate safeguards for

335 *See, e.g.*, Caroline Poplin, *The First Amendment: Not One Size Fits All*, 3 EMORY CORP. GOVERNANCE & ACCOUNTABILITY REV. 30 (2016).

the independence not just of physicians, but also of the information that they are using to make their treatment decisions. When scientific papers, physician continuing education, professional conferences and medical thought leaders are influenced by pharmaceutical companies, this compromises the gatekeeping role of the physician.

The final two assumptions are based on the idea of market primacy—that if left unhindered, market forces will discipline pharmaceutical companies and ensure that they produce the goods and services that consumers want at competitive prices. One has only to look at the performance of U.S. health care markets to find ample empirical evidence that markets have not achieved socially efficient outcomes, and seminal work by economists such as Kenneth Arrow provide the theoretical justifications for why these failures might emerge.[336]

Thus, this second step in the redesign of regulation involves re-evaluating some of the key assumptions used to limit the reach of regulation and support capture and replacing them with a more accurate model of how the industry actually works. With this refined model in place, regulations can be better targeted to areas where private interests diverge from public health needs.

3. Making Regulations More Robust to Special Interests

Part of making regulations more robust to capture is to start with a critical examination of assumptions made at the ground level—revisiting the consequences of thinking about patients as consumers, doctors as learned intermediaries, government as doomed to fail, markets as some laissez-faire ideal. Changes in these assumptions will change the scope and nature of regulation needed. But even with improvements in regulatory design, the system may remain susceptible to capture by special interest groups. This final section explores ways of making regulation more robust to pharmaceutical capture by increasing the costs of and reducing the benefits from capture.

There are at least three different avenues for making regulation more robust to capture.[337] One is to reduce the market pressure on regulators by narrowing the divergence of profit incentives from public health needs.[338] Arguments for

336 *See, e.g.*, Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941 (1963).

337 *See, e.g.*, Levine & Forrence, *supra* note 21 (decomposing models of public-interest regulation into models of motivation and of monitoring; making motivation a variable subject to the constraint of monitoring; examining the role of monitoring costs and motivations in developing a model of regulatory behavior; distinguishing between private versus public interest to reflect motivation and general versus special interests to reflect political dominance).

338 *See, e.g.*, Heled, Vertinsky & Brewer, *supra* note 31 (exploring the consequences of the divergence of private incentives from public health in the pharmaceutical industry and proposing ways of narrowing this divergence); *see also* Marc-André Gagnon, *Corruption of Pharmaceutical*

delinking price of drugs from returns on R&D offer one example of this approach.[339] Carefully structured public-private partnerships that involve a sharing of costs, risk, and control between public and private actors offer another, albeit imperfect, alternative.[340] A second avenue is to create barriers to industry influence that either make it harder and more costly to sway the decisions of regulators, or simply remove pathways of influence. This approach can involve measures that make it more difficult to hide industry influence, such as requirements of transparency.[341] It could include measures that make regulators more accountable for regulatory results, such as improved metrics to measure good performance and independent oversight of agency decisions and outcomes.[342] It could also include measures that make it more costly to exert industry influence in ways that are considered improper, such as strengthening the scope of and penalties associated with anti-kickback statutes or restricting the ability of companies to make campaign contributions or engage in lobbying.[343] Greater restrictions could also be placed on the ability to work in industry after holding important regulatory roles.

Markets: Addressing the Misalignment of Financial Incentives and Public Health, 41 J. L. MED. & ETHICS 571 (2013) (exploring how the current architecture of pharmaceutical markets has caused a misalignment of private incentives and public health; exploring alternatives such as taxes, increased financial penalties, and drug pricing based on value to narrow divergence).

339 *See, e.g.*, James Love, *Inside Views: Delinkage of R&D Costs from Product Prices*, INTELL. PROP. WATCH (Sept. 15, 2016) https://www.ip-watch.org/2016/09/15/delinkage-of-rd-costs-from-product-prices; Brian Till, *How Drug Companies Keep Medicine Out of Reach*, ATLANTIC (May 15, 2013), https://www.theatlantic.com/health/archive/2013/05/how-drug-companies-keep-medicine-out-of-reach/275853.

340 *See, e.g.*, Liza S. Vertinsky, *Patents, Partnerships, and the Pre-Competitive Collaboration Myth in Pharmaceutical Innovation,* 48 U.C. DAVIS L. REV. 1509 (2015) (exploring the role and limits of public-private partnerships in pharmaceutical R&D).

341 Transparency is frequently mentioned in proposals for reform in many different aspects of the product life cycle. It appears most frequently in proposals for more transparency in pricing. *See, e.g.*, Nisarg A. Patel, *Fee-for-Value in the Pharmaceutical Industry: A Policy Framework Applying Data Science to Negotiate Drug Prices*, J. L. & BIOSCIENCES 205 (2017) (proposal for addressing lack of price transparency through the use of an independent review board to provide a value based reimbursement system); Martha S. Ryan & Neeraj Sood, *Analysis of State-Level Drug Pricing Transparency Laws in the United States*, 2 JAMA Network Open 1 (2019). For a view about how transparency might improve conduct through market forces, see, for example, Jennifer E. Miller, *From Bad Pharma to Good Pharma: Aligning Market Forces with Good and Trustworthy Practices Through Accreditation, Certification and Rating*, 41 J. L. MED. & ETHICS 601 (2013) (arguing that metrics that force companies to reveal ethical performance to investors, customers and regulators will allow market forces to improve conduct). For arguments about the benefits of increasing transparency in regulatory decision making, see, for example, Ana Santos Rutschman, Yaniv Heled & Liza S. Vertinsky, *Regulatory Reactivity: FDA and the Response to Covid-19*, Food and Drug Law Journal (*forthcoming 2021*).

342 *See, e.g.*, Light, Lexchin & Darrow, *supra* note 20 (proposing measures to increase independence of agencies like the FDA with gatekeeping roles over drugs).

343 *See, e.g.*, Gagnon, *supra* note 338 (considering the role of increased financial penalties in addressing divergence of private incentives from public health).

A third avenue is to increase the support and rewards for public interest regulation. The gap between private sector marketing salaries and the much lower government regulator compensation is also worth considering, since making regulation a more lucrative job might reduce interests in cultivating future industry ties.

Taken together, the adoption of systemic strategies, increasing the resources devoted to regulation, altering the grounding assumptions to refocus on patients and health, and limiting the divergence of private incentives from public health needs, could provide a regulatory approach strong enough to put regulators and the public interest they are charged to protect, back in control of writing the rules for how pharmaceutical markets operate and whose interests they serve.

CONCLUSION

This Article has offered a theory of pharmaceutical capture that ties together the myriad ways in which pharmaceutical companies exert influence over the construction and regulation of pharmaceutical markets. The pharmaceutical industry is, in effect, now writing its own rules for how pharmaceutical markets operate. The result of pharmaceutical capture is a pharmaceutical industry that is driven largely by profits, often at the expense of health outcomes. The opioid epidemic provides a stark example of the tensions that can emerge between private incentives and public health needs and the harms that can result when corporate actors gain too much influence over health care markets. Rather than seeing the opioid epidemic as an outlier, this Article argues that the opioid epidemic is simply a particularly salient example of pharmaceutical capture at work and a warning of the magnitude of public health harms that can occur as a result.

A popular political response to concerns about the economic and political power exerted by pharmaceutical companies has been to pin the blame on government regulation as impeding the efficiency and innovative power of the "free market." The clarion calls for selective deregulation and/or privatization of the pharmaceutical industry, calls fueled by private sector interests, have become louder and more politically enticing in the wake of what is portrayed as the private sector triumph in producing COVID-19 vaccines. But as this Article has argued, markets—particularly pharmaceutical markets—rely on government regulations to operate, and this push for limiting government control over industry decisions is in many cases simply an effort to substitute one governance structure for another that is more favorable to corporate interests.

This Article concludes with some guidelines for regulatory redesign with the goal of "recapturing" pharmaceutical markets to serve public health needs. Drawing lessons from the industry strategies that have resulted in pharmaceutical capture, it proposes a shift away from existing fragmented regulatory approaches

and towards a regulatory strategy that is holistic and systemic, recalibrated to respond to contemporary market realities, and more robust to special interests. The pharmaceutical industry, working in partnership with public actors, has vast potential to meet even the most daunting of public health challenges, but realizing this potential depends upon the success of this recapture.

"Everybody Knows I'm Not Lazy": Medicaid Work Requirements and the Expressive Content of Law

Kristen Underhill[*]

Abstract:

In a first for the Medicaid program, the Department of Health and Human Services under President Trump allowed states to establish work requirements for program participants who are considered "able-bodied adults." These mandates were halted by litigation, and President Biden's administration is now in the process of withdrawing the waivers. But early experiences with Medicaid work requirements suggested that they can produce widespread losses of benefits. In addition to affecting access, work requirements and other conditions on public benefits can serve an *expressive* purpose: they provide a source of information about a state's values, goals, and beliefs about beneficiaries. Beneficiaries are one audience for this expressive message, but we know little about what they hear when their state makes benefits more difficult to access.

This Article presents an original empirical study of more than 9,000 Medicaid beneficiaries in the Commonwealth of Kentucky, the first state approved for a work requirement program. Using a mix of survey data and qualitative interviews, this Article demonstrates that Medicaid beneficiaries understand work requirements as providing information about the state's values and priorities. But

[*] Professor of Law, Cornell Law School. At the time of this work, I was Associate Professor of Law, Columbia Law School and Associate Professor of Population & Family Health, Mailman School of Public Health, Columbia University. This Article arises from my work as a co-principal investigator of the independent evaluation of a Medicaid § 1115 waiver in the Commonwealth of Kentucky. The research in this Article was funded by the Commonwealth through Medicaid funds for evaluation (which were a combination of state and federal Centers for Medicare & Medicaid Services funding). I am grateful to the individual participants in this research study, who have trusted us with their stories. I am also grateful to my fellow principal investigators, Atheendar Venkataramani and Kevin Volpp, and to our exceptional team of colleagues: Erica Dixon, Kristin Linn, Elizabeth Bair, Will Ferrell, and Genevieve Kanter. Many thanks also to our data collection partners at the National Opinion Research Council (NORC), especially Michelle Strollo, Margrethe Montgomery, Lisa Rosenberger, Rebecca Catterson, and Micah Sjoblom. Thank you to Juliana Bennington, Cecilia Plaza, and Clarisa Reyes-Becerra for outstanding research assistance. I am grateful to Christopher Buccafusco, Elizabeth Emens, Nicole Huberfeld, Gillian Lester, Michelle Mello, Gillian Metzger, Bill Sage, Bob Scott, Sarath Sanga, Susan Sturm, Eric Talley, Karen Tani, participants in the Columbia Law Faculty Workshop, the ASLME Health Law Professors Conference, the Cardozo Law Faculty Workshop, and the Regional Health Law Workshop for invaluable feedback.

depending on their priors, beneficiaries interpreted these messages very differently. Many found work requirements unfair and expressive of disregard toward themselves and other beneficiaries; others believed, however, that the state had validated their identities as taxpayers.

This Article presents these findings and considers implications for expressive theories of law, shifting the paradigm to emphasize that the expressive impacts of law will depend on who is listening.

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INTRODUCTION

"Community engagement requirements are not some subversive attempt to just kick people off of Medicaid . . . Instead, their aim is to put beneficiaries in control with the right incentives to live healthier, independent lives."[1]

"[P]eople who [are] mentally ill, people who didn't graduate from high school. I've got no idea what they're going to do. There's nothing for them. You tell them to go out and get a job and pay a premium or else we'll take away your health care, and they'll just disappear into the streets."[2]

"'If you make these changes, you will kill people.'"[3]

Medicaid has had a close call with work requirements. Requiring program beneficiaries to fulfill quotas of work or education is a longstanding part of the Supplemental Nutrition Assistance Program (SNAP, or food stamps) and Temporary Assistance for Needy Families (TANF, or cash welfare).[4] These requirements have been absent from the Medicaid program, which pays for health care for low-income and certain disabled people. But starting in 2018,[5] the Centers for Medicare & Medicaid Services (CMS) approved waivers that would allow states to require beneficiaries deemed "able-bodied" to meet quotas of work or education to keep their health care. The programs were halted in litigation; although the Supreme Court review granted certiorari and scheduled oral arguments in March of this year, arguments were canceled while the Biden Administration reviewed the approval of work requirement waivers.[6] CMS is now

1 Jessie Hellman, *Trump Administration Defends Medicaid Work Requirements*, HILL (Sept. 27, 2018), https://thehill.com/policy/healthcare/408724-trump-administration-defends-medicaid-work-requirements-after-coverage (quoting CMS Administrator Seema Verma).

2 John Cheves, *Are Bevin's New Medicaid Rules "All About Putting Up Roadblocks for Poor People?"*, LEXINGTON HERALD LEADER (Feb. 2, 2018), https://www.kentucky.com/news/politics-government/article198087454.html (quoting Ronnie Stewart, lead plaintiff in *Stewart v. Azar*, 313 F. Supp. 3d 237 (D.D.C. 2018)).

3 Matthew Cortland & Karen Tani, *Reclaiming Notice and Comment*, YALE J. ON REG. NOTICE & COMMENT (Aug. 13, 2019), https://www.yalejreg.com/nc/reclaiming-notice-and-comment-by-matthew-cortland-and-karen-tani/ (quoting a public comment on Kentucky's § 1115 waiver).

4 Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA), Pub. L. 104–193, 110 Stat. 2105 (1996).

5 A 2017 effort to introduce a state option to impose work requirements was rejected as part of Affordable Care Act (ACA) repeal-and-replace legislation. *See* Laura D. Hermer, *What to Expect When You're Expecting . . . TANF-Style Medicaid Waivers*, 27 ANN. HEALTH L. 37, 38–39 (2018).

6 Megan B. Cole et al., *What the New Biden Administration May Mean for Medicaid*, JAMA

in the process of issuing withdrawals, which will be numerous.[7] During the Trump Administration years, twenty states sought (and ten received) federal approval to require work as a condition of participation.[8]

Medicaid operates as a federal-state partnership, whereby states receive federal money and match it with state funds to purchase health care for low-income individuals. States have discretion in their Medicaid programming, as long as they abide by baseline federal requirements.[9] Under § 1115 of the Social Security Act, however, states can waive out of certain federal rules for experimental programs that are budget-neutral and "likely to assist in promoting the objectives" of the Medicaid statute. Prior waivers have often supported programs that expanded categories of coverage, changed payment models, or funded optional benefits.[10] Breaking from past interpretations by the Department of Health and Human Services (HHS), the Trump Administration supported new conditions on Medicaid participation. Early in the Administration, HHS announced its intention to approve "meritorious innovations that build on the human dignity that comes with training, employment, and independence."[11] After repeal-and-replace efforts failed in Congress, CMS extended a formal invitation to state Medicaid directors, providing guidance for waivers that would condition Medicaid eligibility for able-bodied

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HEALTH FORUM (Jan. 13, 2021), https://jamanetwork.com/channels/health-forum/fullarticle/2775343 (describing pending oral arguments in the Supreme Court); *Justices Call Off Arguments Over Medicaid Work Requirements*, AP NEWS (March 11, 2021), https://apnews.com/article/politics-elections-medicaid-courts-presidential-elections-ecee56622ae33da95196249fb8095b68; Jessie Hellman, *Supreme Court Cancels Arguments in Medicaid Work Requirements Case*, MODERN HEALTHCARE (March 11, 2021), https://www.modernhealthcare.com/medicaid/supreme-court-cancels-arguments-medicaid-work-requirements-case.

7 Sidney D. Watson, *Roll Back Harmful Section 1115 Waivers: Charting the Path Forward*, BILL OF HEALTH (May 12, 2021), https://blog.petrieflom.law.harvard.edu/2021/05/12/section-1115-waiver-withdrawals/ (describing withdrawal of Arkansas and New Hampshire waivers in March 2018, and noting that nine other states have now received letters stating that CMS has "preliminarily determined their work requirement waivers did not promote the objectives of the Medicaid Act").

8 HENRY J. KAISER FAM. FOUND., MEDICAID WAIVER TRACKER: APPROVED AND PENDING SECTION 1115 WAIVERS BY STATE, https://www.kff.org/medicaid/issue-brief/medicaid-waiver-tracker-approved-and-pending-section-1115-waivers-by-state/ (last updated Jan. 23, 2020).

9 *See generally* JAMILA MICHENER, FRAGMENTED DEMOCRACY 8 (2018) (describing the structure of Medicaid and the allocation of authority between states and the federal government).

10 *See* 42 U.S.C. § 1315 (2018); *see also* NAT'L CONFERENCE OF STATE LEGISLATURES, UNDERSTANDING MEDICAID SECTION 1115 WAIVERS 4 (2017), http://www.ncsl.org/Portals/1/Documents/Health/Medicaid_Waivers_State_31797.pdf (noting that waivers prior to the ACA were often used to expand coverage).

11 Letter from Thomas E. Price, Sec'y, U.S. Dep't of Health & Hum. Servs., & Seema Verma, Adm'r, Ctrs. for Medicare & Medicaid Servs., U.S. Dep't of Health & Hum. Servs., to State Governors (Mar. 14, 2017), https://www.hhs.gov/sites/default/files/sec-price-admin-verma-ltr.pdf [hereinafter Letter from Sec'y Price & Adm'r Verma].

adults on work requirement quotas.[12] Beginning with Kentucky,[13] CMS approved Medicaid work requirements reaching 80 to 100 hours per month.[14]

Courts consider the legality of Medicaid waivers on a case-by-case basis, but all work requirement waivers reviewed thus far have been struck down.[15] The United States District Court for the District of Columbia twice vacated CMS's approval of Kentucky's waiver as arbitrary and capricious, on the grounds that the Secretary of HHS did not adequately consider the program's impacts on 95,000 individuals projected to lose coverage.[16] New Hampshire's program received the same decision.[17] Only Arkansas implemented work requirements with penalties for noncompliance; after nine months of operations and a loss of Medicaid coverage for nearly 18,000 people,[18] the District of D.C. likewise struck down the

12 Letter from Brian Neale, Dep. Adm'r & Dir., Ctrs. for Medicare & Medicaid Servs., U.S. Dep't of Health & Hum. Servs., to State Medicaid Dirs. (Jan. 11, 2018), https://www.medicaid.gov/sites/default/files/federal-policy-guidance/downloads/smd18002.pdf [hereinafter Letter from Brian Neale to State Medicaid Dirs.]. This has aligned with broader efforts to expand work requirements throughout public benefits programs, including other "non-cash welfare programs" like federal housing assistance and SNAP. *See* Exec. Order No. 13,828, Reducing Poverty in America by Promoting Opportunity and Economic Mobility, 83 Fed. Reg. 15,941, 15,941–43 (Apr. 13, 2018); COUNCIL OF ECON. ADVISERS, EXPANDING WORK REQUIREMENTS IN NON-CASH WELFARE PROGRAMS (July 2018); Supplemental Nutrition Assistance Program: Requirements for Able-Bodied Adults Without Dependents, 84 Fed. Reg. 66,782 (Dec. 5, 2019); *see also* Lola Fadulu, *Cities Prepare for the Worse as Trump's Food Stamp Cuts Near*, N.Y. TIMES (Jan. 25, 2020), https://www.nytimes.com/2020/01/25/us/politics/trumps-food-stamp-cuts.html (quoting the administration's estimate that 700,000 people will lose food stamps under the new rules). The term "welfare" has powerful negative resonance in U.S. political speech and popular culture. *See* MARTIN GILENS, WHY AMERICANS HATE WELFARE: RACE, MEDIA, AND THE POLITICS OF ANTIPOVERTY POLICY 63, 66 (1999) (describing nuanced views on welfare); DEBORAH STONE, THE SAMARITAN'S DILEMMA: SHOULD GOVERNMENT HELP YOUR NEIGHBOR? 12–16 (2008) (providing a historical overview of welfare stigma); Emily Badger, *The Outsize Hold of the Word "Welfare" on the Public Imagination*, N.Y. TIMES (Aug. 6, 2018), https://www.nytimes.com/2018/08/06/upshot/welfare-and-the-public-imagination.html.

13 Letter from Brian Neale, Deputy Adm'r, Ctrs. for Medicare & Medicaid Servs., U.S. Dep't of Health & Hum. Servs., to Adam Meier, Deputy Chief of Staff, Governor Matthew Bevin (Jan. 12, 2018), https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ky/ky-health-ca.pdf.

14 HENRY J. KAISER FAM. FOUND., *supra* note 8.

15 *See* Nicole Huberfeld, *Can Work Be Required in the Medicaid Program?*, 375 NEW ENGL. J. MED. 788 (2018) [hereinafter Huberfeld, *Can Work Be Required*]. The ethical basis of demonstrations that impose such requirements has been similarly disputed. *See* Harald Schmidt & Allison K. Hoffman, *The Ethics of Medicaid's Work Requirements and Other Personal Responsibility Policies*, 319 JAMA 2265 (2018).

16 Stewart v. Azar, 366 F. Supp. 3d 125 (D.D.C. 2019); Stewart v. Azar, 313 F. Supp. 3d 237, 260 (D.D.C. 2018).

17 Philbrick v. Azar, 397 F. Supp. 3d 11, 33 (D.D.C. 2019).

18 Benjamin Sommers et al., *Medicaid Work Requirements: Results from the First Year in Arkansas*, 381 N. ENGL. J. MED. 1073 (2019).

state's waiver.[19] In February 2020, the D.C. Circuit upheld both the lower court's decisions,[20] halting work requirement activity. The following month, Judge Boasberg also vacated a work requirement waiver in Michigan.[21] The Supreme Court granted certiorari in the Arkansas and New Hampshire cases in December 2020.[22] By that time, an additional 1.7 million people had newly enrolled in Medicaid amid the COVID-19 crisis, while CMS Administrator Seema Verma reiterated her support for work requirement waivers.[23] After the change of administration, however, new HHS Secretary Xavier Becerra requested in March 2021 that the Court remand the case to the agency.[24] By then, President Biden's CMS had withdrawn its approvals of both the Arkansas and New Hampshire waivers, determining that "testing those requirements is not 'likely to assist in promoting the objectives of Medicaid.'"[25] The Court agreed to hold the proceedings in abeyance as of April 2021,[26] and CMS withdrawal of state Medicaid work requirement waivers is in progress.[27]

Work requirements transform Medicaid from a statutory entitlement into an *incentive* to motivate specific behaviors required by the state. Work requirements also present hurdles to accessing benefits, with consequences that depend not only on motivation, but also on structural barriers to fulfilling program terms (e.g., awareness of the requirement, transportation, childcare, access to systems for reporting compliance). The effects of these conditions on program participation and long-term health demand rigorous evaluation,[28] and this Article originated in

19 Gresham v. Azar, 363 F. Supp. 3d 165, 185 (D.D.C. 2019).

20 Gresham v. Azar, 950 F.3d 93 (D.C. Cir. 2020), *cert. granted*, 141 S. Ct. 890 (2020); Abby Goodnough, *Appeals Court Rejects Trump Medicaid Work Requirements in Arkansas*, N.Y. TIMES (Feb. 14, 2020), https://www.nytimes.com/2020/02/14/health/medicaid-work-requirements.html. The Kentucky waiver was not included in this decision because it had already been canceled by a new state administration. Arian Campo-Flores, *Kentucky's New Governor Ends Medicaid Work Requirement*, WALL ST. J. (Dec. 16, 2019), https://www.wsj.com/articles/kentuckys-new-governor-ends-medicaid-work-requirement-11576533315.

21 Young v. Azar, 1:19-cv03526 (D.D.C. Mar. 4, 2020) (vacating CMS's approval of Michigan's work requirements).

22 *See* Gresham, 950 F.3d at 93; Amy Howe, *Justices Agree to Review Legality of Medicaid Work Requirements*, SCOTUSBLOG (Dec. 4, 2020), https://www.scotusblog.com/2020/12/justices-agree-to-review-legality-of-medicaid-work-requirements/.

23 Robert King, *Verma Doubles Down on Supporting Medicaid Work Requirements as Enrollment Swells*, FIERCE HEALTHCARE (Oct. 7, 2020), https://www.fiercehealthcare.com /payer/verma-doubles-down-supporting-medicaid-work-requirements-as-enrollment-swells.

24 Reply Brief for the Federal Petitioners at 2, Becerra v. Gresham, 141 S. Ct. 2461 (2021) (Nos. 20-37 and 20-38).

25 *Id.*

26 Becerra, 141 S. Ct. 2461.

27 *See* Watson, *supra* note 7 (describing ongoing withdrawals).

28 Kristen Underhill et al., *Fulfilling States' Duties to Evaluate Medicaid Waivers*, 379 N. ENGL. J. MED. 1985 (2018).

one such effort.

But beyond the effects of program terms on work activity and access to benefits, work requirements in benefits programs may also exert *expressive* impacts.[29] A robust line of research proposes that law serves as a source of information, emphasizing how the communicative impacts of law can foster compliance and the entrenchment of norms. Here, I show that work requirements communicate information about the goals of Medicaid, the abilities and lives of beneficiaries, and the relationship between beneficiaries and the state.

This Article recasts work requirements as a source of information to beneficiaries, presenting an original qualitative study with beneficiaries in Kentucky in the months before the planned rollout of Kentucky HEALTH. I argue that these signals matter—and specifically, that they are in fact *co-produced* by states and beneficiaries themselves, filtered through beneficiaries' normative priors. This contributes a new theoretical dimension to scholarship on law's expressive impacts, which has made few forays into the problem of how listeners' prior commitments may affect their interpretation of the expressive content of law. In this study, I found that Medicaid beneficiaries interpreted work requirements as information about the state's intentions and beliefs, the state's perception of beneficiaries generally, and the state's views about them personally. Specifically, participants tended to interpret work requirements in relation to how they thought *other* program participants behaved. Some viewed other Medicaid beneficiaries as like themselves—participating in Medicaid due to accidents and hardship, and likely to be harmed by work requirements. But others viewed their peers as character-driven, lacking in work effort, and demanding a response by the state. Prior research has demonstrated the central role of racism and racial stereotypes in the design and perception of means-tested programs,[30] and these stereotypes were relevant here as well. Several White participants invoked racial stereotypes specifically when discussing benefits eligibility, implicitly distancing themselves from other beneficiaries. But the large majority of participants across racial groups did not speak openly on race—we did not interrogate race-related beliefs specifically, and social norms may have prevented more open disclosures.

Narratives that focus primarily on how law impacts *others*—and particularly narratives that dissociate oneself from similarly situated peers—challenge public choice theory, which suggests that we reason through law based on our own self-

29 For an overview of expressive theories of law, see RICHARD H. MCADAMS, THE EXPRESSIVE POWERS OF LAW (2016).

30 *See* GILENS, *supra* note 12, at 60-79 (identifying racist stereotypes implicated in opposition to welfare); MICHENER, *supra* note 9, at 33-59 (charting a history of public assistance and describing how states used flexibilities in their administration of Medicaid in ways that disadvantaged people of color; noting at page 54 that "by dint of federalism, Medicaid policy produces *unequal politics* and deepens already yawning racial, class, and geographic disparities in the United States" (emphasis in original)).

interest, rather than the impact of law on others.[31] But on a deeper look, the results may also *align* with public choice theory for beneficiaries whose dominant perspective is that of taxpayers, rather than beneficiaries. Although these beneficiaries' material self-interest may lie in access to health care benefits, they may view their own character and identity interests as better served by a work requirement policy. These findings resonate with psychological research on fundamental attribution bias: the phenomenon by which we view others' decisions as evidence of their character, while we view our own choices as informed by circumstance.[32] These findings also invoke past research on benefits uptake[33] and welfare stigma,[34] where many participants seek to distinguish their uptake from that of other beneficiaries.

Finally, this Article contributes nuanced descriptive findings to work on Medicaid work requirements. I highlight that even without any explanatory information from the state, beneficiaries make independent efforts to interpret what the law conveys, drawing on their prior beliefs and experiences. And, although recent research on work requirements has emphasized opposition to new requirements among beneficiaries,[35] I find a more complex story in Kentucky.

This Article proceeds in the following Parts. Part I introduces expressive legal theory. Part II describes the landscape of work requirement conditions on Medicaid participation, with particular attention to § 1115 waivers. Part III sets forth the empirical study, focusing on narratives in which Medicaid beneficiaries describe their reasons for Medicaid participation, their perceptions of other participants, their awareness of conditions planned in the state § 1115 program, and their interpretation of the purposes and messages underlying these new program elements. Part IV draws lessons from these findings, considering implications for expressive theories of law, as well as for compliance with conditions on public benefits programs.

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31 1 THE OXFORD HANDBOOK OF PUBLIC CHOICE 6-8, 17-20 (Roger D. Congleton et al. eds., 2019).

32 See *infra* Part IV.

33 *See generally* JOE SOSS, UNWANTED CLAIMS (2000) (drawing on in-depth interviews with participants in two public benefits programs to identify how program uptake is political action that can simultaneously empower claimants and reinforce their marginalization).

34 GILENS, *supra* note 12, at 63, 66.

35 Jessica Greene, *Medicaid Recipients' Early Experience with the Arkansas Medicaid Work Requirement*, HEALTH AFF. (Sept. 5, 2018), https://www.healthaffairs.org/do/10.1377/hblog20180904.979085/full/ [hereinafter Greene, *Medicaid Recipients' Early Experience with the Arkansas Medicaid Work Requirement*]; Jessica Greene, *What Medicaid Recipients and Other Low-Income Adults Think about Medicaid Work Requirements*, HEALTH AFF. (Aug. 30, 2017), https://www.healthaffairs.org/do/10.1377/hblog20170830.061699/full/ [hereinafter Greene, *What Medicaid Recipients and Other Low-Income Adults Think about Medicaid Work Requirements*].

A word on language may be helpful. Despite an imperfect fit, I follow popular and scholarly language in using the term "work requirements" to refer to Medicaid conditions that require beneficiaries to spend time in paid employment, job seeking, training, education, or caregiving.[36] I have also quoted the terminology "able-bodied," which is used by states and CMS to designate individuals who qualify for work requirements. State § 1115 waivers define able-bodied individuals by reference to what they are not: not pregnant, elderly, children, disabled, or "medically frail" (a regulatory term that encompasses people with serious or complex health conditions).[37] I note, however, that "able-bodied" is a fraught term with historical resonance and connotations on the basis of race and class,[38] and which conveys moral judgments about nondisabled people who receive public aid.[39] My intention here is not to invoke these judgments, but rather to participate in conversation with advocates, scholars, agency personnel, and states using the term.

I. EXPRESSIVE THEORIES OF LAW

Expressive theories of law, which emphasize the pathways by which legal rules encode and convey information, have an extensive reach.[40] The focus of this work tends to be how the information communicated through legal rules—typically information about morality, social norms, or risk/reward calculus—can

36 "Work requirements" is misleading for this purpose, and may even be harmful, because it obscures the range of alternative activities by which beneficiaries may fulfill their hourly quotas. CMS and states that have proposed these conditions in Medicaid have used the term "community engagement requirements" instead.

37 42 C.F.R. § 440.315(f) (2021) ("[T]he State's definition of individuals who are medically frail or otherwise have special medical needs must at least include those individuals described in § 438.50(d)(3) of this chapter [regarding certain categories of children], individuals with disabling mental disorders (including children with serious emotional disturbances and adults with serious mental illness), individuals with chronic substance use disorders, individuals with serious and complex medical conditions, individuals with a physical, intellectual or developmental disability that significantly impairs their ability to perform 1 or more activities of daily living, or individuals with a disability determination based on Social Security criteria or in States that apply more restrictive criteria than the Supplemental Security Income program, the State plan criteria."); HENRY J. KAISER FAM. FOUND., KEY STATE POLICY CHOICES ABOUT MEDICAL FRAILTY DETERMINATIONS FOR MEDICAID EXPANSION ADULTS (2019), https://www.kff.org/report-section/key-state-policy-choices-about-medical-frailty-determinations-for-medicaid-expansion-adults-issue-brief/.

38 Emily Badger & Margot Sanger-Katz, *Who's Able-Bodied, Anyway?*, N.Y. TIMES (Feb. 3, 2018), https://www.nytimes.com/2018/02/03/upshot/medicaid-able-bodied-poor-politics.html. The term dates at least back to Elizabethan poor laws, which required work as a condition of assistance. Hermer, *supra* note 5, at 41, 41 n.24.

39 Badger & Sanger-Katz, *supra* note 38. The Supplemental Nutrition Assistance Program (SNAP) uses the term as well, sometimes using the acronym ABAWDs (able-bodied adults without dependents) to designate the group that qualifies for work requirements.

40 *See, e.g.*, RICHARD H. MCADAMS, THE EXPRESSIVE POWERS OF LAW (2015).

motivate or deter compliance among those who are subject to the new rules.[41] One insight of expressive legal theories is that laws can lead subjects to internalize the norms expressed, thereby facilitating compliance and minimizing enforcement burdens.[42] But expressive legal theories are capacious enough to consider "expression" that may be unintended or unreflective of lawmakers' actual beliefs.[43] On their own, even without any deliberate intentions by the legislature, governor, or any other speaker, laws "always ha[ve] expressive meaning."[44] When interpreting the expressive impacts of laws, we should therefore contemplate not only what the speakers of such laws intend, but also what the laws themselves express as detached from the intentions of their drafters.

A deep scholarly literature has considered how laws express information.[45] Richard McAdams, a central theorist in this area, recently surveyed the field with attention to the ways in which law "influences beliefs, emotions, or behavior by what it expresses"[46]—noting a broader emphasis across scholars on how the expressive content of law affects compliance. On this view, law communicates information, which affects beliefs, which then shape individual behavior.[47] Law can exert this impact through multiple pathways. One such pathway draws on decision theory: where people must coordinate their behavior—such as when many people drive or consume a common nonexcludable resource—law can signal a

41 *Id.* at 3–6.

42 *Id.*

43 *See* Elizabeth S. Anderson & Richard L. Pildes, *Expressive Theories of Law: A General Restatement*, 148 U. PA. L. REV. 1503, 1506–08 (2000) (clarifying what is meant by "expression"). In expressive legal theories, expression refers to "the ways an action or a statement . . . manifests a state of mind." *Id.* But that state of mind may not in fact be shared by the speaker. As Anderson and Pildes write, "not everything that expresses a state of mind is caused by that state of mind"—such as "the musician who plays sad songs without feeling sad oneself." *Id.*

44 *Id.* at 1508.

45 *See, e.g.*, LAWRENCE M. FRIEDMAN, IMPACT: HOW LAW AFFECTS BEHAVIOR ch. 1 (2016); MCADAMS, *supra* note 40; Matthew D. Adler, *Expressive Theories of Law: A Skeptical Overview*, 148 U. PA. L. REV. 1363 (2000); Anderson & Pildes, *supra* note 43; Robert Cooter, *Expressive Law and Economics*, 27 J. LEGAL. STUD. 585 (1998); David DePianto, *Sticky Compliance: An Endowment Account of Expressive Law*, 2014 UTAH L. REV. 327 (2014); Alex Geisenger, *A Belief Change Theory of Expressive Law*, 88 IOWA L. REV. 35 (2002); Alex C. Geisenger & Michael Ashley Stein, *Expressive Law and the Americans with Disabilities Act*, 114 MICH. L. REV. 1061 (2016); Dan M. Kahan, *Social Influence, Social Meaning, and Deterrence*, 83 VA. L. REV. 349 (1997); Lawrence Lessig, *The Regulation of Social Meaning*, 62 U. CHI. L. REV. 943 (1995); Richard H. McAdams, *A Focal Point Theory of Expressive Law*, 86 VA. L. REV. 1649 (2000); Richard H. McAdams, *An Attitudinal Theory of Expressive Law*, 79 OR. L. REV. 339 (2000); Richard McAdams & Janice Nadler, *Coordinating in the Shadow of the Law*, 42 L. & SOC'Y REV, 865 (2008); Cass R. Sunstein, *On the Expressive Function of Law*, 144 U. PA. L. REV. 2021 (1996); Maggie Wittlin, *Buckling Under Pressure: An Empirical Test of the Expressive Effects of Law*, 28 YALE J. ON REG. 419 (2011).

46 MCADAMS, *supra* note 40, at 13.

47 *Id.*

"focal point" that facilitates coordination.[48] Namely, law *suggests* a choice that then becomes salient, and different actors with competing interests can organize their activity accordingly (e.g., avoiding crashes or preserving scarce resources).[49]

Where coordination among actors is not a significant demand, however—such as when Medicaid-eligible individuals enroll in benefits—a different pathway of *direct* signaling may more relevant. Law communicates information directly to people who are bound by its mandates, because when people become aware of a law (regardless of whether the law applies to them personally), they draw conclusions about *how* and *why* the law exists. This Article focuses on ways in which these conclusions embed people's prior views of law, lawmakers, social norms, and empirical facts. These conclusions can affect people's behavior (as most expressive legal theorists discuss), as well as affecting people's attitudes about the law or the world around them. The ways that people identify signals in law have been arranged in three categories: attitudinal signaling, risk signaling, and violations signaling.

"Attitudinal signaling" occurs when laws express suggestions about social norms or attitudes. Individuals who interpret law as conveying attitudinal signals might reasonably conclude that if the law requires a behavior (say, paying taxes or refraining from discriminatory behavior), public attitudes concur with the law. If social norms matter—if we fear social costs of nonconformity, or if being like others is of intrinsic importance to us—we may update our own practices accordingly.[50]

Another category of information is "risk signaling," by which the law implies facts about hazards that exist in the world. For example, if I know I will incur legal penalties for driving my child around without a car seat, I may usefully conclude that lawmakers think this is a dangerous choice. I may rationally update my behavior to reflect this new risk information because I care about my child's safety.

But perversely, realizing that the law takes steps to penalize my reckless choices might also raise my suspicion that *others* do not behave safely: a mechanism known as "violations signaling." If I conclude that legislators adopted a car seat law because *other* parents drive around with their kids loose in the back seat, I will receive perverse information about permissive social norms. A well-known example of violations signaling can occur when lawmakers raise sanctions

48 *Id.* at 22; THOMAS SCHELLING, THE STRATEGY OF CONFLICT (1963); Richard H. McAdams, *A Focal Point Theory of Expressive Law*, *supra* note 40; Richard H. McAdams, *Beyond the Prisoners' Dilemma*, 82 S. CAL. L. REV. 209 (2009); McAdams & Nadler, *supra* note 45.

49 MCADAMS, *supra* note 40, at 22, 62 (noting limitations on the scope of this theory).

50 For some pushback on this point, see Robert E. Scott, *The Limits of Behavioral Theories of Law and Social Norms*, 86 VA. L. REV. 1603, 1621–37 (2000) (arguing that expressive theories explaining how law influences social norms are imprecise and lacking in mechanisms to explain internalization).

for tax evasion, which may prompt us to believe that many others shirk paying their taxes. None of us wants to be the chump who pays her taxes while others shirk—so violations signaling may paradoxically *increase* violations.[51]

The impacts of expression are distinct from the direct incentive impacts of law. For instance, if I know my state is raising taxes for sugary soda, I might purchase less soda simply because it is more expensive (direct incentive impacts). But when I learn about this law, the fact that my legislature made this choice may also cause me to update my beliefs (expressive impacts). I may conclude that my fellow citizens disfavor soda (or, worse, soda-drinkers), and I may be concerned about drinking a disfavored beverage; this mechanism may be stronger if we view laws as reflecting popular preferences (which may be a stronger connection for legislation or popular referenda as compared to agency regulation). I may also conclude that the legislature thinks that soda is bad for me, and is actively trying to put it further out of reach. Or, perversely, I may conclude that the legislature raised soda taxes because soda is wildly popular (particularly true for taxes, where I might believe that the legislature is motivated to raise as much revenue as possible), and thereby take the opposite lesson about peer norms. These new beliefs may affect my choices, wholly apart from the fact that soda is more expensive than it was before.

Of course, another possible expressive interpretation is that legislators (and, by extension, the voters in my state) simply have it out for me, as well as for my fellow soda drinkers, and that we have lost a battle that implicates our identity. When this is true, laws convey not only information about social norms and risk, but also information about the relative standing of social groups. Dan Kahan and Donald Braman's work on cultural cognition has been a formative contribution to this field, which McAdams has called the "expressive-politics theory of law."[52] A soda tax, for example, may teach the soda drinker that others think she is irresponsible, that she is deserving of punishment, or that she is an expedient means of raising revenue for the state. Individuals who resent or cheer laws may thus view the enactment of legal rules as elevating or undermining their own cultural identities—such as the enactment of Prohibition as a symbolic victory for Protestant advocates,[53] or the regulation of firearms as a threat to hierarchical and

51 MCADAMS, *supra* note 40, at 162.

52 *Id.* at 13.

53 *See generally* MCADAMS, *supra* note 40, at 14 (drawing on JOSEPH GUSFIELD, SYMBOLIC CRUSADE: STATUS POLITICS AND THE AMERICAN TEMPERANCE MOVEMENT (1982) to note the view that "law is a symbol over which political groups struggle").

individualistic cultural values.[54]

Given the focus on compliance behavior in expressive legal literatures, expressive-political effects such as feeling validated or "disrespected" by legal rules have played a supporting role in behavioral analyses of expressive law.[55] But a separate thread of literature on incentives and motivation can draw links between these emotions and behavior. "Motivation crowding" theory rests on the premise that offering individuals incentives, penalties, or mandates can interfere with their intrinsic motivation to behave as requested.[56] Many possible messages that can exert this effect: if individuals interpret a legal rule as insulting,[57] distrustful,[58] hostile,[59] arbitrary,[60] evidence of reprehensible values,[61] evidence of detrimental social norms,[62] or negative information about the task,[63] the rule may interfere with intrinsic motivation to behave as desired. I therefore view the distinction between expressive impacts on *identity* ("expressive-politics" theory, per McAdams) and expressive impacts on *behavior* as highly collapsible, and I will consider both as potential pathways to behavior.

Expressive legal theories have limits. For instance, such theories only function well when individuals know the law, or when *enough* individuals are aware of law

54 MCADAMS, *supra* note 40, at 14 (drawing on a body of work by Dan Kahan and Don Braman to note that "social groups view regulation as a political test of their cultural values . . . . There being symbolic competition among social groups, the members of one group will favor the laws they perceive as expressing their social standing").

55 *See, e.g.*, MCADAMS, *supra* note 40, at 13 ("If one subjectively feels respected by the law, that gain is an expressive consequence. If one feels disrespected, that loss is an expressive harm . . . [B]ut the main event here is behavior.").

56 Kristen Underhill, *Money that Costs Too Much*, 94 IND. L.J. 1109 (2019); Kristen Underhill, *When Extrinsic Incentives Displace Intrinsic Motivation: Designing Legal Carrots and Sticks to Confront the Challenge of Motivational Crowding-Out*, 33 YALE J. ON REG. 213 (2016).

57 Roland Bénabou & Jean Tirole. *Intrinsic and Extrinsic Motivation*, 70 REV. ECON. STUD. 489, 491 (2003).

58 Ernst Fehr & Simon Gachter, *Fairness and Retaliation: The Economics of Reciprocity*, 14 J. ECON. PERSP. 159, 177 (2000); Bruno S. Frey, *A Constitution for Knaves Crowds out Civic Virtues*, 443 ECON. J. 1043 (1997);

59 Tore Ellingsen & Magnus Johannesson, *Pride and Prejudice: The Human Side of Incentive Theory*, 98 AM. ECON. REV. 990, 992 (2008) (noting the difference between profit-maximizing and mission-oriented motivations).

60 *See* Robert Eisenberger & Judy Cameron, *Detrimental Effects of Reward: Reality or Myth?*, 51 AM. PSYCHOLOGIST 1153, 1162–63 (1996) ("When reward is presented independently of performance, people may learn they cannot influence reward presentation, resulting in reduced motivation.").

61 Antoine Beretti et al., *Using Money to Motivate Both "Saints" and "Sinners": A Field Experiment on Motivational Crowding-Out*, 66 KYKLOS 63, 66 (2013); Uri Gneezy et al., *When and Why Incentives (Don't) Work to Modify Behavior*, 25 J. ECON. PERSP. 191 (2011).

62 Dan M. Kahan, *The Logic of Reciprocity: Trust, Collective Action, and Law*, 102 MICH. L. REV. 71, 79 (2003)

63 Roland Bénabou & Jean Tirole, *Incentives and Prosocial Behavior*, 96 AM. ECON. REV. 1652, 1654 (2006).

to shift prevailing norms.[64] The interviews for this study gave participants information about the legal rules before exploring their interpretations, but other sources of information may be lacking.[65] Moreover, little is known about the half-life of law's expressive signals—although learning about law may affect beliefs, little research has considered the durability of those changes. Beliefs do not always drive action. But despite these limitations, expressive theories provide useful frameworks for understanding how people bound by law may interpret legal rules.

II. CONDITIONS IN MEDICAID

Through the lens of expressive law, Medicaid conditions can convey both intended and inadvertent expressive meanings. CMS and states have explained their intended rationale for these waiver terms in guidance, state applications, and CMS approval letters, as well as public statements by state governors and CMS leadership. These messages use the language of beneficiary dignity, income, and health. Commentators in academia and advocacy, however, have interpreted Medicaid conditions as expressing states' disregard of beneficiaries, animus towards some or all individuals receiving public assistance, or misunderstanding of the social and economic constraints that beneficiaries experience.[66] Largely absent from the conversation have been the messages received by beneficiaries themselves. This Part will introduce Medicaid waivers through an expressive lens, considering particularly the signals proffered by states and CMS.

A. Work Requirement Waivers

Medicaid is an open-ended public assistance program financed jointly by state and federal revenues, and operated by states in compliance with federal regulations under the Social Security Act (SSA).[67] Medicare and Medicaid were established via amendment to the SSA in 1965; because the legislation principally focused on the enactment of Medicare,[68] the Medicaid program was little-noticed at the time,

64 *See* Kristen Underhill, *Perceptions of Protection under Nondiscrimination Law*, 46 AM. J.L. & MED. 21 (2020).

65 *See* Greene, *Medicaid Recipients' Early Experience with the Arkansas Medicaid Work Requirement*, *supra* note 35; Margot Sanger-Katz, *One Big Problem with Medicaid Work Requirement: People are Unaware It Exists*, N.Y. TIMES (Sept. 24, 2018), https://www.nytimes.com/2018/09/24/upshot/one-big-problem-with-medicaid-work-requirement-people-are-unaware-it-exists.html.

66 *See infra* Section III.D and accompanying notes.

67 LAURA KATZ OLSON, THE POLITICS OF MEDICAID (2008).

68 *Id.* at 23.

and mandatory populations and benefits were initially narrowly defined.[69] But in the decades since its enactment, Medicaid has expanded into the largest federal health insurance program,[70] covering 75 million children and adults on average per month.[71] Federal legislation throughout the 1980s and 1990s expanded eligible populations and benefits,[72] and the Affordable Care Act expansion was a transformative step nudging Medicaid toward a social insurance program[73]—one of near universal applicability,[74] although still under state control. Many scholars have considered the origins and impacts of local control over public benefits programs,[75] including Medicaid,[76] and although local control has created opportunities to identify the impact of policy features, decentralization has also contributed to access disparities on the basis of race and class.[77]

Two sources of variation—§ 1115 waivers and optional Medicaid expansion—have driven heterogeneity in Medicaid programming, yielding unprecedented new conditions for Medicaid eligibility.

First, a majority of states are now using § 1115 waivers to implement experimental or demonstration programming, which reflects decades of waiver approvals. Under § 1115 of the Public Welfare Amendments, added to the SSA in 1962, states who wished to experiment with new models of welfare programming

69 MICHENER, *supra* note 9, at 42; OLSON, *supra* note 67, at 26; ROBERT STEVENS & ROSEMARY STEVENS, WELFARE MEDICINE IN AMERICA: A CASE STUDY OF MEDICAID 57-72 (2003) (describing the initial design of Medicaid, and noting at page 57 that it "was not a sweeping program of assistance to all those who were poor, even within a state . . . [T]he federal subsidy followed . . . existing welfare classifications").

70 OLSON, *supra* note 67, at 8.

71 Medicaid also covers close to 5 million each month through the Children's Health Insurance Program (CHIP), Medicaid programming specifically for children. CMS FAST FACTS, CTRS. FOR MEDICARE & MEDICAID SERVS., U.S. DEP'T OF HEALTH & HUMAN SERVS., https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Fast-Facts/index.html (last updated Mar. 12, 2021). These figures do not exclude individuals with dual eligibility, who receive both Medicare and Medicaid.

72 MICHENER, *supra* note 9, at 44–45.

73 Nicole Huberfeld & Jessica L. Roberts, *An Empirical Perspective on Medicaid as Social Insurance*, 46 U. TOLEDO L. REV. 545, 545 (2015).

74 Nicole Huberfeld, *The Universality of Medicaid at Fifty*, 15 YALE J. HEALTH POL'Y L. & ETHICS 67 (2014). Large exclusions continue to be enforced, however, for recent migrants and long-term migrants who do not meet "qualified" standards (including undocumented migrants). Recent "public charge" regulations also allow citizenship determinations to consider Medicaid uptake as a factor suggesting that a migrant is likely to become a "public charge" in the U.S., which is expected to deter uptake among many migrants who are legally qualified to use the program.

75 *See, e.g.*, KAREN TANI, STATES OF DEPENDENCY: WELFARE, RIGHTS, AND AMERICAN GOVERNANCE, 1935-1972 (2016); SOSS, *supra* note 33.

76 MICHENER, *supra* note 9; David A. Super, *Laboratories of Destitution*, 157 U. PA. L. REV. 541 (2009).

77 MICHENER, *supra* note 9, at 54.

could seek permission for temporary waivers of federal requirements.[78] The Secretary of the Department of Health, Education and Welfare (now HHS) had authority to approve waivers for an "experimental, pilot, or demonstration project," as long as she judged those programs "likely to assist in promoting the objectives" of the statute.[79] States could initially seek waivers to modify the Aid to Families with Dependent Children (AFDC) welfare program; when Medicaid was added to the SSA in 1965, § 1115 extended to some provisions of Medicaid as well.

Initial state waivers for both AFDC[80] and Medicaid programming[81] were restricted in scope, rarely statewide, and directed toward administrative changes. But the 1980s brought a new wave of waivers to AFDC under President Reagan, including new conditions for beneficiaries such as job training and welfare-to-work programming.[82] In 1982 and 1983, HHS facilitated these waivers by exempting § 1115 experiments from oversight by institutional review boards, which review research protocols for compliance with federal research ethics standards.[83]AFDC waivers expanded further under Presidents Bush and Clinton, culminating in program-wide work requirements for TANF (the replacement for AFDC) and SNAP under welfare reform in 1996.[84]

Until recently, waiver terms in state Medicaid programs have been qualitatively different from those tested in AFDC and TANF, and many tended to broaden eligibility, expand benefits, or improve care delivery. Medicaid waivers

78 Lucy A. Williams, *The Abuse of § 1115 Waivers*, 12 YALE L. & POL'Y REV. 8, 10-11 (1994).

79 Public Welfare Amendments of 1962, Pub. L. No. 87-543, 76 Stat. 172, 192 (codified as amended at 42 U.S.C. § 1315 (2018)); Williams, *supra* note 78.

80 Williams, *supra* note 78, at 14.

81 Sidney Watson, *Out of the Black Box into the Light: Using Section 1115 Medicaid Waivers to Implement the Affordable Care Act's Medicaid Expansion*, 15 YALE J. HEALTH POL'Y L. & ETHICS 213, 215 (2015) [hereinafter Watson, *Out of the Black Box into the Light*].

82 Williams, *supra* note 78, at 16.

83 *Id.* at 19–24; *see also* 47 Fed. Reg. 9208 (Mar. 4, 1982) (giving notice that "the Secretary has decided to waive the requirements . . . relating to protection of human subjects, as they pertain to demonstration projects, approved under section 1115 of the Social Security Act, which test the use of cost-sharing . . . in the Medicaid program"). This waiver was expanded in 1983 to include all section 1115 demonstrations. Williams, *supra* note 78, at 22.

84 Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA), Pub. L. 104-193, 110 Stat. 2105 (1996). The PRWORA requirements differed markedly from the welfare-to-work experiments in prior § 1115 waivers. Section 1115 waivers had been structured to offer unpaid work to recipients of public benefits, and refusal to accept the proffered work resulted in a penalty. The PRWORA provisions did not require states to generate work opportunities for participants, who were expected to find jobs independently. *See, e.g.*, ; David A. Super, *A Hiatus in Soft-Power Administrative Law*, 65 UCLA L. REV. 1590 (2018) [hereinafter Super, *A Hiatus*]; David A. Super, *"Work Requirements" for Public Benefits Are Really Just Time Limits*, LA TIMES (Jan. 15, 2018), https://www.latimes.com/opinion/op-ed/la-oe-super-work-requirements-20180115-story.html.

grew under the Clinton and Bush administrations,[85] and they focused on expanded eligibility, coverage of optional benefits, increased cost-sharing for beneficiaries, and managed care approaches.[86] In the absence of any Medicaid statutory authority for programmatic waivers, statewide experimental waivers have come to fill this gap, and large-scale waivers (many with thin evaluations and extensive policy similarity to other states) have become the norm.[87] Medicaid was exempted from work requirements in the 1996 welfare reform, primarily because Medicaid was largely restricted to populations considered less capable of working.[88] Although states continued to seek flexibility in the early years of the Obama Administration,[89] these continued to expand eligibility and to seek payment and organizational reform, rather than placing new conditions on benefits.

The most recent wave of § 1115 waivers has ushered in an unprecedented degree of flexibility, brought about due to the extension of Medicaid to a new category (adults deemed "able-bodied") and the ability of states to refuse Medicaid expansion. The ACA mandated the expansion of Medicaid to all individuals below 138% of the federal poverty level,[90] enforced via the same mechanism that had been in place since 1965: states that failed to cover any mandatory population, including the new expansion group, would be ineligible for all Medicaid funds.[91] Challenges to this provision culminated in the Supreme Court's 2012 decision in *National Federation of Independent Business v. Sebelius*[92] (*NFIB*), which stripped the statute of its enforcement mechanism.

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85 MICHENER, *supra* note 9, at 46; Hermer, *supra* note 5, at 42-45; Watson, *supra* note 81, at 214.

86 Expansions in cost-sharing were also enabled by the Deficit Reduction Act of 2005, along with permission for states to offer more limited benefits to some groups of beneficiaries. Hermer, *supra* note 5, at 44–45.

87 Watson, *supra* note 94, at 215 ("[By the time of the ACA], waivers no longer seemed to be about testing new and innovative ideas likely to further the purpose of the Medicaid Act. Instead, waiver approvals seemed to reflect a particular administration's policy preferences: President Clinton's for simply allowing states more flexibility from federal rules to pursue their own priorities and President George W. Bush's for promoting private insurance models with thinner benefits and higher cost-sharing. Successive federal administrations seemed chronically unconcerned about whether waivers were budget neutral for the federal government. Some waivers have continued for decades with no public evaluation of their impact on Medicaid access, cost, or quality.").

88 *Id.*

89 *Id.*

90 Patient Protection and Affordable Care Act, Pub. L. 111-148 § 2001(a), 124 Stat. 119, 271 (Mar 23, 2010) (codified at 42 U.S.C. § 1396a(a)(10)(A)(i)(VIII) (2018)). The statutory language extends the limit to 133% of the federal poverty level, and a separate provision of the ACA allows an income eligibility disregard in the amount of 5 percentage points of the federal poverty level. *Id.* § 2002(a) (as modified by the Health Care and Education Reconciliation Act of 2010, Pub. L. 111-152, § 1004(e)(2), 124 Stat. 1029, 1034 (March 30, 2010) (codified at 42 U.S.C. § 1396a(e)(14)(I) (2021))).

91 42 U.S.C. § 1396c (2018).

92 Nat'l Fed'n of Indep. Bus. v. Sebelius, 567 U.S. 519 (2012).

The *NFIB* decision was an inflection point in the history and purpose of § 1115 waivers.[93] States after *NFIB* had a valuable political bargaining chip—they could choose to expand Medicaid to the new population, but in exchange they demanded new concessions from CMS in approving waiver terms. Eager to secure Medicaid expansion, the Obama Administration approved waivers from states with expanded copayment requirements, premiums as a condition of participation,[94] and stick-based incentives that required individuals to participate in healthy behavior activities to retain certain benefits. Indiana's waiver was the most demanding, which allowed program lockouts (disenrollment) for beneficiaries who did not make premium payments.[95] HHS continued to disallow other waiver terms, however, including work requirements proposed by Indiana, Utah, Arizona, and Pennsylvania.[96]

The Trump Administration changed the emphasis of § 1115 waivers. Under criteria released in November 2017, the Administration's goals for experimental Medicaid programming included "support[ing] coordinated strategies to address certain health determinants that promote upward mobility, greater independence, and improved quality of life," and "incentive structures that promote responsible decision-making."[97] These emphases, combined with the expansion of Medicaid to populations considered "able-bodied," resulted in the approval of waiver terms that more closely resembled conditions used in TANF and SNAP.[98]

Foremost among these terms was work requirements (or in HHS terms, community engagement requirements). A joint letter from CMS Administrator Seema Verma and HHS Secretary Tom Price announced the department's policy change in 2017, welcoming applications with work requirements.[99] In January 2018, CMS issued new waiver guidelines in a letter to state Medicaid directors.[100] The agency invited programs "designed to promote better mental, physical, and emotional health," and asked states to "consider a variety of activities" for meeting work hour quotas in high-unemployment areas. Unlike the early AFDC

93 MICHENER, *supra* note 9, at 46; Abbe R. Gluck & Nicole Huberfeld, *What is Federalism in Health Care For?*, 70 STAN. L. REV. 1689, 1729 (2018); Super, *A Hiatus*, *supra* note 84; Watson, *supra* note 81, at 214.

94 Sidney D. Watson, *Premiums and Section 1115 Waivers: What Cost Medicaid Expansion?*, 9 ST. LOUIS UNIV. SCH. L. HEALTH L. & POL'Y 265, 271 (2016).

95 Montana, Arizona, and Iowa also gained approval for lockouts, but allowed re-enrollment if outstanding premiums were paid. Watson, *supra* note 94, at 267.

96 *State Waivers List*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/index.html (last visited Nov. 22, 2021).

97 ELIZABETH HINTON ET AL., HENRY J. KAISER FAM. FOUND., SECTION 1115 MEDICAID DEMONSTRATION WAIVERS 9 (2019).

98 Hermer, *supra* note 5, at 58–64.

99 Letter from Sec'y Price & Adm'r Verma, *supra* note 11.

100 Letter from Brian Neale to State Medicaid Dirs., *supra* note 12.

experiments, however, Medicaid funds could not be used to pay for job training or "work supports" such as commuting or childcare.[101] Ten states received approvals to institute work requirement terms, and ten more states had applications pending at the end of the Trump Administration.[102] Only Arkansas implemented penalties for work requirement noncompliance, lasting from June 2018 until the program was halted in March 2019.[103]

The Trump Administration's emphasis on expanding work requirements for benefits programming reached beyond Medicaid. In April 2018, President Trump signed the "Executive Order Reducing Poverty in America by Promoting Opportunity and Economic Mobility," which describes benefits programs as "delay[ing] economic independence, perpetuat[ing] poverty, and weaken[ing] family bonds" through "long-term Government dependence."[104] The order sets forth new "Principles of Economic Mobility," which begin with "strengthening existing work requirements for work-capable people and introducing new work requirements when legally permissible."[105] A 2018 report by the president's Council of Economic Advisers echoed the executive order, advocating the extension of work requirements to "non-cash welfare programs"[106] like Medicaid, federal housing assistance, and SNAP for adults with dependents. HHS also reversed guidance by the Obama administration that had signaled a willingness to *waive* work requirements in § 1115 waivers applicable to TANF.[107] A White House plan for reorganizing federal agencies, announced in summer 2018, would have consolidated federal benefits programming in one agency, tasked in part with setting "uniform work requirements to be implemented across all welfare

101 *Id.*

102 HENRY J. KAISER FAM. FOUND., *supra* note 8. Several states with pending waivers also have incoming governors or legislatures who have publicly opposed these terms, so ongoing progress is uncertain. Todd Leeuwenburgh, *New Democratic Governors May Block Medicaid Work Requirements*, BLOOMBERG L., (Dec. 27, 2018), https://news.bloomberglaw.com/health-law-and-business/new-democratic-governors-may-block-medicaid-work-requirements.

103 *See* Sommers et al., *supra* note 18.

104 Exec. Order No. 13,828, Reducing Poverty in America by Promoting Opportunity and Economic Mobility, 83 Fed. Reg. 15,941, 15,941 (Apr. 13, 2018).

105 *Id.*

106 COUNCIL OF ECON. ADVISERS, EXPANDING WORK REQUIREMENTS IN NON-CASH WELFARE PROGRAMS 2 (2018).

107 Information Memorandum TANF-ACF-IM-2017-01 from Clarence H. Carter, Dir. Office of Family Assistance, to State and Territorial Agencies Administering TANF on Rescinding Guidance Concerning Waiver and Expenditure Authority under Section 1115 of the Social Security Act (Aug. 30, 2017), https://www.acf.hhs.gov/ofa/resource/tanf-acf-im-2017-01 ("More than just a means of income, work creates opportunities for individual growth, instills personal dignity, and provides low-income families with a clear pathway to financial self-sufficiency.").

programs."[108] Other regulations also tightened work requirements in SNAP, which was projected to end benefits coverage for approximately 700,000 recipients.

CMS's approval of state work requirement waivers was immediately challenged in the District of D.C. by a group of Medicaid beneficiaries in Kentucky, who argued that the state's waiver was not likely to assist in promoting the primary objective of the Medicaid Act, defined in the statute as "furnishing medical assistance . . . [to] individuals[] whose income and resources are insufficient to meet the costs of necessary medical services."[109] The waivers, argued advocates for beneficiaries, were projected to lead to large losses of coverage, which is incompatible with Medicaid's central goal. The District of D.C. (Judge Boasberg) vacated the Kentucky waiver and a series of others, deciding that CMS had failed to consider the impacts on coverage, and in so doing failed to assess whether the waivers were likely to assist in promoting the objective of furnishing medical assistance.[110] The D.C. Circuit later upheld the decision with respect to Arkansas and New Hampshire, echoing this reasoning.[111] The Supreme Court granted certiorari to hear the consolidated Arkansas and New Hampshire cases,[112] but as of April 2021 is holding the case in abeyance.[113] President Biden's HHS is now in the process of reviewing and rescinding waivers that granted permission for states to use work requirements in Medicaid,[114] and has already rescinded its approval of the Arkansas and New Hampshire programs.[115]

Given these decisions and the change of administration, work requirements are unlikely to take effect in Medicaid in the near future, particularly during the COVID-19 recovery. The Families First Coronavirus Response Act suspended

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108 GEN. SERVS. ADMIN. & THE OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT OF THE U.S., DELIVERING GOVERNMENT SOLUTIONS IN THE 21ST CENTURY 29 (2018), https://usace.contentdm.oclc.org/digital/collection/p16021coll11/id/2520/.

109 42 U.S.C. § 1396-1 (2018); Stewart v. Azar, 313 F. Supp. 3d 237, 260 (D.D.C. 2018).

110 *See* Young v. Azar, 1:19-cv03526 (D.D.C., March 4, 2020) (vacating the waiver in Michigan); Philbrick v. Azar, 397 F. Supp. 3d 11, 33 (D.D.C. 2019) (vacating the waiver in New Hampshire); Stewart v. Azar, 366 F. Supp. 3d 125 (D.D.C. 2019) (vacating the waiver in Kentucky); Gresham v. Azar, 363 F. Supp. 3d 165 (D.D.C. 2019) (vacating the waiver in Arkansas).

111 Philbrick v. Azar, No. 19-5293, 2020 WL 2621222, at *1 (D.C. Cir., May 20, 2020) (affirming vacatur of the waiver in New Hampshire); Gresham v. Azar, 950 F.3d 93, 104 (D.C. Cir. 2020) (affirming vacatur of the waiver in Arkansas).

112 Azar v. Gresham, 141 S. Ct. 890 (2020).

113 Becerra v. Gresham, 141 S. Ct. 2461 (2021).

114 Watson, *supra* note 7; *see also* Erin Brantley et al., *As the Biden Administration Begins Unwinding Them, Medicaid Work Experiments Remain Unreasonable, Unnecessary, and Harmful*, HEALTH AFF., Feb. 17, 2021, https://www.healthaffairs.org/do/10.1377/hblog20210216.717854/full/ (summarizing political and legal developments in work requirement waivers during the first months of the Biden Administration).

115 Reply Brief for the Federal Petitioners at 5, Becerra v. Gresham, 141 S. Ct. 2461 (2021) (Nos. 20-37 and 20-38).

enforcement of SNAP work requirements during the public health emergency,[116] and the HHS Office of Children and Families urged states to give TANF recipients good-cause exemptions from work requirements, and expanded non-recurrent short-term benefits that are exempt by design.[117] But among conservative lawmakers, work requirements as a condition of participation in means-tested programs are very much alive.[118] As of May 2021, for example, thirty-six or more states have announced an intention to reinstate work search requirements as a condition of receiving unemployment insurance benefits.[119] As COVID-19 recedes, interest in work requirements seems likely to increase once more.

B. Proffered and Observed Signals of Medicaid Work Requirements

New conditions in Medicaid § 1115 waivers encode a range of values, norms, and information about states and their citizens. This Section will consider the *intended* messages (e.g., messages that lawmakers *intend* to convey to beneficiaries, political actors, and the general public) of new § 1115 conditions, as proffered by CMS and waiver states, as well as some of the messages identified by observers. The variation in signals here foreshadows what the study demonstrated: the expressive impact of law is largely in the eye of the beholder, and in fact co-produced by the law and the normative priors of the observer. This Part discusses the public messaging that waiver proponents sought to encourage, followed by the signals read into the laws by observers with very different normative viewpoints.

1. Signals Proffered by CMS and States

CMS and states proffered several purposes for Medicaid work requirements.

116 Families First Coronavirus Response Act, Pub. L. 116-127, § 2301, 134 Stat. 177, 188 (2021); *see also* U.S. DEP'T AGRIC., FNS-GD-2020-0016, SUPPLEMENTAL NUTRITION ASSISTANCE PROGRAM (SNAP) – FAMILIES FIRST CORONAVIRUS RESPONSE ACT AND IMPACT ON TIME LIMIT FOR ABLE-BODIED ADULTS WITHOUT DEPENDENTS (ABAWDS) (2020) (providing guidance to state administrators to implement the suspension of work requirements in the SNAP program).

117 U.S. DEP'T HEALTH & HUM. SERVS., TANF-ACF-PI-2020-01 (QUESTIONS AND ANSWERS ABOUT TANF AND THE CORONAVIRUS DISEASE 2019 (COVID-19) PANDEMIC) (2020).

118 Jeff Stein and Matt Viser, *White House to Work with States on Reimposing Work-Search Requirements Following GOP Outcry*, WASH. POST (May 10, 2021), https://www.washingtonpost.com/us-policy/2021/05/10/biden-unemployment-benefits/ (describing GOP arguments that unemployment benefits are discouraging labor force participation, as well as Democrats' rejoinders that child care and COVID-19-related barriers are still preventing many from working).

119 Sydney Ember, *Unemployment Pay May Again Require a Job Search. Is It Too Soon?*, N.Y. TIMES (May 16, 2021), https://www.nytimes.com/2021/05/16/business/unemployment-job-search-requirements.html; Sarah Hansen, *At Least 36 States Are Reimposing Work Search Requirements on Unemployment Benefits Recipients*, FORBES (May 17, 2021), https://www.forbes.com/sites/sarahhansen/2021/05/17/at-least-36-states-are-reimposing-work-search-requirements-on-unemployment-benefits-recipients/?sh=5d0dbcb158f8.

Foremost is the goal of advancing public health, on the theory that completing work or other qualifying activities will raise incomes, self-esteem, and dignity, which will in turn drive health improvements. In their 2017 letter to state governors, Verma and Price argued that "the best way to improve the long-term health of low-income Americans is to empower them with skills and employment . . . [through] innovations that build on the human dignity that comes with training, employment, and independence."[120] In an address to the National Association of Medicaid Directors in November of 2017, Verma further clarified the administration's position on work requirements:

> The Medicaid program is a promise to help individuals live up to their highest potential, leading healthier, more fulfilling, and more independent lives . . . . [States] . . . want to develop programs that will help them break the chains of poverty and live up to their fullest potential . . . . For the future of our country, we need all Americans to be active participants in their communities . . . . [M]eaningful work is essential to . . . economic self-sufficiency, self-esteem, wellbeing, and improving [] health . . . Believing that community engagement requirements do not support or promote the objectives of Medicaid is a tragic example of the soft bigotry of low expectations consistently espoused by the prior administration. Those days are over.[121]

Verma later elaborated on this justification by invoking compassion for Medicaid beneficiaries, writing, "True compassion is lifting Americans most in need out of difficult circumstances . . . . We owe it to these Americans to try whatever may help them achieve the dignity and self-sufficiency they deserve."[122]

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120 Letter from Sec'y Price & Adm'r Verma, *supra* note 11. Before her appointment as CMS, Verma had previously designed § 1115 waivers for Kentucky and Indiana, both of which had proposed work requirements but were not approved under the Obama Administration.

121 Seema Verma, Adm'r, Remarks at the National Association of Medical Directors (NAMD) 2017 Fall Conference (Nov. 7, 2017), https://www.cms.gov/newsroom/fact-sheets/speech-remarks-administrator-seema-verma-national-association-medicaid-directors-namd-2017-fall [hereinafter Verma Remarks].

122 Seema Verma, *Making Medicaid a Pathway Out of Poverty*, WASH. POST (Feb. 4, 2018), https://www.washingtonpost.com/opinions/making-medicaid-a-pathway-out-of-poverty/2018/02/04/4570736a-0857-11e8-94e8-e8b8600ade23_story.html ("the compassionate nature of [states seeking approval for "work and community-engagement incentives"] encouraged the creativity to design a system to help the new able-bodied, working-age Medicaid population unlock their fullest potential . . . . The new flexibility requested by states will allow them to partner with us to help program beneficiaries live healthy, fulfilling lives as independently as possible."). In

CMS statements focused not only on promoting health, dignity, and higher incomes, but on a range of other objectives as well. Promoting state flexibility as a good in itself is among them, and CMS communications have stressed the desirability of acceding to state preferences. Invoking national economic interests and social interests ("for the future of our country") provides a separate purpose for such waivers, on the theory that work requirements will motivate more economic participation, and that this participation will be meaningful on a national scale. Multiple CMS communications, as well as Trump's executive order promoting work requirements,[123] have also evinced a purpose of returning the Medicaid program to its "original" intentions at the time of enactment, in contrast to fulfilling the expansionist intentions of the ACA Congress. Another stated goal has been to use new Medicaid conditions—such as premiums, waivers of benefits, and waivers of retroactive eligibility—to "creat[e] greater alignment between Medicaid's design and benefit structure with common features of commercial health coverage, to help working age, non-pregnant, non-disabled adults prepare for private coverage." This latter goal implies that private coverage is normatively more desirable than public benefits, and that it appropriate for the state to educate beneficiaries about this coverage. Finally, both CMS and states have invoked a purpose of cost control. Verma has noted that "[w]ith Medicaid being an open-ended entitlement, the program has grown and grown and states have spent more and more . . . diverting state resources from other areas such as education and economic development."[124] Reducing program costs, whether for its own sake or to reallocate funds to other priorities, is here a similar intention.[125]

Each of these justifications communicates attitudes about beneficiaries and their lives, as well as beliefs about the causal relationships between program requirements and beneficiaries' choices. For example, the income- and health-

a blog post after approval of Wisconsin's waiver, Verma again advocated that the requirements reflect "true compassion," arguing, "It is not compassionate to lower our expectations such that we are content to leave Americans with inherent worth on the sidelines of life." Seema Verma, Adm'r of Ctrs. for Medicare & Medicaid Servs., U.S. Dep't of Health & Hum. Servs., *CMS Approves Innovative Wisconsin Plan to Improve Health and Lift Individuals from Poverty*, CTRS. FOR MEDICARE & MEDICAID SERVS. BLOG (Oct. 31, 2018), https://www.cms.gov/blog/cms-approves-innovative-wisconsin-plan-improve-health-and-lift-individuals-poverty; *see also* Letter from Brian Neale to State Medicaid Dirs., *supra* note 12 (describing the purposes of work requirements as "to promote better physical, mental, and emotional health" and "to help individuals and families rise out of poverty and attain independence").

123 *See* Exec. Order No. 13,828, Reducing Poverty in America by Promoting Opportunity and Economic Mobility, 83 Fed. Reg. 15,941, 15,941 (Apr. 13, 2018).

124 Verma Remarks, *supra* note 121.

125 This is also part of the ostensible reasoning behind recent guidance allowing states to convert their Medicaid expansion programs into block grants, which will allow states to impose premiums and work requirements. Letter from Calder Lynch, Dir., Ctrs. for Medicare & Medicaid Servs., to State Medicaid Dirs. (Jan. 30, 2020), https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/smd20001.pdf.

promotion rationales communicate that CMS and states place a high premium on work, as well as a central belief that waivers are needed to align individual-level incentives to increase beneficiaries' economic activity. These justifications support a particular view of able-bodied Medicaid beneficiaries (i.e., that they can engage in work or volunteering, but do not because they lack appropriate individual incentives), as well as a view of social context (i.e., that employment and volunteer opportunities are available—such that work requirements may be described as compassionate rather than unrealistic). Each justification also suggests a set of social norms that may be present among the general population, as well as embodying the normative views of CMS with respect to the social desirability of qualifying activities for the low-income population specifically. The expressions of compassion and the language of obligation also highlight a message about government-citizen relationships: namely, that the government's role as Medicaid programmer includes caretaking for beneficiaries ("we owe it to these Americans"), and that beneficiaries owe reciprocal duties in response ("we need all Americans to be active participants").

From CMS's intended purposes, observers might also deduce information about the extent to which Medicaid beneficiaries currently work, and the extent to which working (or not working) results from actions within beneficiaries' capacity and control—such that a work requirement enforced by Medicaid exclusion could in fact change behavior by supplying powerful extrinsic motivation. For instance, CMS's approval letter for Kentucky noted the strength of the disenrollment incentive as a feature that distinguished Kentucky from prior demonstrations that provided only "referrals to employment services or encouragement to seek employment."[126] As CMS noted, "Kentucky HEALTH's community engagement incentive is likely to be more effective than other incentives or referrals to employment services, as it provides for the consequence of eligibility suspension for non-compliance."[127] The agency's focus on the importance of individual motivation is particularly salient given the structural feature that federal Medicaid funds cannot be used for the purposes of providing work support services like childcare, transportation for work duties, or "workfare" job slots.[128]

States echoed CMS's characterization of work requirements as

126 Letter from Demetrios L. Kouzoukas, Principal Deputy Adm'r, Ctrs. for Medicare & Medicaid Servs., U.S. Dep't of Health & Hum. Servs., to Stephen Miller, Comm'r, Cabinet for Health and Fam. Servs., Ky. 3 (Jan. 12, 2018), https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ky/health/ky-health-cms-appvl-011218.pdf.

127 *Id.*

128 States that choose to provide these services must use their own funds to do so.

compassionate,[129] dignity-building,[130] and health-promoting.[131] States' § 1115

129 *See Arkansas's Work and Community Engagement Requirement Update*, ARKANSAS.GOV (Sept. 14, 2018), https://governor.arkansas.gov/news-media/weekly-address/arkansas_s-work-and-community-engagement-requirement-update.

130 Letter from Heather K. Smith, Medicaid Dir., Wis. Dep't of Health Servs., to Brian Neale, Deputy Adm'r, Ctrs. for Medicare and Medicaid Servs. 32 (Jan. 12, 2018) [hereinafter Wisconsin Application] (enclosing the state's application for a § 1115 waiver) ("Project Goals [include] . . . Help[ing] more Wisconsin citizens become independent and rely less on government-sponsored health insurance"). Governor Walker also described her goal of adding 30-hour-per-week work requirements to all public benefits programs to transition people from "government dependence to true independence through the dignity of work." Scott Bauer, *Walker Signs 9 Bills Limiting Wisconsin Welfare Into Law*, AP NEWS (Apr. 10, 2018), https://www.apnews.com/053c515a4f6b4d519965c145deeb0f3a; *see also* Letter from Matthew G. Bevin, Governor, Ky., to Sylvia Burwell, Sec'y, U.S. Dep't of Health and Hum. Servs. 6 (Aug 24, 2016) [hereinafter Kentucky Application] (enclosing the state's application for a § 1115 waiver) ("Kentucky HEALTH [is] a demonstration project designed to provide dignity to individuals as they move towards self-reliability, accountability, and ultimately independence from public assistance"); Letter from Christopher T. Sununu, Governor, N.H., to Alex Azar, Sec'y, U.S. Dep't of Health and Hum. Servs. 1 (July 23, 2018) [hereinafter New Hampshire Application] (enclosing the state's application for a § 1115 waiver) ("The attached amendment is designed to provide dignity to individuals as they move towards self-reliability, accountability, and ultimately independence from public assistance.").

131 *See, e.g.*, Kentucky Application, *supra* note 130, at 4 ([T]he program encourages members to improve their health by incentivizing preventive care, participation in disease management programs, and healthy lifestyles."); Letter from Eric Holcomb, Governor, Ind., to Norris Cochran, Acting Sec'y, U.S. Dep't of Health and Hum. Servs. 5 (Jan. 31, 2017) [hereinafter Indiana Application] (enclosing the state's application for a § 1115 waiver) ("the State seeks to increase participation in the Gateway to Work initiative to connect members to gainful employment, in a way that improves physical and mental health" and the individual's overall financial stability and well-being"); New Hampshire Application, *supra* note 130, at 18, (testing whether community engagement requirements "will lead to improved health outcomes and greater independence through improved health and wellness"); State of Alabama, Medicaid Workforce Initiative, Section 1115 Demonstration Application 3 (September 10, 2018) [hereinafter Alabama Application] ("Alabama Medicaid believes that increasing employment through employment and job training requirements, will improve health outcomes."); Letter from Thomas J. Betlach, Dir., Ariz. Health Care Cost Containment System, to Seema Verma, Adm'r, Centers for Medicare and Medicaid Servs. 5 (Dec. 19, 2017) [hereinafter Arizona Application] (enclosing the state's application for a § 1116 waiver) ("The gains and employment that will result from this initiative will facilitate and enhance positive health outcomes for Arizonans."); State of Mississippi, Medicaid Reform Demonstration Project, Medicaid Workforce Training Initiative, 1115 Revised Waiver Demonstration Application 6 (Jan. 16, 2018) [hereinafter Mississippi Application] ("[The Division of Medicaid] is seeking this waiver to assist individuals with building a foundation for success – both in their personal life and their health. Our goal is to begin building a future of healthy citizens in the state of Mississippi."); Letter from Barbara R. Sears, Dir., Ohio Dep't of Medicaid, to Alex Azar, Sec'y, U.S. Dep't of Health and Hum. Servs. 6 (April 30, 2018) (enclosing the state's application for a § 1115 waiver) ("The goals of this 1115 Demonstration waiver are (i) to promote economic stability and financial independence, and (ii) to improve health outcomes via participation in work and community engagement activities."); Utah Dep't of Health, Medicaid, State of Utah 1115 Primary Care Network Demonstration Waiver, Adult Expansion Amendment Request 5 (June 22, 2018) [hereinafter Utah Application] ("The State's goals [include] . . . Improv[ing] the health and well-being of individuals through incentivizing work engagement.").

waiver applications have also uniformly presented the goal of promoting financial independence,[132] including incentivizing beneficiaries to find "meaningful employment"[133] and positions with employer-sponsored insurance.[134] Some states have also extended health-promotion and financial stability arguments to the children of beneficiaries, arguing that work requirements will improve the lives of members' children through increased parental income.[135] Many states and governors explicitly characterized employment, or the lack thereof, as a "social determinant of health"[136] that can be remedied by requiring beneficiaries to engage

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132 Letter from Asa Hutchinson, Governor, Ark., to Thomas Price, Sec'y, U.S. Dep't of Health and Hum. Servs. 8 (June 30, 2017) [hereinafter Arkansas Application] (enclosing the state's application for a § 1115 waiver) ("Arkansas proposes to . . . Promot[e] independence through employment."); Arizona Application, *supra* note 131, at 4 ("[Arizona] seeks to support Arizonans in pursuing their educational goals, building their technical skills, and gaining the income, independence, and fulfillment that come with employment."); Letter from Jeffrey Colyer, Lieutenant Governor, Kan., to Eric D. Hargan, Acting Sec'y, U.S. Dep't of Health and Hum. Servs. 4 (Dec. 26, 2017) [hereinafter, Kansas Application] (enclosing the state's application for a § 1115 waiver). ([T]he goal . . . is to help Kansans achieve healthier, more independent lives by coordinating service and supports for social determinants of health and independence in addition to traditional Medicaid benefits.").

133 See, e.g., Letter from Lynne A. Valenti, Cabinet Sec'y, S.D. Dep't of Soc. Servs., to Timothy Hill, Center for Medicare and Medicaid Services 39 (Aug. 10, 2018) [hereinafter, South Dakota Application] (enclosing the state's application for an § 1115 waiver) ("Career Connector will encourage participants to obtain meaningful employment."); Arizona Application, *supra* note 131, at 1 ("[T]his waiver is designed to provide low-income, able-bodied adults with the tools needed to gain and maintain meaningful employment.")

134 See, e.g., Wisconsin Application, *supra* note 130, at 40 (aiming to "increase participants' ability to obtain and maintain employment and employer-sponsored health care"); Arizona Application, *supra* note 131, at 1 ("For able-bodied adults, Medicaid is an important solution for temporary life circumstances, but should not be a long-term substitute for private health insurance."); Utah Application, *supra* note 131, at 5 ("The State's goals [include] . . . Support[ing] the use of employer-sponsored insurance by encouraging work engagement and providing premium reimbursement for employer-sponsored health plans."); Letter from Ricker Hamilton, Acting Comm'r, Maine Dep't of Health and Hum. Servs., to Tom Price, Sec'y, U.S. Dep't of Health and Hum. Servs. 1 (Aug. 1, 2017) [hereinafter Maine Application] (enclosing the state's application for a § 1115 waiver).("[G]oals of this demonstration [include] . . . to promote financial independence and transitions to employer sponsored or other commercial health insurance" (1); "DHHS must be able to prioritize limited resources for children, elderly, and the disabled, instead of turning Medicaid into an entitlement program for working-age, able-bodied adults" (4)).

135 Alabama Application, *supra* note 131, at 4 ("[Key objectives include] improv[ing] the health outcomes of children enrolled in Medicaid, by assisting their parents in finding and succeeding at employment activities.").

136 Kansas Application, *supra* note 132, at 12 ("Employment plays a major role in adult life, frequently bringing with it a sense of accomplishment personal satisfaction, self-reliance, social interaction, and integration into the community, which can ultimately impact an individual's social determinants of health and independence."); New Hampshire Application, *supra* note 130, at 10 ("It

in work requirement activities, and by enforcing the requirement through exclusion from Medicaid benefits. Encouraging beneficiaries to raise their incomes enough to leave public benefits programs was another common goal,[137] as was reserving benefits for those at greatest disadvantage.[138] Others emphasized cost control[139] as a subsidiary objective,[140] and a few highlighted that work requirements will strengthen the state workforce.[141]

2. Observed Signals

Commentators have suggested alternative interpretations for work requirements and other conditions on benefits eligibility. Conservative commentators have explicitly noted the expressive nature of these conditions,

is in New Hampshire's economic and financial interest to facilitate sustained employment or a return to sustained employment for as many participants as possible. Gaining financial stability will enable some participants to mitigate negative environmental factors and economic factors that can contribute to poor health."); Arizona Application, *supra* note 131, at 4 ("It is well-recognized that determinants of health include social and economic factors such as education and employment. A number of studies have shown that employed individuals are both physically and mentally healthier, as well as more financially stable, as compared to unemployed individuals.").

137 New Hampshire Application, *supra* note 131, at 1 ("the robust work and community engagement component [of the approved application] will work to lift thousands of Granite Staters towards independence and self-sufficiency."); Wisconsin Application, *supra* note 130, at 42 ("[O]ut-of-pocket requirements are designed to prepare members for the norms of the private marketplace and ease transitions from public to private insurance . . . Wisconsin encourages Medicaid as a temporary solution rather than a replacement for employer-sponsored and private health insurance as a long term coverage source."; Arkansas Application, *supra* note 132, at 1 ("Together, these amendments to the [§ 1115] demonstration seek to test innovative approaches to . . . encouraging movement up the economic ladder, and facilitating transitions from Arkansas Works to employer-sponsored insurance and Marketplace coverage.")

138 Maine Application, *supra* note 134, at 1("[G]oals of this demonstration [include] . . . to preserve limited financial resources for the State's most needy individuals, ensuring long-term fiscal sustainability for the MaineCare program.")

139 Wisconsin Application, *supra* note 130, at 40 ("Wisconsin is seeking the opportunity for further innovation by establishing policies that will . . . slow down the rising costs of health care spending."; Mississippi application, *supra* note 131, at 5 ("With each passing year, [the Mississippi Division of Medicaid] finds it more difficult to provide the array of services necessary for the population we are charged to serve . . . with few resources at our disposal.")

140 This is mindful of prior case law on § 1115 waiver authority, which has noted that mere cost control via a benefits cut is an insufficient basis for granting waivers. Newton-Nations v. Betlach, 660 F.3d 370 (9th Cir. 2011); Beno v. Shalala, 30 F.3d 1057 (9th Cir. 1994).

141 Indiana Application, *supra* note 131, at 8 ("The State believes [the work requirement] will lead to improved overall health for members, as the correlation between employment and better physical and mental health has been documented, as well as a better-trained workforce within the State of Indiana with individuals who are able to transition to the private market.")

noting that they "send a message" or embody appropriate social norms.[142] Observers on both the right and left have also framed work requirements as a response to popular anger about the cost and coverage of Medicaid compared to ACA exchange plans. ACA-compliant plans commonly have high deductibles despite federal tax subsidies,[143] and premiums are contentious. As Atul Gawande has noted, "Anger about Medicaid is not surprising. We have taxpayers with jobs that provide no health coverage paying for poorer people to have coverage they couldn't dream of—with no premiums, copays, or deductibles . . . . This is bound to create bitterness about who is deserving and who is not."[144] Beyond these views, some have approached work requirements from a pragmatic perspective, suggesting that the most important purpose of work requirements is to allow the brokering of compromises between the expansion and non-expansion camps. On this view, work requirements can enable productive political compromises; for jurisdictions where unconditional benefits are not politically palatable, coupling Medicaid expansion with work requirements may be the only viable path to maintain or initiate Medicaid expansion.[145]

For many commentators, however, beliefs about states' rationales for Medicaid work requirements have been sharply negative. Some argue that work

142 *See, e.g.*, Michael R. Strain, *A Work Requirement for Medicaid Isn't 'Cruel,'* BLOOMBERG OPINION (Jan 17, 2018), https://www.bloomberg.com/opinion/articles/2018-01-17/medicaid-work-requirement-should-be-given-a-chance; RON HASKINS, MERCATUS CENTER, GEO. MASON UNIV., USING GOVERNMENT PROGRAMS TO ENCOURAGE EMPLOYMENT, INCREASE EARNINGS, AND GROW THE ECONOMY 24 (Nov. 21, 2017), https://www.mercatus.org/publications/using-government-programs-encourage-employment-increase-earnings-and-grow-economy ("Americans strongly believe that able-bodied people on welfare should be required to work . . . Americans expect government to require work when some citizens are taxed so that other citizens who are able-bodied can receive welfare."); Ron Haskins, *Trump's Work Requirements Have Been Tested Before. They Succeeded*, WASH. POST (July 25, 2018), https://www.washingtonpost.com/opinions/trumps-work-requirements-have-been-successful-before--under-bill-clinton/2018/07/25/cbfbcdc0-9039-11e8-8322-b5482bf5e0f5_story.html?utm_term=.9950a3cace40.

143 Rachel Dolan, *High-Deductible Health Plans*, HEALTH AFF. (Feb. 4, 2016), https://www.healthaffairs.org/do/10.1377/hpb20160204.950878/full/.

144 Austin Frakt, *Upshot extra: Medicaid work requirements edition*, INCIDENTAL ECONOMIST (Jan. 22, 2018), https://theincidentaleconomist.com/wordpress/upshot-extra-medicaid-work-requirements-edition/. *See also* Atul Gawande, *Is Health Care a Right?*, NEW YORKER (Oct. 2 2017), https://www.newyorker.com/magazine/2017/10/02/is-health-care-a-right (noting a neighbor's view that "basic services like trash pickup, a sewer system, roadways, police and fire protection, schools, and health care . . . can be provided only through collective effort and shared costs. When people get very different deals on these things, the pact breaks down. And that's what has happened with American health care.").

145 Jeff Stein, *How Trump May End Up Expanding Medicaid, Whether He Means to or Not*, WASH. POST (Jan. 28, 2018), https://www.washingtonpost.com/business/economy/how-trump-may-end-up-expanding-medicaid-whether-he-means-to-or-not/2018/01/28/df2ee6e8-01e1-11e8-8acf-ad2991367d9d_story.html.

requirements are simply efforts to cut benefits enrollment; in the Kentucky waiver case before the District of D.C., an amicus group of deans and scholars argued that work requirements "will lead millions to lose Medicaid under untested conditions designed to drive people off the program—a blatantly political agenda that is directly counter to Medicaid's purpose."[146] This argument is based on the premise that there are steep or insurmountable structural barriers that prevent many Medicaid beneficiaries from working twenty-plus hour weeks; Andy Slavitt, Acting Administrator for CMS during the end of the Obama administration, was outspoken in opposition to the requirements as threatening coverage for workers with irregular hours, people with unrecognized disabilities, and people who are unable to comply with administrative reporting burdens.[147] Some have attributed more sinister intentions to waiver designs; for example, state-granted exemptions from work requirements have been identified as evidence of racial animus (or at the least, conscious discriminatory impact),[148] while other identify work requirements as a means of controlling beneficiaries,"[149] Finally, some see the

146 Brief for Deans, Chairs, and Scholars as Amici Curiae in Support of Plaintiffs, Stewart v. Azar, No. 1:18-cv-152, (D.D.C. Jan. 18, 2019). Scholar David Super has described benefits as "time limits" on participation, particularly in jurisdictions that do not provide beneficiaries with work supports or offer workfare slots. Super, *A Hiatus*, *supra* note 84. Similarly, Medicaid scholar Sara Rosenbaum has argued, "[T]he consequences of using work, reporting requirements, and lock-outs [is] not to temper the reach of an expansion but [to] strip benefits away." Sara Rosenbaum, *Experimenting on the Health of the Poor: Inside* Stewart v. Azar, HEALTH AFF. (Feb. 5, 2018), https://www.healthaffairs.org/do/10.1377/hblog20180204.524941/full/. Economist Paul Krugman has argued that "pain is the point," rather than financial sustainability of the program: "[I]t's about stigmatizing those who receive government aid." Paul Krugman, *Dollars, Cents and Republican Sadism*, N.Y. TIMES (Jan. 11, 2018), https://www.nytimes.com/2018/01/11/opinion/dollars-cents-republican-sadism.html; *see also* Michael Hiltzik, *Trump Storms Ahead with Medicaid Work Rules, Even Though They're Disastrous for Enrollees*, L.A. TIMES (Nov. 26, 2018), https://www.latimes.com/business/hiltzik/la-fi-hiltzik-medicaid-work-20181126-story.html ("This is such a cynical and malevolent policy . . . Their programs aren't designed to 'extend coverage' as they claim, but narrow it. Their goal is to save money, and if that means sentencing the nation's lowest-income residents to lives of poor health and joblessness, to them that's just gravy.").

147 Andy Slavitt, *JAMA Forum: Work Requirements for Health Coverage*, NEWS@JAMA (July 18, 2018), https://newsatjama.jama.com/2018/07/18/jama-forum-work-requirements-for-health-coverage/. As Slavitt wrote, "The implication is that some people with lower incomes need an incentive to work, and that access to medical services is such an incentive. This is an inference, even setting aside the moral value judgment, that is without the facts to back it up." *Id.*

148 Nicholas Bagley & Eli Savit, *Michigan's Discriminatory Work Requirements*, N.Y. TIMES (May 8, 2018), https://www.nytimes.com/2018/05/08/opinion/michigan-medicaid-work-requirement.html; Emily Badger & Margot Sanger-Katz, *Which Poor People Shouldn't Have to Work for Aid?*, N.Y. TIMES (May 15, 2018), https://www.nytimes.com/2018/05/15/upshot/medicaid-poor-michigan-work-requirements.html.

149 Laura D. Hermer, *Medicaid: Welfare Program of Last Resort, or Safety Net?*, 44 WM. MITCHELL L. REV. 1203, 1224 (2018); *see also* Hermer, *supra* note 5, at 53–54; Huberfeld, *supra* note 15; Amicus Brief of Deans and Scholars, Stewart v. Azar, No. 1:18-cv-152, (D.D.C. Jan. 18, 2019).

potential purpose of such waivers as having little to do with beneficiaries, but much to do with the political currency of waivers to undermine the intent of Congress with respect to Medicaid eligibility.[150] Waivers on this view are political end runs—ways in which an administration and states hostile to Congressional intent can evade legislative restrictions.

On these views, the expressive content of Medicaid conditions is far different from the way that CMS and the states have articulated their intentions. For many observers, the role of the state is not to empower citizens or to act as a compassionate custodian, but instead to control and punish those who are disadvantaged by poverty.[151]

III. A STUDY OF KENTUCKY MEDICAID BENEFICIARIES

Thus far, there has been little study of how work requirements and their expressive content are interpreted by beneficiaries. Two studies identified preliminary views of work requirements in Kentucky[152] and Arkansas,[153] largely documenting negative views and contextual factors that may make compliance impossible. This Part reports a large-scale, representative study that brings scholarship on expressive law to the new territory of public benefits conditions.

A brief summary of findings is as follows: When beneficiaries found meaning in work requirements, their interpretations rested on their prior beliefs. Beneficiaries had divergent beliefs about the work requirement, and their existing views about themselves and other Medicaid participants accounted for much of this heterogeneity. Specifically, they viewed conditions not just through the lens of their own Medicaid participation, but instead based on their beliefs about why *other beneficiaries* receive Medicaid. Beneficiaries almost uniformly described their own Medicaid participation as a matter of circumstance. Participants differed, however, in how they viewed Medicaid uptake by others. Although many beneficiaries viewed other Medicaid participants to have similar (circumstantial) motivations, some instead described other beneficiaries as motivated by character, including a willingness to "take advantage" of public benefits and unwillingness to work.

This heterogeneity led to divergent beneficiary interpretations of waiver terms

150 Jessica Bulman-Pozen, *Preemption and Commandeering Without Congress*, 70 STAN. L. REV. 2029, 2036-37 (2018).

151 *See* Nicole Huberfeld, *Federalism in Health Care Reform*, in HOLES IN THE SAFETY NET: FEDERALISM AND POVERTY 197 (Ezra Rosser, ed., 2019).

152 Greene, *What Medicaid Recipients and Other Low-Income Adults Think about Medicaid Work Requirements*, HEALTH AFF. (Aug. 30, 2018).

153 Greene, *Medicaid Recipients' Early Experience With the Arkansas Medicaid Work Requirement*, HEALTH AFF. (Sept. 5, 2018).

like work requirements. Those who viewed other Medicaid participants as motivated by (undesirable) character traits found confirmation of their beliefs in the work requirement conditions. Many such participants also saw their identities—as taxpayers, not as beneficiaries—affirmed by the state's perceived concern about reciprocity between taxpayers and Medicaid participants. But in contrast, beneficiaries who viewed others' participation as similar to their own—that is, driven by contextual factors—were more likely to view themselves as personally implicated by the state's view that Medicaid beneficiaries lack work motivation. For this group, work requirements communicated unrealistic expectations, disregard, racial animus, and punitive goals of the state. These divergent views may drive different patterns of responsive behavior, different attitudes about compliance, different perceptions of the legitimacy of the regulations, and different long-term views about inclusion or exclusion. Although the requirements in this study did not take effect, the views described here have crucial relevance to expressive legal theories and identify compelling hypotheses for studying the expressive content of laws can shape their consequences.

A. Kentucky HEALTH

Kentucky faces many public health challenges. Eight of the U.S. counties with the greatest declines in life expectancy since 1980 are located in southeastern Kentucky.[154] This region has elevated mortality from cancer, cardiovascular disease, and substance use disorder, as well as heightened risk factors including smoking, physical inactivity, and obesity. The state ranks 42nd in overall health, 47th in health behavior, 49th in smoking and substance use, and last in preventable hospitalizations[155] Unemployment and intergenerational poverty[156] drive health outcomes throughout the state.

Under Governor Steven Beshear, Kentucky expanded Medicaid in 2014. The expansion has been widely considered a public health success, leading to a 20% reduction in the uninsured population and alleviation of health insurance coverage disparities based on age, marital status, education, and income.[157] Governor Matt

154 Olga Khazan, *Kentucky Is Home to the Greatest Declines in Life Expectancy*, THE ATLANTIC, May 8, 2017, https://www.theatlantic.com/health/archive/2017/05/kentucky/525777/.

155 UNITED HEALTH FOUND., AMERICA'S HEALTH RANKINGS: ANNUAL REPORT 2017 (2017).

156 Raj Chetty et al., *Where is the land of opportunity? The geography of intergenerational mobility in the United States*, 129 Q. J. ECON. 1553 (2014).

157 See, e.g., Joseph Benitez et al., *Did Health Care Reform Help Kentucky Address Disparities in Coverage and Access to Care among the Poor*, 53 HEALTH SERV. RES. 1387 (2017); Benjamin Sommers et al., *Three-Year Impacts of the ACA: Improved Medical Care and Health among Low-Income Adults*, 36 HEALTH AFF. 1119 (2017); Benjamin Sommers et al., *The Impact of State Policies on ACA Applications and Enrollment*, 34 HEALTH AFF. 1010 (2015); Benjamin Sommers et al., *Changes in Utilization and Health among Low-Income Adults after Medicaid Expansion or Expanded Private Insurance*, 176 JAMA INTERNAL MED. 1501 (2016).

Bevin, who took office in 2016, ran on a program to "repeal and replace" the ACA, and vowed to restructure Medicaid or end the expansion. The state initially applied for a § 1115 waiver, and the application estimated that approximately 428,000 beneficiaries—a third of statewide program participants—would qualify as non-disabled adults.[158] Before Verma became CMS Administrator, her consulting firm SVC Inc. advised the state on the development of the Kentucky HEALTH waiver, including the work requirement design.[159] Governor Bevin eventually committed to end the Medicaid expansion if the waiver was rejected, and he issued a provisional executive order reversing the expansion if any part of the Kentucky HEALTH program was struck down.

In 2018, CMS approved Kentucky HEALTH. The waiver required beneficiaries deemed "able-bodied" to complete eighty hours per month of employment, job searching, education, training, volunteering, or caregiving.[160] Beneficiaries who failed to comply after a one-month grace period would have their coverage suspended. Beneficiaries were also required to pay monthly premiums, set in tiers ranging from $1 to $15 depending on income. Beneficiaries who missed too many consecutive payments would be automatically disenrolled and locked out of the program for six months, if they made more than the federal poverty limit.

A roller coaster of vacaturs and reapprovals ensued. Beneficiaries challenged the program as arbitrary and capricious, led by 62-year-old beneficiary and former social worker Ronnie Stewart.[161] The plaintiffs faced health problems and contextual barriers to work, and urged vacatur of the waiver for failing to advance the purposes of Medicaid. Amid few precedents on § 1115 waiver authority,[162] Judge Boasberg's first decision focused on whether the Secretary of HHS had abused his discretion in approving the new waiver elements as "likely to assist in promoting" the program goals.[163] Although Boasberg suggested that CMS had some leeway to interpret the purposes of Medicaid, the Social Security Act specifies that the program must at least "furnish[] medical assistance" to beneficiaries.[164] Kentucky had projected that 95,000 Kentucky beneficiaries would lose Medicaid coverage under the waiver. With no evidence that CMS had

158 Kentucky Application, *supra* note 130, at 4.

159 Jessica Glenza, *Trump's Pick for Key Health Post Known for Punitive Medicaid Plan*, THE GUARDIAN (Dec. 4, 2016), https://www.theguardian.com/us-news/2016/dec/04/seema-verma-trump-centers-medicare-medicaid-cms.

160 Kentucky Application, *supra* note 130, at 18.

161 *See* Cheves, *supra* note 2.

162 Only a few cases to date have decided challenges to Medicaid experimental waivers on the merits, including *Beno v. Shalala*, 30 F.3d 1057 (9th Cir. 1994), and *Newton-Nations v. Betlach*, 660 F.3d 370 (9th Cir. 2011).

163 Stewart v. Azar, 313 F. Supp. 3d 237 (D.D.C. 2018).

164 42 U.S.C. § 1315 (2012).

considered how the waiver would help furnish medical assistance, Judge Boasberg found the approval arbitrary and capricious; the decision remanded the waiver to CMS for reconsideration.[165]

CMS re-issued the waiver for public comment,[166] and within months re-approved the program with all terms intact. The new decision letter further detailed CMS's proffered purposes of the Medicaid program,[167] including not only "furnishing medical assistance," but also "advanc[ing] the health and wellness needs of . . . beneficiaries," "increas[ing] beneficiaries' financial independence," and to "ensur[ing] the fiscal sustainability of the Medicaid program."[168] In March 2019, Judge Boasberg once again struck down the waiver, finding that the Secretary had again failed to consider whether the program would help furnish medical assistance.[169] The decision also addressed the Secretary's other suggested goals, finding that they were not "independent objectives" of the act—rather, Judge Boasberg concluded that the primary objective of the Medicaid statute is to furnish medical assistance, and the Secretary's consideration of other goals was an insufficient substitute when this goal is lacking.[170]

While the decision as on appeal in the D.C. Circuit, Kentucky had a change of state administration, as voters brought Democratic governor Andy Beshear to office as Bevin's successor. Beshear canceled the Kentucky HEALTH portion of the state's § 1115 waiver in December 2019.[171]

B. Study Methods

This Article presents baseline survey data and qualitative results from a study that was intended to evaluate Kentucky HEALTH, for which I was one of the principal investigators.[172] Section 1115 requires waivers to include an evaluation.

165 *Stewart*, 313 F. Supp. at 272.

166 Cortland & Tani, *supra* note 3.

167 Letter from Paul Mango, Chief Principal Deputy Adm'r and Chief of Staff, Ctrs. for Medicare & Medicaid Servs., U.S. Dep't of Health & Hum. Servs., to Carol H. Steckel, Comm'r, Dep't for Medicaid Servs., Commonwealth of Ky., Nov. 20, 2018, https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ky/ky-health-ca.pdf.

168 *Id.* at 2.

169 Stewart v. Azar, 366 F. Supp. 3d 125 (2019).

170 *Id.* at 270-72.

171 Governor Andy Beshear, Commonwealth of Ky., Executive Order Relating to the Kentucky Medicaid Expansion Program, 2019-00, Dec. 16, 2019 (rescinding Executive Order 2018-040, in which Governor Bevin directed the cancellation of the Medicaid expansion program in Kentucky in the event that the Kentucky HEALTH work requirement waiver was struck down in court).

172 Other principal investigators were Kevin Volpp and Atheendar Venkataramani at the University of Pennsylvania.

Although past evaluations were often of low methodological quality,[173] regulations issued after the ACA specify a set of outcome criteria for § 1115 programs,[174] as well as evaluation expectations.[175] The goals of the evaluation in Kentucky were to identify the impact of the § 1115 program on insurance coverage, health care utilization, health behaviors, socioeconomic outcomes, and health outcomes.

This Article draws on two sources of data.[176] First was a statewide survey of 9,396 Medicaid beneficiaries, which gathered data between April-September 2018.[177] Participants were drawn from the state's Medicaid enrollment roster, sampled to mirror the population of waiver-eligible Medicaid beneficiaries statewide based on geographical distribution, race, ethnicity, and sex. The overall response rate was approximately 17%.[178] This response rate is comparable to other studies of the Medicaid population, and we reduced nonresponse bias by analyzing a weighted dataset that adjusted for the sociodemographic characteristics of the Medicaid expansion population eligible for the waiver.[179] Demographic characteristics of the sample can be found in Table 1.

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173 U.S. GOV'T ACCOUNTABILITY OFF., GAO-18-220, MEDICAID DEMONSTRATIONS: EVALUATIONS YIELDED LIMITED RESULTS 1 (2018), https://www.gao.gov/products/GAO-18-220 [hereinafter GAO Report].

174 42 CFR § 431.428 (2018).

175 42 CFR § 431.424 (2018).

176 Funding for this study was provided by the Commonwealth of Kentucky through Medicaid expenditures, which include both state and federal funding at the 50% match rate for administrative expenses. Procedures in this study were approved by the Institutional Review Board of NORC, the Columbia IRB, and the University of Pennsylvania IRB.

177 We invited participants to take part in the survey by both mail and phone. NORC sent mailings to participants in hard copy first, along with three reminder mailings for non-responsive participants, and then followed up by phone. Participants were given the option to complete the survey themselves by web, or to complete the survey by phone with a trained interviewer calling from NORC. The survey took approximately 30 minutes and included questions in the domains listed above. All data were de-identified and cleaned before being transmitted to the evaluation team, and the final dataset was weighted to account for survey nonresponse and the distribution of the overall waiver-eligible beneficiary population by age, sex, race and ethnicity, federal poverty level, and employment status. Participants were each paid $25 in cash by mail to compensate them for their time spent on the survey, and each participant completed an informed consent process by phone or by web before answering any survey questions. All participants were informed that their participation would have no effect on their Medicaid benefits, and that the researchers are independent from the state. Participants were permitted to refuse to answer any questions that they wished to leave blank.

178 For a full description of study methods, see Atheendar Venkataramani et al., *Assessment of Medicaid Beneficiaries Subject to Community Engagement Requirements in Kentucky*, 2 JAMA NETWORK OPEN e197209 (2019); Kristin Linn et al., *The Design of a Randomized Controlled Trial to Evaluate Multi-Dimensional Effects of a Section 1115 Medicaid Demonstration Waiver with Community Engagement Requirements*, 98 CONTEMP. CLINICAL TRIALS 106173 (2020).

179 Venkataramani et al., *supra* note 178, at 10.

Table 1. Demographic Characteristics of Survey Sample

	Overall (n = 9,396)
Age, mean (SD)	36.1 (11.9)
Female	47.1%
Race	
Non-Hispanic White	78.4%
Non-Hispanic Black	11.3%
Hispanic	3.8%
Other	5.5%
Education	
< High School	10.9%
High School	53.8%
Some College	18.1%
4-yr College or more	16.6%
Employed	58.1%

Second, this Article draws on 127 qualitative interviews, which took place May-November 2018. All of the interview participants would have been enrolled in Kentucky HEALTH if it had taken place. The study recruited qualitative participants from among the survey respondents, ensuring variation in geography, age, race and ethnicity, and sex.[180] Interviews were audio-recorded, transcribed, and analyzed using the NVivo qualitative data analysis program.[181] Interviews followed a pre-set agenda of open-ended questions, including a section on awareness and perceptions of the waiver. Interviewers described waiver elements using language that was designed to be neutral in content and tone, including information about the community engagement requirement and premiums. Interviewers did not provide any information about the perceptions or goals of CMS or the state. Demographic characteristics of the qualitative sample can be found in Table 2.

Many of the findings of this study draw on participants' normative

180 Survey respondents were asked if they would be willing to participate in a one-hour qualitative follow-up call, which was compensated by an additional $25 for their time if they were selected. Survey participants who were willing to participate were entered into a separate database, and qualitative researchers from NORC reached out to those participants by phone to schedule a qualitative interview. Participants provided separate informed consent to the qualitative interview by phone before answering any interview questions, and they were told that participation is voluntary and would have no effect on their Medicaid benefits.

181 Analysis involved generating a thematic coding structure and applying codes to transcript text.

commitments and self-identification in categories like "taxpayer," "beneficiary," "worker," and "conservative." If we had unlimited time and resources for interviews in this study, it would have been helpful to include measures of normative commitments (e.g., the group-grid questionnaire measuring individualist/communitarian and hierarchist/egalitarian commitments,[182] measures of political party affiliation, etc.), as well as including specific interview agenda models focusing on how participants described their economic and political identities. It would also have been helpful to include an interview module on race and Medicaid eligibility. But the primary goals of this study were originally to evaluate the § 1115 waiver, so we dedicated the bulk of interview time to health care access and experiences, health status, Medicaid perceptions, family finances, and perceptions of the waiver. Where the findings below discuss aspects of participants' identities (e.g., taxpayer, beneficiary), they are drawn on the frequency and enthusiasm with which participants described particular aspects of their personal experience (e.g., comments on paying taxes, working, and contributing to government funding; comments on using Medicaid, relying on Medicaid, or fearing that Medicaid will change in a way that is detrimental to them personally). The process by which participants elevate particular aspects of their identity when discussing public benefits is of great interest here, and it merits a separate study.

Table 2. Demographic Characteristics of Qualitative Sample

	Overall (n = 127)
Age, mean (SD)	40.6 (12.7)
Female	51.9%
Race	
Non-Hispanic White	69.2%
Non-Hispanic Black	21.3%
Hispanic	2.4%
Other	7.1%
Education	
< High School	9.4%
High School	52.0%

182 See, for instance, the scale used to assess group-grid commitments in Dan M. Kahan et al., *Culture and Identity-Protective Cognition: Explaining the White-Male Effect in Risk Perception*, 4 J. EMP. LEGAL STUD. 465 (2007).

Some College	17.3%
4-yr College or more	20.5%
Employed	44.1%

C. Views About Medicaid Participation

Beneficiaries' beliefs about Medicaid and waiver terms are reported in Table 3. Across all participants, approximately 65% believed that health care is a right, and 68% believed it should be "free for everyone." A majority of beneficiaries agreed that it is the responsibility of the state (55%) and federal government (61%) to "make sure everyone has health care." Most participants believed that Medicaid is "like a health insurance program" (76%), although 46% agreed that Medicaid is "like a welfare program."[183] Approximately 67% reported that "a lot of people in this country don't respect people on Medicaid." This resonates with past research on stigma in means-tested public benefits: although Medicaid differs from cash welfare in some respects (e.g., benefits can only be used for insurance, enrollment can take place through venues other than welfare offices, and many people are aware that working often does not provide access to health insurance[184]), people eligible for Medicaid have reported concerns about being perceived as "lazy" and being treated poorly by others due to Medicaid uptake.[185] Participants in means-tested programming are also exposed to a more general stigma attaching to poverty, with the implication that poverty is due to personal deficiency such as a lack of motivation to work.[186]

Participants diverged in their beliefs about work requirements in Medicaid. Approximately 52% supported work requirements to any extent, but only 29% believed that employed people are more deserving of health care, and only 23% agreed that Medicaid should "only be for people who cannot work." A large majority (78%) opposed premiums.

183 This question draws on a Kaiser Family Foundation survey asking people to classify Medicaid as health insurance or welfare.

184 Jennifer Stuber & Mark Schlesinger, *Sources of Stigma for Means-Tested Government Programs*, 63 SOC. SCI. & MED. 933 (2006); Jennifer Stuber & Karl Kronebusch, *Stigma and Other Determinants of Participation in TANF and Medicaid*, 23 J. POL'Y ANALYSIS & MGMT. 509 (2004).

185 *Id*.

186 Sung Hyun Yun & Robert D. Weaver, *Development and Validation of a Short Form of the Attitude toward Poverty Scale*, 11 ADVANCES IN SOC. WORK 174 (2010); *see also* Nicole Huberfeld & Jessica L. Roberts, *Health Care and the Myth of Self-Reliance*, 57 B.C. L. REV. 1, 1 (2016) (describing how people who use Medicaid and other public benefits are viewed as "dependent" and lacking in self-sufficiency, while noting the irony that private health insurance is heavily subsidized by less-visible tax breaks, such that "all Americans lead subsidized lives and could move from the private to the public system").

These findings provide an initial framework for understanding beneficiaries' views of the Medicaid program. The following Sections synthesize quantitative and qualitative findings to explore how participants described their own and others' participation in Medicaid.

Table 3. Beneficiary Beliefs: Percentage Agreeing by Race and Gender (N=9,396)

		By Race				By Gender		By Employment Status		
	All	Non-Hispanic White (N=7,316)	Non-Hispanic Black (N=1,108)	Hispanic (N=368)	Non-Hispanic Other (N=251)	Male (N=4,042)	Female (N=5,341)	Employed (N=5,553)	Unemployed (N=3,400)	Retired, Disabled, Don't Know (N=441)
Work										
If people are able, they should be required to spend time volunteering or working to stay on Medicaid.	51.8	53.1	53.3	58.7	50.5	50.8	53.1	56.6	45.6	42.7
People who work are more deserving of health care.	28.7	26.5	31.6	36.8	42.3	30.7	26.5	30.8	26.4	21.8
Medicaid should only be for people who cannot work, like children, disabled people, and the elderly.	23.4	21.7	24.8	31.2	28.8	24.9	21.7	22.1	24.4	31.8
I am satisfied with the opportunity for a person in this country to get ahead by working hard.	73.5	74.6	78.2	81.5	77.3	72.7	74.6	74.7	72.9	65.5

Premiums										
People should be required to pay some money out of pocket each month to have Medicaid.	22.3	20.6	19.6	29.7	23.3	23.8	20.6	24.6	19.6	16.9
Rights and Duties in Health Care										
Health care is a right, not a privilege	65.0	66.3	66.6	74.1	66.8	63.9	66.3	65.4	65.7	56.4
Health care should be free for everyone.	68.1	68.6	75.7	77.8	71.9	67.6	68.6	67.2	70.4	60.0
It is the responsibility of the state government to make sure everyone has health care.	54.8	55.5	67.2	67.5	65.6	54.2	55.5	54.9	55.1	52.8
It is the responsibility of the federal government to make sure everyone has health care.	60.8	61.7	72.3	71.5	68.1	60.0	61.7	61.2	61.2	53.8

Medicaid and Perceived Stigma										
Medicaid is like a health insurance program, like Medicare, that helps people pay for health care.	76.4	78.6	78.9	80.0	67.4	74.5	78.6	77.6	75.3	71.1
Medicaid is like a welfare program, like food stamps to help people pay for food	46.3	46.0	42.8	53.2	49.5	46.6	46.0	46.1	47.1	42.7
A lot of people in this country don't respect people on Medicaid.	67.2	71.2	55.3	68.4	53.6	63.7	71.2	67.0	67.8	66.0

1. Personal Uptake

Participants invariably described their Medicaid participation in terms of the contextual factors that motivated the choice. Many participants anticipated and sought to rebut the idea that their own participation in Medicaid arose from low motivation to work, or from a preference for Medicaid over employer-sponsored or privately purchased insurance.

When interpreting these findings, it is important to be mindful of social desirability bias—the desire to report answers that signal good character, avoid embarrassment, and minimize the disclosure of negative information.[187] Given the high awareness of Medicaid stigma reported above, participants may have been keen to give an impression of being industrious, of desiring to work, and of qualifying for Medicaid due to their circumstances rather than their character. Social desirability bias is inescapable in this type of study design. Notably, participants' reports of past work history and current workforce participation found support in survey data on employment, as 44% of qualitative and 58% of survey respondents were in fact working. Reports of disability-related and caretaking-related reasons for not working were also bolstered by our survey findings.[188]

Although participants cited circumstantial reasons for participating in Medicaid, the specific reasons varied. A substantial number of participants explained that they had to join Medicaid due to the individual mandate provision of the Affordable Care Act. Some welcomed enrollment, but others who opposed using Medicaid signed up out of fear that they would be fined.

> I signed up when Obamacare went into effect . . . Legally I had to have this insurance, or they were going to fine me . . . [T]hey seem to think I should get everything for free and not have to do any work. Which I can honestly say, that's been great for me. I still don't think it's right . . . I hated Barack Obama (Laughter). I think you should have skin in the game.

A few participants had attempted to obtain individual health insurance through the ACA exchange—with the intention of purchasing commercial plans—but instead were directed to Medicaid. One described this experience as follows, taking

187 *See, e.g.*, Robert J. Fisher, *Social Desirability Bias and the Validity of Indirect Questioning*, 20 J. CONSUMER RES. 303 (1993); Maryon F. King & Gordon C. Bruner, *Social Desirability Bias: A Neglected Aspect of Validity Testing*, 17 PSYCHOL. & MARKETING 79 (2000). This bias may be stronger when data are collected by phone (as here), rather than by web. *See, e.g.*, Frauke Kreuter et al., S*ocial Desirability Bias in CATI, IVR, and Web Surveys: The Effects of Mode and Question Sensitivity*, 72 PUB. OPINION Q. 847 (2009).

188 *See* Venkataramani et al., *supra* note 178, at 5.

care to explain that it would have been her preference to "try and pay something" instead of getting benefits at no cost:

> I actually was going to try and get an individual health plan through the ACA, but there's a criterion that says, "If you meet requirements for Medicaid, then they will not give you a subsidy." . . . It was either you take Medicaid or you pay full price for insurance on the market without any government subsidy at all . . . . I originally thought, "Well, we can try and pay something," and that wasn't a choice . . . . I couldn't [pay full price] because I was unemployed.

Many others explained that they had chosen to participate in Medicaid as a result of a layoff or an extended period without employment ("Oh, I didn't have no choice, I needed some insurance, and . . . . Well, like I said, I was outta work."; "We didn't really have any other choice just since neither of us were working."). These participants described ACA plans as too expensive, or they noted that they worked in jobs that did not offer health insurance. Comments like one respondent's statement, "I couldn't afford nothing else," were common. As one participant noted, "Well, we needed insurance, but we never could afford it. When we signed up for this, I could afford this."

A number also described the choice to participate Medicaid in terms of family need, which they prioritized above any of their own objections to participating; several had children or spouses with intensive medical needs, such as diabetes or autism, and had signed up for insurance as a family. As one participant described, "Because of my son's diabetes we can't afford his health care under our private pay . . . . So, we applied for the health care . . . . I have to have insurance because of my son. I cannot go without." Another participant described needing insurance during a time when he was unemployed and his wife's diabetes escalated:

> I'll be honest with you, we're a poor working family. Nobody's working at the moment, but poor working family, and if we would've had to try to come up with the money to get the [insulin] pump or even part of it, [we couldn't have gotten it.] . . . Medicaid approved it . . . . Without them, I don't know what we would have done.

Some had gone without insurance for years, but then enrolled in Medicaid after experiencing an unexpected illness, sometimes requiring expensive testing and repeated appointments. Importantly, Medicaid expansion applies retroactive eligibility to the expansion population, meaning that at the time of sign-up, the prior three months of their qualifying medical expenses are paid for by the

Medicaid program.[189] As one participant described, "[I signed up] because I needed the help with figuring out what was wrong with me . . . . I didn't know I had [irritable bowel syndrome] and I was going to a free clinic at that time and the doctors there put me through so many tests." Enrolling in Medicaid both made it possible for this participant to see additional specialists, and enabled her to pay for recent medical expenses incurred before joining.

Many participants voiced uneasiness about Medicaid stigma. They sometimes described evolution in their own views about Medicaid participation, or they explained why they did not fit stereotypes about Medicaid participants. For example, one participant said, "I want to be able to take care of myself. I don't want the state to take care of me." Or as another argued, "I do all of the right things, I report my income, I'm not cheating any systems, I'm not doing anything wrong, but I'm still not getting a leg up either." Some participants described how stigma varies according to politics; as one noted, "[D]efinitely people view you differently if you have [Medicaid]. But I have pretty liberal friends, so they're not really like that." Another put the point in terms of her own changing views:

> [W]hen I was younger growing up in a fairly well-to-do family, there was seemingly a prejudice against [Medicaid] because it seemed like it was a hand-out. Looking back at it, it was very foolish for me to feel that way. But with age and experience comes a different perspective . . . . I think it's a great benefit[.]

A few participants noted that they participated in Medicaid *in order* to work. These respondents argued that Medicaid made them more productive because they were healthy enough to carry out their jobs. One participant drew on this experience to challenge the assumptions behind Medicaid stigma:

> I know that there are people that think I shouldn't have it . . . that I should be working harder for my health care or suffering more (chuckles) . . . . I don't share that . . . I think especially somebody with a chronic illness . . . who want[s] to be a productive member of society . . . . [I]t's the only way I can be a productive member really . . . . But, yes, I have family members who are very insulted by the fact that I've stooped low enough to go onto public aid.

189 MaryBeth Musumeci & Robin Rudowitz, *Medicaid Retroactive Coverage Waivers: Implications for Beneficiaries, Providers, and States*, KAISER FAMILY FOUND. MEDICAID (Nov. 10, 2017), https://www.kff.org/medicaid/issue-brief/medicaid-retroactive-coverage-waivers-implications-for-beneficiaries-providers-and-states/; *Eligibility*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/eligibility/index.html (last visited Nov. 22, 2021).

Throughout these narratives of Medicaid participation, the common thread was therefore the contextual and situational factors that motivated participation choices. Where participants sought to characterize their own traits, particularly work motivation, they often defined themselves in distinction to perceived Medicaid stereotypes of individuals willing to accept public benefits without working.

2. Uptake by Others

Participants viewed uptake by others in three ways: (1) some believed that others used Medicaid due to (undesirable) character traits; (2) some believed that other Medicaid participants were divided between those who sincerely needed help and those who were using benefits unnecessarily; and (3) some believed that other Medicaid beneficiaries were similar to themselves, or even worse off in terms of income, opportunity, and ability. In contrast to explanations of their own participation, respondents were more likely to rely on character attributions, personality, and demographic factors such as age or race when describing Medicaid participation by others.

Throughout these conversations, explanations resting on character attributions were not phrased in terms of positive characteristics (e.g., resourcefulness) but rather in terms of negative character traits such as laziness, non-reciprocity, willingness to take advantage of collective goodwill, inability to prioritize expenses and time, and selfishness in the consumption of benefits that are paid for by taxpayers and intended for individuals in worse circumstances. Descriptions of beneficiaries who "abuse the system" were common, and many participants bolstered these comments with reference to individuals that they knew, or individuals living in Kentucky generally.

> [P]eople are just sitting around not working and using Medicaid. And they're not wanting to work . . . . [T]here are a lot of people that are just not really making any kind of an effort to get a job or work or not be using the system, or abusing the system.
>
> It's not people who can't afford anything . . . . I guarantee you if you looked at the everyday lives of those people, they still had Cokes, and cigarettes, and gas. If you can afford all of those things, you can afford 15 dollars to go and see a doctor that the state's paying 5,000 for you to see.
>
> I look at welfare, I've been around people a lot in my life that abused the system. And I mean, there are people that need it . . . . But, there's got to be a limit. And I've known way, many people

> that just, they want to do nothing. Because they don't have to. Because the government's going to come in and wipe their butt for them.

Many participants who described others' participation as ill-motivated believed that work was indeed available to those who sought it; the perceived availability of work was a central premise in the view that other beneficiaries did not need to rely on Medicaid. Some participants also argued that generous benefits design allowed other beneficiaries to make self-serving choices instead of seeking work.

> We have a ton of available jobs. People just don't think they want them. They have too much pride. But I don't understand if you have too much pride to go work in a factory place, but you don't have too much pride to live off the state.

> I think that [Medicaid] should be a stepping stone. But I think that, especially in our state, too many years have gone by where people are dependent on it. I think they're taking advantage of it . . . . [I]t's a lot easier to just stay on those programs . . . . I think that's wrong . . . I work very, very hard to take care of myself and my family, and to move forward, and to finish school. And I just don't have the heart to use my time and my tax dollars to take care of people that won't even meet themselves in the middle.

As the latter quote reflects, some participants deliberately distinguished between their own participation compared to that of others. These participants tended to prioritize their identities as taxpayers contributing to Medicaid benefits, over their identities as beneficiaries receiving benefits. Other participants sought to draw explicit distinctions between themselves and others on the program, such as the following:

> Now, you and I both know there's people out there that draw checks all their lives that ain't . . . not able to work. They could work . . . . They could do things . . . . 'Course like in my own case, the doctor says I'm not able to work.

> Everybody knows I'm not lazy. I've always worked for my living and I still would be today if I hadn't had all those [health] problems . . . . [My husband and I] always worked for our living (laughter). Some of these young people don't like working.

> (laughter) . . . They're not having to pay the taxes me and him did, so for the money pot, there won't be as much money in there for things if everyone doesn't work . . . .

A few participants conflated character-based explanations with race or national origin, which aligns with a large body of prior research on public views of welfare stereotypes and race-based perceptions of work motivation.[190] Racism has long been a cornerstone of Americans' views on need-based public assistance, driving much of the stigma associated with participation and shaping views on access.[191] It was rare for participants to speak outright about race, particularly when describing their views of people on Medicaid. Where they did discuss race, it was with disclaimers trying to distance themselves from racism (and for one participant, these disclaimers were the only indication that he was alluding to race). These revealed underlying assumptions that connected beliefs about race with assumptions about work and deservingness for benefits. Given longstanding and ingrained stereotypes about race, poverty, and public benefits, it is likely that many of participants' comments about other Medicaid beneficiaries had an underlying subtext involving race—particularly when White participants were distinguishing themselves from beneficiaries generally. We did not ask about race explicitly, however, and social desirability bias may have limited participants' openness about race.[192] The participants in our sample who were people of color did not discuss race-based stereotypes when talking about Medicaid participation, but again, racism and stigma may have been an underlying theme of comments referencing poverty and benefits eligibility.[193] Two participants identifying as White invoked racial stereotypes in the following quotes:

> I'm not trying to put down any race, but one time when I did try to go get food stamps, two black girls was [there] . . . one was pregnant then, and they was bragging about how much they got

190 *See, e.g.*, JOE SOSS, RICHARD C. FORDING & SANFORD F. SCHRAM, DISCIPLINING THE POOR (2011); GILENS, *supra* note 12; Richard C. Fording, Joe Soss & Sanford F. Schram, *Race and the Local Politics of Punishment in the New World of Welfare*, 116 AM. J. SOCIOLOGY 1610 (2011); RACE AND THE POLITICS OF WELFARE REFORM (Sanford F. Schram, Joe Brian Soss & Richard Carl Fording, eds.) (2003); ROBERT C. LIEBERMAN, RACE AND THE AMERICAN WELFARE STATE (2001); Martin Gilens, *"Race Coding" and White Opposition to Welfare*, 90 AM. POLIT. SCI. REV. 593 (1996).

191 *See* MICHENER, *supra* note 9; GILENS, *supra* note 12.

192 Interviewers for this study were women familiar with the Medicaid context and/or cultural characteristics of Southern states. Interviewers included several women of color and several White women.

193 If there had been more room and flexibility in the interview agenda, we would have liked to include race as a specific topic of conversation in all interviews. Given time constraints (and the need to cover multiple topics, including health care, finances, health status, and the waiver), that was not possible in this study.

> per month . . . . [T]hat just hit me the wrong way . . . . And according to what I hear on the news and everything, every one of the, uh, illegal aliens is coming in and getting help, and we've got people here that's Americans that's needing more help, and I just don't agree with all that.
>
> I hope they only do [work requirements] for these people that are like, faking [eligibility], you know . . . but they don't have any distinguation about [i.e., they don't distinguish between] me and the next guy. You know, "[Name of Respondent]'s hurt. [Name of Respondent]'s got a bad back. [Name of Respondent] can't do this," as opposed to the guy just sitting out here, soaking up the benefits. So, I was going to be lumped in with everyone and be made to do the same thing. There was no distinction, as far as the way it was writ . . . . So, I was confused [about the work requirements]. Like I said, kind of hurt. Kind of aghast by the fact that if I could, I would be out there working right now. I'd love to be out there working right now. I've worked my whole life. But I've got neighbors who've never struck a lick at nothing. You know, get $6,000 a month—or, a year—back on their income taxes because they have a bunch of kids. And I'm going to be lumped in with these people? . . . And I'm not biased or racist or any—bigotist, or anything like that. But I'm in a position to where I feel like I'm in a different position, but lumped in with one situation. If that makes sense.

The prior descriptions show participants who were skeptical of others' rationales for participating in Medicaid, often reflecting broader stereotypes of low-income people and people of color. Other respondents saw a more mixed picture, in which some beneficiaries may "take advantage" but others use Medicaid due to situational factors more analogous to their own reasons for participating. These participants often expressed frustration that individuals who participate in Medicaid due to negative character attributes were consuming resources that should be going towards needier cases, as well as burdening taxpayers who contribute to the Medicaid budget.

> [T]here are some folks who do take advantage, but then there are folks that genuinely need help. Otherwise, they're not able to really comfortably make it or even just make it, meaning afford all of the other necessities, like power, food. I know from my family and I, we cut corners . . . . The things that we can control

> are not mortgage, are not electricity . . . . Folks are needing assistance versus just riding that free ride.
>
> [P]eople take advantage of what's there for the needy. I mean, we don't choose to need all of this. I don't choose to have to depend on the government to help with my son. But life happens . . . . When there are idiots that do stupid things like taking advantage of [Medicaid], they're hurting families, they're hurting children . . . . Or they're hurting elderly people . . . or they're hurting families like mine. It's not fair to us that we have to reap what they sow.
>
> If there was a way to magically know who needs it and who doesn't, that'd be wonderful, but there's not.

Finally, some participants avoided character-driven explanations for why other beneficiaries participate in Medicaid. Instead, this group argued that other Medicaid beneficiaries may be equivalently needy or *worse* off than they were personally. These participants tended to explain other beneficiaries' choices in situational terms analogous to their own, often referring to age, disability, or difficulties finding employment, securing transportation, and maintaining health in rural environments.

> [O]lder people that are on a fixed income [couldn't afford Medicaid premiums] . . . . Especially in this part of the state, unemployment [i.e., the proportion of people unemployed] is great. It is twice, double, the national average. So, I don't see a lot of people being able to afford it. Not just the elderly but a lot of people.
>
> I know how to advocate for myself but a lot of people don't . . . . [P]eople . . . are already in precarious economic conditions. Precarious health conditions . . . I know I'm more educated than most.
>
> There's people, their situations aren't as decent as mine . . . [work requirements and premiums] would have been challenging for people because a lot of people don't have transportation . . . Shoo! The cost of public transportation is on their legs because two dollars up and two dollars back, that's four dollars a day . . . . You have people in these rural areas that are in the mountains, they really—there's barely a fricking grocery store. But you want them to go and volunteer and work . . . .

For many participants, there was a sharp distinction in how they viewed their own Medicaid uptake as driven by contextual explanations, while they viewed other beneficiaries as participating due to a lack of motivation to work. These perceptions are consonant with a body of psychological research describing fundamental attribution bias (also known as "correspondence bias" or "the actor-observer effect"). Under this bias, individuals attribute their own behavior to context and situational factors, while they attribute others' behavior to character and personality characteristics.[194] Given participants' keen awareness (and, often, internalization) of Medicaid stigma, they may have been reluctant to challenge the stigma wholesale, but eager to distinguish themselves from other beneficiaries on character grounds.

Beliefs about the beneficiaries of public benefits programs as undeserving and unwilling to work are also a central part of more recent scholarship seeking to explain what Arlie Hochschild has described as "the Great Paradox": residents of Republican-leaning states have had greater uptake of federal aid and often health and economic problems of greater severity than in Democratic-leaning states. The voters and cultural norms of such states, however, express greater political resistance to public funds and public programming.[195] Hochschild has shown how Kentucky exemplifies this trend—considered a red state since the early 1990s, Kentucky saw rates of federal social benefits rise to approximately 23% of the average citizen's income by 2015, while the average ideological position of the state's Congressional representatives has moved markedly rightward.[196] Interviews by Hochschild and others document frustration and resentment toward beneficiaries of TANF, Social Security disability benefits, SNAP, and Medicaid

194 *Attribution Theories*, ENCYCLOPEDIA OF PSYCHOLOGY VOL. 1 (2004); Daniel T. Gilbert & Patrick S. Malone, *The Correspondence Bias*, 117 PSYCHOL. BULL. 21 (1995); Edward E. Jones & Victor A. Harris, *The Attribution of Attitudes*, 3 J. EXPERIMENTAL SOC. PSYCHOL. 1 (1967). For treatments of this bias in legal academic writing, see Jon Handon & David Yosifon, *The Situation: An Introduction to the Situational Character, Critical Realism, Power Economics, and Deep Capture*, 152 U. PA. L. REV. 129 (2003); Jon Hanson & David Yosifon, *The Situational Character: A Critical Realist Perspective on the Human Animal*, 93 GEO. L.J. 1 (2004).

195 ARLIE RUSSELL HOCHSCHILD, STRANGERS IN THEIR OWN LAND 8-10 (2016); *see also* SUZANNE METTLER, THE GOVERNMENT-CITIZEN DISCONNECT 1-26 (2018) (stating on page 5 that "[c]ollectively, Americans rely increasingly on a wide array of policies to aid them in times of need . . . and yet elections produce growing numbers of public officials whose principal aim is to terminate, restructure, or sharply reduce the size of several of those very programs"; noting that in the 2012 and 2016 presidential elections as well as local elections, voters in jurisdictions most dependent on federal aid tended to support GOP candidates).

196 *Id*. at 14.

who are perceived as taking advantage of public funding.[197] Some participants in the present study reflected similar frustrations, even though they were all on the receiving end of Medicaid support. In recent work, Suzanne Mettler has shown that "social identities and political affiliations" tend to "compete with or overwhelm the impact of firsthand experiences of social policies"[198]—a dynamic that also lies at the bedrock of expressive-politics theories about law.

Our findings also demonstrate a second important source of divergence: *some* of the participants in our study relied on negative character inferences when describing other beneficiaries, while *others* tended to see other beneficiaries as similar to themselves (or in some cases, facing even worse circumstances). Why were some participants inclined to see other beneficiaries in contextual terms, while other participants sought character explanations for benefits uptake? Literature on fundamental attribution bias has shown variation according to some personal characteristics, with lower levels of bias among people with lower beliefs in free will,[199] lower levels of personal stress,[200] and membership in non-cohesive or discordant groups.[201] We have separately considered political ideology and employment status, in data reported elsewhere.[202]

D. The Expressive Content of Work Requirements

Exploring how beneficiaries viewed others' participation in Medicaid is indispensable for understanding the messages they saw in the Kentucky HEALTH conditions. As this Section will show, participants tended to reason through the meaning and desirability of premiums and work requirements based on their views about other Medicaid participants. Where participants viewed others as motivated primary by character, they tended to identify Medicaid conditions as expressing messages that reinforced these beliefs—such as the belief that many other beneficiaries abuse the system, that work is a desirable corrective, and that other program participants would benefit from character education promoted by the new

197 Hochschild, *supra* note 195, at 1156–161; *see also* Eduardo Porter, *Where Government is a Dirty Word, but Its Checks Pay the Bills*, N.Y. TIMES (Dec. 21, 2018), https://www.nytimes.com/2018/12/21/business/economy/harlan-county-republican-welfare.html (documenting similar sentiments in Kentucky).

198 METTLER, *supra* note 195, at 6-7.

199 Oliver Genschow et al., *Belief in Free Will Affects Causal Attributions When Judging Others' Behavior*, 114 PNAS 10071 (2017).

200 Jennifer T. Kubota et al., *Stressing the Person: Legal and Everyday Person Attributions Under Stress*, 103 BIOL. PSYCHOL. 117 (2014).

201 Anouk Rogier & Vincent Yzerbyt, *Social Attribution Correspondence Bias, and the Emergence of Stereotypes*, 58 SWISS J. PSYCHOL. 233 (1990).

202 Kristen Underhill et al., Hours and Penalties for Approved Medicaid Work Requirement Policies Differ from Public Preferences: Results from a Statewide Survey in Kentucky (Dec. 8, 2021) (unpublished manuscript) (on file with author).

rules. When participants viewed others as similar to themselves—resorting to Medicaid due to their context—they tended to express reservations about the feasibility of fulfilling the new requirements, and they tended to impute state attitudes that were more invidious.

We elicited these data by asking participants about what they believed to be the state's purposes in enacting new Medicaid terms. Although *perceived purposes* are conceptually distinct from *expressive* messages, we used this framing to keep the conversation concrete enough for discussion. We did not supply the participants with any information about state or CMS rationales; all results were offered spontaneously by respondents.

Finally, although most participants treated "the state" as monolithic, a few also attributed attitudes and intentions to specific state actors—usually the governor, who had claimed Medicaid work requirements as a signature policy goal. We did not provide participants with any information about the distribution of authority over Medicaid; we simply described the waiver as a project of "the state."

1. Reciprocity and Accountability to Taxpayers

Among participants who viewed other Medicaid participants as ill-motivated, most believed that the purpose of Medicaid conditions was to exclude the undeserving. These accounts viewed the state as sending strong expressive messages that affirmed the value of work, such that work effort could (and *should*) serve as an appropriate criterion for rationing claims by able-bodied people to public assistance. This signaling of social norms is a prime example of "attitudinal signaling" that prioritizes a particular social norm, along with the "risk signaling" message that work is intrinsically good for individuals enrolled in public assistance. These participants also saw the work requirement as an *informational* signal that affirmed their belief that many Medicaid participants were sitting idle (what McAdams might call "violations signaling"). These signals also suggest a role for confirmation bias in the expressive impacts of law; confirmation bias suggests that we readily identify and believe information that aligns with our prior views.[203]

For example, one participant believed work requirements are "a good way to start to filter out the people that are just taking advantage of [Medicaid]"; another suggested that "it's going to deter a lot of lazy people." As these quotes suggest, participants often took work requirements as an invitation to discuss other beneficiaries' motivations.

203 Raymond S. Nickerson, *Confirmation Bias: A Ubiquitous Phenomenon in Many Guises*, 2 REV. GEN. PSYCHOL. 175 (1998).

> [Work requirements will provide] proof, I guess, that you're actually doing what you're supposed to be doing to keep your coverage and your Medicaid and not just mooching the system like a lot of people seem to do . . . . [I]t just kind of seems like some people get content with Medicaid and they just keep, you know, not working or whatever.

> I really feel like they're making all these changes because a lot of people are just comfortable . . . . [I]f they have Medicaid . . . they can go to the doctor. They don't have to pay for much of anything, if anything . . . . They don't care if they work . . . . Now, they're trying to kind of change that and make people be more like get them back to work and contribute and, you know, be a functional normal member of society . . . . They're making you get up and be [productive], you know, go to the doctor or making sure you're not just going to the ER for, you know, pain pills, or whatever.

These participants tended to characterize (and justify) work requirements as promoting norms of reciprocity, such that individuals who accept public assistance owe duties of social productivity to taxpayers in return. On this view, the state plays a dual role: the state uses its authority to incentivize and educate Medicaid beneficiaries in social norms, but also serves as a guardian to prevent taxpayers from being "taken advantage of" by beneficiaries who do not reciprocate their contribution to the program.

This view was particularly popular among participants who prioritized their own identities as taxpayers, rather than as Medicaid beneficiaries. These participants were simultaneously both beneficiaries and taxpayers, but when they discussed their views of the Medicaid program, they talked first and primarily about their role as taxpayers. They described their contributions to state taxes, and agreed that Medicaid beneficiaries should owe work effort as a condition of benefits. Only secondarily did this group reflect on how the work requirements would affect them personally, if at all. Many participants were themselves working (about 44% in the qualitative sample), and more had worked in the past before becoming disabled or unemployed. For participants who were aware of Medicaid stigma, the taxpayer identity was also a more socially desirable selection than the identity of beneficiary. Some also interpreted the state's actions as information suggesting that taxpayers—including themselves—had become increasingly frustrated with the program.

> I feel like people were getting tired of—they feel like they're taking care of other people. Their tax money is going to waste on helping other people instead of what they want it to be used for.

> Health care is not really free even though people think it's free. Somebody's paying for it. Taxpayers are paying for it and it's not really unreasonable to have some accountability [for] the people that are receiving the benefits of the government program. There needs to be some accountability for those people that are receiving. Or I should say, for those people receiving it to the taxpayers because that's who they're responsible to . . . . [I work] 60 hours [a week] . . . . [T]here's a lot of people that do abuse the system.
>
> [T]here's got to be accountability somewhere with receiving the free service.

Further emphasizing the state's role in guarding taxpayers' investments, some participants expressed the worry that conditions would not be adequately enforced:

> [I]f it does get implemented, I think they need to put some checks and balances in place so that it doesn't get abused. How easy would it be if I put in my own hours for the community service I've done, to just say, "You know what? I put in my 20 hours," and I didn't put in a single hour this week . . . . [I'd want] more information on maybe what checks and balances they have in place.

Recall that every participant in these qualitative interviews would be expected to fulfill the work requirements—they would *themselves* be subject to enforcement. Calling for more rigorous enforcement may seem to run counter to their interests. But these participants' views were animated by their perceptions of others on Medicaid, and by their choice of their own taxpayer identity as the lens through which they viewed the purpose and content of work requirement conditions. Terms like "accountability," "responsibility," and "contributing to society" animated these discussions, and reflected messaging advanced by Governor Bevin.[204] Many participants cited their own economic productivity, either current or past, to illustrate the desirable behavior that they believed the state

204 *See, e.g.*, Deborah Yetter, *Bevin Unveils Plan to Reshape Medicaid in Ky.*, Courier Journal, Jun. 22, 2016, https://www.courier-journal.com/story/news/politics/2016/06/22/bevin-unveils-plan-reshape-medicaid-ky/86211202/ (quoting Bevin's statement, "We are robbing people of the ability to do for themselves [without the waiver]"); Governor Matthew Bevin, Executive Order Relating to Medicaid Expansion, 2018-040, Jan. 12, 2018, at 1–2 (citing CMS's goal of "promot[ing] responsible decision-making," and Kentucky-s goal of "empower[ing] and incentiviz[ing] individuals to improve their health outcomes, ameliorate their socioeconomic standing, and gain employer sponsored coverage or other commercial health coverage").

wanted to induce among other beneficiaries. These perceptions again called to mind the expressive-politics theory—through setting Medicaid conditions, the state confirms (or denigrates) the social standing of groups with congruent beliefs. Participants viewed their social standing as taxpayers to be affirmed by the state's new conditions on Medicaid, and viewed their identities as Medicaid beneficiaries to be secondary.

Among individuals who opposed the program overall, some also expressed sympathy for the state's perceived rationale for requiring work effort as a means of deterring unnecessary uptake of benefits. They, too, saw the conditions as violations signaling, showing that some others take unfair advantage of the Medicaid program. Among this group, opposition to the work requirements generally invoked the situational factors that beneficiaries thought would make compliance difficult, such as the lack of transportation or childcare. A few participants summed up this tension:

> Maybe [the work requirement] is a little more reasonable, because (sigh) maybe they're just trying to get less people to take advantage of it. But if they have to do 20 hours of work, then maybe they won't even try to get on [Medicaid] . . . . [M]y husband and I are both able-bodied people, and we don't have the time or money; it would cost us money to volunteer . . . . And then losing benefits because of that I don't think is fair.

> I think 20 extra hours a week out of someone else's week is a lot. And if it's someone that doesn't have a car or the transportation to get where they need to get for it, that's going to be kind of difficult. Or if they have children, they're already taking the time out for a job or whatever, I think 20 hours a week is a lot . . . . I think that if they lowered the amount of hours . . . . And it made sense for whatever they were including job-wise or whatever the activity was. I think that would be okay for a penalty . . . . I would stick with [my] job anyways. But if that job didn't count, I don't, then it would be hard to do that extra 20 hours a week.

These participants viewed Medicaid beneficiaries as complex and varied. By remarking on the reciprocity rationale for program conditions, they interpreted the requirements as confirming that some beneficiaries lack work motivation, and therefore the program requirements may not signal a negative motivation by the state. But these participants also relied on personal knowledge to identify contextual barriers that will make compliance difficult or impossible for many beneficiaries, including themselves. Participants in this group tended to suggest reduced penalties or requirements, but did not oppose work requirements in all

forms.

2. Character Education for Beneficiaries

Among participants who viewed other beneficiaries as likely to abuse the system, many also believed that the purpose of work requirements was to educate beneficiaries in social norms (namely, work ethic). For this group, work requirements signaled that many beneficiaries *currently* lack motivation or character traits that are normatively desirable. A further signal, however, was that these character traits are malleable and capable of being shaped by incentive design. Many participants characterized Medicaid as a "stepping stone"—a training program that should be a pathway to higher incomes—making it an appropriate and desirable role for the state to educate beneficiaries in prosocial character traits.

Notably, this is a slightly different idea of state purpose than the reciprocity point. On the reciprocity explanation, the state is enforcing terms of an agreement between beneficiaries and taxpayers. Character education is distinct—on this view, the state is incorporating education as part of a custodial role toward Medicaid beneficiaries, who have learned (wrongly) to use public benefits instead of working. Participants who saw work requirements as a means of education viewed them not as exclusionary, but rather as instilling the social norms and character traits that other beneficiaries need to participate in society.

> I think that it is to build up people that aren't meeting the requirements. There are a lot of people that will go down to the food stamp office and they'll sign up for everything. And then, they don't hold up their end of anything. So, I think the responsibility is a part of that educating the society and the community like that to maintain these things . . . . You don't just grow up and have four kids, and not get married, and the state will take care of you . . . . [T]hat's what our communities are being taught.

> [I]f you are an able-bodied adult, you should be working, period. These are a stepping stone. All of these programs are stepping stones until you get to a point where you take care of these things on your own. You need to be working. You need to be going to school.

A few participants contrasted the work requirements in Kentucky HEALTH with current Medicaid policy, under which Kentucky offers benefits to all

individuals below 138% the federal poverty level without conditions on participation. These participants noted that the Medicaid program currently lacks education for beneficiaries, which they viewed as an integral part of the state's custodial role.

> [Right now] people are just doing whatever, and no one's following up, and there isn't any type of education. There isn't any kind of building, or any foundation, or anything like that . . . I think that's costing the state a lot of money. I think that it's not helping.

> Sometimes when people are just constantly given something it's "I want, I want" and then they get an entitlement mentality. Whereas if we have to work for something we tend to take a little bit more pride in it and we own it more . . . . Unfortunately, I don't know if that's possible in this day and age because people get more and more "I want."

As these quotes suggest, Medicaid conditions communicated norms about desirable work behavior (attitudinal signaling), norms about the value of work (risk signaling), and the prevalence of idleness among beneficiaries (violations signaling). And although many beneficiaries experienced these signals as a personal affront, others found that the laws confirmed their priors about *others* in the program. Recall also that these participants had carefully distinguished their own Medicaid participation (due to context) from the character-driven participation by others. As a result, this group of respondents had insulated themselves from the negative character implications of work requirements.

3. Promoting Social Inclusion and Dignity

A few participants viewed the purpose of work requirements as promoting the social inclusion of beneficiaries in community life. These participants tended to see the state as affirming their own beliefs that "involvement" or "community" is an important part of social life. This message again entailed a descriptive inference about Medicaid beneficiaries—namely, that they are isolated. It also aligned with participants' views about the role of the state as custodial, on the idea that it is appropriate for the state to require social inclusion for beneficiaries' own good.

> Maybe [the new requirements are] to give people a sense of involvement . . . . I just feel like maybe it's the state's way of saying, "There are people out there that maybe don't really feel like they're part of what's going on." . . . [I]f you want to keep

> receiving the benefits, then come to be a part of the community, and be a part of the discussion, and be a part of everything that's going on.

This participant explicitly identified the waiver terms as a signal—"the state's way of saying" that community participation is desirable, and perhaps even *owed* by recipients of public assistance.

A related custodial purpose was to promote beneficiaries' dignity. Many participants perceived work requirements as announcing social norms about the intrinsic value and dignity inherent in work. There was substantial overlap between these participants and those who viewed the purpose of the waiver as encouraging accountability or character education. For these participants, work requirements not only expressed the value of work, but also provided an incentive for participants to realize dignitary gains *for their own good*. One participant argued, for instance, that for participants who do work, "You'll feel better about yourself. You'll feel better about your home. You'll set an example for your children and it will change generations as time goes on." As another noted, "I think that it's very, very important for [work requirements] to be put into place so that someone can feel more prideful in themselves and their family. And they can set a better example."

Premiums, too, were sometimes interpreted as having a dignity-promoting rationale; as one participants noted, these requirements "are just to . . . let people, you know, just pay a little and feel like they're worthy." This aligns with some statements that beneficiaries had made about their own preferences to purchase plans on the ACA exchanges rather than using Medicaid benefits; for these participants, self-paying for health insurance was normatively desirable, and it was appropriate for the state to use benefits conditions so that other beneficiaries would realize this sense of dignity.

4. Coercion and Exclusion

I now turn to participants who viewed other beneficiaries as similarly situated to themselves. This group was more likely to view work requirements and other conditions as a *personal* affront. They saw work requirements as evidence of the coercive and arbitrary power of the state. These participants also resisted the informational inference that work requirements meant that many beneficiaries lack work ethic—instead, they viewed the state as (at best) inattentive, and (at worst) disingenuously aware that participants would be unable to comply. Even when these participants believed that *some* other beneficiaries abused the program, they believed that the large majority of beneficiaries were, like themselves, in genuine need of assistance.

In this group, some simply resented that the state would require them to take actions that they may have chosen to do anyways, out of intrinsic willingness, which is a prime example of motivational crowding-out. As one participant said, "It doesn't bother me if I had to volunteer to work. But it's the fact that you were trying to make me volunteer [that bothers me]." As another participant put it,

> People do things because the government forces them into it . . . . [T]he government practicing behavior modification to get the citizens to do what it wants them to do somehow just sounds evil . . . I don't trust government. Any time any government starts running in there trying to control your actions because they know better than you do, yeah, that's how we start Hitler, you know?

Beyond sheer resistance to coercion via incentive, however, many participants also viewed work requirements and other conditions as punitive, in large part because they viewed the requirements as expressing moral inferences about themselves and other beneficiaries.

> [E]verybody says Kentuckians are lazy and—I don't know. We're like one of the poorest states in the United States . . . . You make one of the poorest states in the United States pay a premium and all of this stuff . . . you're taking just a small group of people [who abuse the system] and you're penalizing a whole larger group of people . . . I don't see anything other than a moral judgment and a stereotype that's driving this, and profit margins.

> My eyebrow kind of went up when you said you lose insurance for six months [for not paying a premium] because it's, well . . . . Arguably, that's punishing but to what end is that punishment? Is it the reactive, "Let's get them"? Or is it a general reminder or helping? I would think it would be the first. It would be the more predatory and, "Let's get them for that."

Some expressed concerns not in terms of coercion and punishment, but also in terms of outright exclusion. On this view, rather than viewing waiver terms as compassionate or setting high expectations, participants perceived waiver conditions as expressive of disregard, misunderstanding and intentional harm.

> You'll have more people off of Medicaid than who are on Medicaid, which is probably what they want anyway.

> To me, it felt like them trying to get out of paying [benefits] is like, "We'll make it so difficult that [you won't use the

> program]" . . . I feel like that money's been mishandled, and they want to make it harder and harder, and you get less back of what they promised.
>
> I mean, it's absolutely inhumane and incomprehensible . . . . It doesn't provide any kind of incentive at all. It causes added stress and panic . . . . That does not motivate me to be productive. Motivating me to be productive is I do the best I can and I know I will get the help I need whenever I need it . . . I think rather than being an incentive it's a punishment . . . . People who can't pay—it's not, again, that they're lazy. Perhaps something else is happening. I mean, again, I don't always have the money at the right moment . . . . It's supposed to be a safety net, not, "We're going to judge and punish you."

In the latter quote, the participant views work requirements as a sign that the state is insensitive to beneficiaries' situational constraints. She also takes a strong view of the appropriate role of the state in administering public assistance programs—the role is not to educate, or to incentivize behavior change, but rather to supply services that enable individual health and productivity.

This participant also suggests another interpretation of waiver terms as expressing the state's distrust of beneficiaries, including her personally; she discusses how the incentive of losing her benefits does not "motivate her to be productive," but instead notes that she is already independently (intrinsically) motivated to be productive. She needs health care, not extrinsic motivation to work. Like many of the participants above, she has interpreted work requirements as communicating that beneficiaries lack motivation. But, unlike some of the prior speakers, this participant views the messages as a personal indictment.

5. Racism and Animus

A few participants interpreted the waiver as expressing animus by the state towards low-income individuals, including racial animus toward poor people of color. These participants described and criticized longstanding stereotypes about people of color as lacking in work motivation.[205] Through this lens, participants viewed work requirements as targeting public assistance recipients of color. Participants also referred to stigma associated with poverty generally, including moral judgments about the reasons why people are poor. As one participant argued,

> [The state chose these terms] [b]ecause [the governor] is a racist

205 *See* GILENS, *supra* note 12.

> person who is full of entitlement and believes that poverty is tied to immoral judgment on somebody's worth. I mean, it's that Protestant work ethic . . . if you are poor you have brought it on yourself. And good people tend to make enough money and be fine. So, if you are poor, there is some moral issue . . . . He believes the stereotype that anybody on Medicaid is on Medicaid because they're lazy and don't want to work . . . . We're doing the best we can. Many of us have complicated health issues that if not treated would then force us to have to stop working . . . . Social programs take away from their profit margin and they're prejudiced to think that this is out of laziness. Which is what my family says too.

Other participants echoed these views, naming racism outright as a motivation:

> Facilitator: What are some of the reasons the state might be making these changes?
>
> Respondent: Negative opinions about our former president. Add racist views to that, too. I want to add that. Racist stereotypes, yeah.

Here, the participant's interpretation of the waiver is set in context of their views about the permeation of social stereotypes into government generally, and they particularly attribute those stereotypes to state leadership. It was rare, however, for participants to interpret Medicaid requirements as revealing racial animus on the part of the state. Approximately 30% of qualitative interview respondents were people of color,[206] but only one spoke openly about racism when reacting to the program. Non-Hispanic White participants were the remainder of the sample, and again, only one or two interpreted the requirements as revealing racism. But many people of color, as well as many Non-Hispanic White participants, understood the requirements as revealing insensitivity or disregard of poor people. Views about race and racial stereotypes may lie under the surface in these statements, as they did when participants discussed their own views of Medicaid beneficiaries. Again, social desirability or fears about confidentiality may have made it difficult for participants of all races to discuss racism or race-based beliefs openly in this study.

206 *See supra* Table 2.

6. Arbitrariness

A few participants characterized waiver terms as purely arbitrary, signaling disregard. Rather than interpreting any signals with relevance to beneficiaries, they viewed waiver terms as evidence that the state makes choices "for no reason." Some attributed this decision to an exercise of power by the governor personally, while others attributed it to the state as a whole.

> Because [the governor] decided that poor people need to pay for their stuff and—that's it . . . . See, I don't understand it. If all these other countries that aren't as, quote unquote, "rich" as the United States can have free universal health care, why the heck haven't we gotten free universal health care? . . .
>
> I don't understand why they want to do all that and make the changes anyway. Really, I mean if you're out trying to do what you know, the best you can do and then they take it away from you . . . . I know some people abuse it. I understand that, but as long as I'm able to work, I'm going to work, you know . . . I'm just sorry that I can't afford health care.

Some participants who believed new Medicaid conditions to be arbitrary drew the conclusion that the state was acting with indifference to beneficiaries unable to afford health care. This message tended to alienate beneficiaries who expected or desired a different role for the state, which was reflected in statements about feeling powerless, overlooked, or misunderstood by the government.

> There's some people that can't work, you know. Because there is actually some people here that can't work. (pause) But it don't do me no good to have my own opinion. (chuckle) They don't give a shit about what I think.
>
> Our government doesn't seem to want to understand regular people and what goes on, and what the implications are.
>
> They're going to do it anyway, so I really don't have an opinion on it . . . . [I]f they voted, and a lot of people said no, they probably would do it anyway.
>
> I think they need to go back to the drawing board and come up with something better . . . . Because, you know, there's other people in this world beside the people with money, you know . . . .

> The emergency rooms all don't halfway want to, you know, treat them right. You know what I'm saying? They won't give them the care that they need because they don't have insurance. You know it's hard. You know. People deserve to be able to live.

Some participants in this study were surprised that the state was funding research about their perceptions and beliefs, and some were energized by the chance to express their opinion about state decisions. Others, however, expressed the belief that that their views would be of no importance to the state; as one participant noted, "it doesn't do me much good to think anything about it, because it's going to happen whether I like it or not." Where participants viewed Medicaid conditions as arbitrary, they tended to view these conditions as a sign of disregard.

7. Politics

Some participants perceived the state's purpose in Medicaid waivers as a matter of pure politics; although this rationale was distinct from arbitrariness, participants interpreted a similar level of disregard for beneficiaries. These participants connected the Kentucky HEALTH program to national politics, and they situated Medicaid conditions in the broader frame of repealing the Affordable Care Act, citing the change in state leadership from a Democratic to a Republican governor. Others suggested that state leaders simply wanted to develop a unique Medicaid program to raise their national reputation.

> I was really pleased after Obamacare got introduced . . . . [T]hat was the first time I had insurance since forever . . . . And KY Connect [the state's ACA exchange platform under the prior governor's administration], I thought that was handled brilliantly . . . . But then they scrapped it, and it feels like now they're trying to cram in quickly this other program . . . . I feel a lot of it has to do with the political level on the national level. They decided they wanted to erase everything Obama did . . . . So I feel a lot of it is just rushed-out policy that they're forcing upon people just because of this innate hatred for everything he did, whether it was good or bad.

> [I]t's all caught up right now in political BS . . . . I hate talking about the country I live in. I was born in the greatest country on the planet and I still believe that. But right now we've got political stuff that's gotten so far divided that we're not fighting about issues any more. We're fighting about political ideology that doesn't allow for getting things done.

Regardless of how participants interpreted the state's specific political goal—including a desire to be novel, a desire to replace policies enacted by the Obama administration, or a desire to promote specific political ideas—participants who saw the waiver as purely political viewed the consequences of policy choices for Medicaid beneficiaries as unimportant to the state. This was particularly true among participants who anticipated negative results from waiver terms.

> Folks are playing politics with other human beings' lives.

> The governor said he wants to follow the path of our president and "I'm going to help him get rid of affordable health care," and for political reasons. I guess if you want to do that and get votes, it's not about whether or not people are well or not . . . . It's politics and I know it is.

> I think it's because they're wanting to do something unprecedented . . . I feel like you're making a poor state even poorer by doing that . . . . Because you're going to have all these people who are sick. Not going to be able to get their medicine and get Medicaid because of these requirements that you're doing . . . . I feel like it's unfair and it's unjust.

For participants who viewed the waiver terms as having an exclusively political rationale, the policy terms seemed to convey few messages about beneficiary choices, character, or social norms. Instead, for these participants, the only relevant signal was that that beneficiaries' interests had been absent from the waiver's objectives.

8. Financial Sustainability

I have thus far focused on state purposes proffered by participants who viewed other beneficiaries as dissimilar from themselves, compared to participants who viewed other beneficiaries as similarly context-driven. But a final explanation cut across both of these groups, and this was the idea that the state was needed work requirements or premiums to make the program financially sustainable. Participants interpreted the new requirements as a credible signal that the Medicaid program had gotten too expensive for the state.

Throughout many of the interviews, participants reiterated that Kentucky is a poor state, and they perceived the Medicaid program as oversubscribed and underfunded. A few blamed this on spending decisions by the state legislature—in the words of one participant, "They were trying to reduce their losses for the budgets and stuff. A lot of governmental crap." As another participant described,

"I think they've used the money . . . that's set aside for the seniors . . . I know they've used it for other things." Participants believed that Medicaid would be financially burdensome to the state, and a few blamed physicians as well as beneficiaries for adding to program costs.

> I think that one of the aspects would be to cut back on some costs, to have some revenue generated back into the system . . . . Fifteen dollars per person [per month, as a Medicaid premium] is going to add up really fast. The majority of our state is on government assistance. The majority. So, that would add up very, very quickly in our state.

> I guess they're trying to put a limit toward the budget on the funding that they funded to these health care providers and stuff. Making sure that they're not gunning up the money . . . . Because since Obamacare and stuff has been around, I noticed there's a whole lot of doctors that are taking advantage . . . . They tack on extra stuff because they know that Obamacare is going to pay for it.

These explanations tended to be acceptable to most participants, and embodied messages that they found unobjectionable and largely separate from views about beneficiaries. A few of these participants also commented that the Medicaid program was valuable to them. As one noted, "[I]f $3 is what they need to keep that program going, I'm willing to do that $3." To these participants, efforts to keep the program sustainable expressed concern for beneficiaries and the durability of benefits.

> I don't know how healthy this program is right now . . . . But if it gets to be where there's not enough money to cover everyone, then they might just have to cancel, you know. You can't keep on if you don't have the money . . . . [I]f it gets cancelled for everybody then it hurts everybody . . . . [T]hey need to make changes to it to make it to where it can be solid and not just lose tons of money.

Although the costs of Medicaid featured most prominently in discussions about premiums, some also described cost-saving as a primary rationale for work requirements, including not only likely disenrollment from the program, but also the economic value of work and community service activities provided by people complying with the requirements. Others drew a connection between employment or volunteer activities and the state economy.

> They need more able-bodied people to work and do community

> service or something along those lines to help pay for their Medicaid . . . . [T]hat would pay money that's going to other organizations for helping hire people to do these things. So then you would take more money out of one budget and just be able to put it towards another.

In addition to financial sustainability, a few participants also perceived that employment or volunteer activities were intended to aid third parties, including businesses or elderly people in need of help. On this view, the waiver was not only about modifying beneficiary behavior, but also about mobilizing beneficiaries' time as a resource to meet third parties' needs. As one participant noted, "Businesses or whatever, that could use some help . . . . It's kind of free labor on their end . . . kind of a win-win, I guess." Another participant (who had previously worked as a condition of SNAP benefits) noted, "I think it would be nice like that . . . . Because it'll help other peoples . . . . Old people they can't get out . . . . A lot of young people are here and they can do it."

Other participants acknowledged state revenue-raising as a possible goal, but doubted that these funds would go toward sustainability of the Medicaid program. Some believed instead that premiums would be "big money" intended for state legislators, and expressed frustration with state representative salaries and spending decisions. Others characterized savings as a fig leaf to mask political ends.

> They said they're low on funds I guess in the medical area or whatever . . . . But I don't think so. I think this is just a big old money scheme thing. That they're just trying to get more money out of people than usual.

> Oh, the optics of, you know, we're saving the state money . . . because we're not having to pay for these people.

> [T]hey trying to save money. That's all. Save money. I just think it's pretty messed up, putting all these stipulations on people, you know. And some people just can't do it. And it's because they can't do it, you're going to not give them health benefits? You're not going to allow them to see a doctor, dental? Teeth need pulling, you'll let them suffer and be in pain because they can't afford to see a dentist? Come on. That don't make sense. It don't make sense. It's not right. You know? . . . [I]t's hard times right now . . . . The politicians are covered. Believe that. They probably get the best benefits in the world. They gonna let the little person

suffer.

On this skeptical view, the expressive message of waiver requirements would again be one of general disregard for beneficiaries, casting the state in the position of extracting beneficiary resources rather than acting in other roles.

E. Summary of Study Results

Beneficiaries held variable views about Medicaid conditions, which were framed by their beliefs about other beneficiaries' choices to participate in the program. Those who viewed others' participation as motivated by (negative) character attributes were more likely to interpret conditions as evidence confirming those beliefs, and supported work requirements and, to a lesser extent, premiums, as a means of intervening. This group tended to deflect the personal relevance of the messages sent by work requirements. In fact, they were more likely to reach for other identities that they found more meaningful and affirming—such as the identity of taxpayer—when reasoning about the expressive content of these conditions.

But those who viewed others' participation as similar to their own, though the lens of contextual factors such as poverty, disability, and difficulty finding work, saw a far different set of messages. This group was more likely to perceive work Medicaid conditions as punitive, exclusionary, coercive, and communicative of animus. They were also more likely to view conditions as arbitrary and expressive of the state's disregard toward the beneficiary population. These two views clashed not only in beliefs about the purposes and expressive content of conditions, but also in beneficiaries' own support for the conditions.

These findings lend support to ideas about the expressive content of law, but add the key insight that expressive content depends on the beholder—and specifically, it is mediated by the ways that the beholder views other regulated people.

IV. WHAT WORK REQUIREMENTS TELL US

As the prior Part described, beneficiaries' views about Medicaid conditions in this study were richly nuanced and attentive to a range of communicative signals expressed by the waiver, which were largely informed by their beliefs about the lives and decisions of other beneficiaries. Many participants in this study exhibited fundamental attribution bias, in which they interpreted their own uptake of public health insurance in terms of their circumstances, while interpreting others' uptake as evidence of character and purposeful choice. This Article does not answer the

question of whether work requirements are helpful (they were not, in Arkansas[207]), or whether they are desirable. But these findings contribute a textured view of how beneficiaries may interpret work requirements as a condition of health care.

This Part will consider two conclusions. The first is a theoretical contribution to expressive legal theory, which must contend with heterogeneity in how individuals deduce information content from the law—and, indeed, with the larger issue that expressive content is not set by states, but is rather co-produced by the state and the listener, who brings her own normative priors. I then draw on crowding-out theory to suggest that expressive messages previously considered tangential to compliance, such as identity affirmation or communications of distrust, may in fact be important mediators of compliance behaviors.

A. Heterogeneity in the Expressive Impacts of Law

Expressive legal theory moves the focus of law from its incentive impacts (the extent to which laws adjust the costs and benefits of different choices) to its expressive impacts, by which law communicates information to others, including those who are subject to its mandates. Although work in expressive law has deduced a wide range of plausible messages that law might send—including messages about social norms, risk and benefits of different choices, and the pervasiveness of rule violation—this body of research has not yet pursued the problem of heterogeneity in how subjects understand the signals sent by new rules. Moreover, we have long thought about expressive law as a communication from state to subject, or from state to observer. We have done little, however, to grapple with the issue of whether these communications are co-produced by the state and the listener, and whether they depend in part on the listener's own normative commitments.

This Article offers a new view of how people who are subject to the law draw inferences about its expressive content. First, even without proffered information about a law's intentions, people interpret law as a source of information about social norms, state beliefs about risks and benefits, the prevalence of behavior among a regulated population, and the relationship between citizens and the state. This expressive content is separate from the incentive impacts of these laws—although many participants discussed how they would manage the new behavioral requirements, they focused more directly on what they believed these conditions

207 The most recent assessment the Arkansas work requirements suggest that this program feature may have resulted in widespread losses of insurance coverage in Arkansas, but it did not affect employment. Many adults subject to the new regulations reported confusion about the policy requirements. Benjamin Sommers et al., *Medicaid Work Requirements: Results from the First Year in Arkansas*, 381 N. ENGL. J. MED. 1073 (2019), https://www.nejm.org/doi/full/10.1056/NEJMsr1901772.

meant about themselves, others, and the state. The participants in this study were not given any information about why the state or CMS sought to include the waiver terms. They nonetheless drew inferences from the content of the new conditions. Some of these were aligned with the purposes proffered by the state and CMS, but others were opposed—this suggests that both intended and unintended messages are relevant to understanding the expressive impacts of law.

Second, findings show that when a state places new conditions on public benefits, people subject to the law may deduce expressive messages through the lens of how they view *other* beneficiaries. Where people saw other beneficiaries as motivated by character, they were likely to view the expressive content of conditions as affirming those beliefs. But where people saw other beneficiaries as motivated by context—deserving in the same way that they themselves were—they were likely to identify messages that were invidious, coercive, exclusionary, and personally threatening. Expressive legal theory has made few efforts to identify how regulated individuals vary when interpreting new rules. Other research on phenomena like motivated reasoning,[208] biased assimilation,[209] confirmation bias,[210] and the credibility heuristic[211] have suggested that once we hold normative priors, we seek out and prioritize information that we believe confirms our ideas.

This finding extends prior work. Scholars in politics and sociology have noted that Americans' views of welfare are largely shaped by views of moral desert (often driven by race),[212] and that perceptions of beneficiaries are key determinants of support for welfare policy.[213] This Article confirms these insights, extends them to the beneficiary population, and explains the applicability of these views to an expressive theory of the law.

An important corollary is that participants who viewed themselves as dissimilar from other beneficiaries were somewhat insulated against the negative character implications of new benefits conditions. Although these participants were Medicaid beneficiaries, they selected the role of taxpayers when reasoning through benefits conditions, and they explained their own Medicaid participation as driven by circumstances separate from their character. When these participants interpreted conditions as revealing negative information about beneficiaries' work ethic, they were then primed to separate themselves from these judgments—the

208 *See* EYAL ZAMIR & DORON TEICHMAN, BEHAVIORAL LAW AND ECONOMICS 58 (2018).

209 *See* Charles G. Lord et al., *Biased Assimilation and Attitude Polarization: The Effects of Prior Theories on Subsequently Considered Evidence*, 37 J. PERSONALITY & SOC. PSYCHOL. 2098 (1979).

210 *See* Nickerson, *supra* note 203 (reviewing research evidence for confirmation bias).

211 Chanthika Pornpitakpan, *The Persuasiveness of Source Credibility: A Critical Review of Five Decades' Evidence*, 34 J. APPL. SOC. PSYCHOL. 243 (2004).

212 GILENS, *supra* note 12, at 60–79.

213 METTLER, *supra* note 195, at 106.

bad information confirmed their view of other beneficiaries, but it was not personally threatening because the respondents had already done the cognitive work of distinguishing themselves from this group. Messages that we might assume to present an affront therefore made little personal impact—and indeed, they appeared affirming to such participants for other identity reasons, such as an expressive-politics victory for their political or taxpayer identity.

Participants who viewed themselves as *similar* to other beneficiaries did not readily dissociate themselves from others. As a result, they saw the negative expressive content of Medicaid conditions as an indictment of their own work ethic. And conversely, they did not reason through the impact of requirements from the perspective of the taxpayer, but rather considered how the law would affect beneficiaries in circumstances similar to their own.

Because people bring their prior normative commitments into their interpretation of law, there is also a limit to how much lawmakers can do to ensure that law conveys their intended meaning. *All* of the participants here thought work requirements expressed a rich set of expectations, intentions, and facts. From this perspective, benefits conditions serve as a form of communication that can either affirm or affront those who are subject to the new rules. Drawing on the expressive-politics theory, this also suggests that the expressive impacts of laws produce paradoxes, such that people who are *both* regulated *and* validated in different ways may react unpredictably to law.

Further work is needed to identify other sources of heterogeneity in expressive impacts of law, as well as the operation of cognitive biases in the types of lessons that people draw from legal rules. But this Article provides a starting point for understanding how the expressive content of law depends in part on the priors of the listener—even when that listener is someone subject to the new rule.

B. Compliance Motivation

Moving from theoretical to practical insights, the expressive content of benefits conditions may predict compliance with the new benefits terms. Much scholarship in expressive law is concerned with compliance, and notably how expressive signals can motivate compliance behavior. But this scholarship has largely dismissed certain signals—such as signals that convey distrust, disrespect, or an unexpected relationship between government and citizens—as only tangentially relevant to compliance.[214] Based on the literature of motivational crowding-out, however, these signals may be highly relevant to compliance motivation. Crowding-out theories suggest pathways by which incentives, penalties, or mandates interfere with intrinsic motivation for engaging in a given

214 MCADAMS, *supra* note 40, at 13–16, 260–61.

task.[215] Work requirements transform the Medicaid program from a public entitlement into an incentive for working—or more precisely, because people begin *ex ante* with Medicaid eligibility that is then put at risk for noncompliance, the prospect of losing Medicaid serves as a stick (a negative incentive) that penalizes the failure to work. Crowding-out can result when incentives signal information about the task, the principal's views of the agent, the principal's moral values, and the supportiveness of social norms.[216]

The participants in this study believed that work requirements and premiums expressed a number of messages; any of which might affect crowding-out. This was particularly true of the beneficiaries who opposed work requirements. Many such participants read this condition to mean that the state had negative views of Medicaid beneficiaries, or that the state had wholly disregarded beneficiary well-being—each of which could lead to undermine compliance motivation. Some believed that the state's adoption of new terms was coercive, "unjust," "unfair," or "inhumane," revealing moral values that could prompt disengagement. Crowding-out theory would predict that participants who perceive hostile, coercive, or personally insulting expressive content will have greater difficulty complying with the new terms. But those who viewed the conditions as congruent with their own identities and beliefs may not be susceptible to crowding-out effects.

CONCLUSION

This Article provides an in-depth view of how Medicaid beneficiaries interpret the expressive content of conditions on benefits, focusing on work requirements and premium terms common to emerging § 1115 waivers. Part III of this Article described the methods and results of a mixed-methods study of Medicaid beneficiaries eligible for a planned work requirement waiver; results relied on surveys and qualitative interviews to construct a nuanced view of how beneficiaries understand work requirements as revealing information about themselves, the state, or other beneficiaries. The study's findings suggest that beneficiaries interpret Medicaid conditions to express information, but they perceive variable signals depending on their normative commitments. These views were framed by how participants viewed *other* Medicaid beneficiaries. Participants who viewed other beneficiaries as character-driven (i.e., ill-motivated and lazy) saw work requirements as affirming their view, and as affirming their own value as taxpayers. Conversely, respondents who viewed others as circumstance-driven saw work requirements as a signal of coercion, punitive intent, and disregard, and

215 *Id.* at 162–65.

216 *See* Underhill, *When Extrinsic Incentives Displace Intrinsic Motivation*, *supra* note 56 (citing literature).

they identified the requirements as a personal threat.[217]

These findings make several contributions: a descriptive account of Medicaid beneficiaries' perceptions of work requirements, a theoretical contribution to expressive legal theory, and a set of practical considerations for compliance motivation. Descriptively, this work presents a vivid picture of how Medicaid beneficiaries perceive work requirements. Findings demonstrate heterogeneity in perceptions, wherein some participants are energetically opposed to work and premium requirements for themselves and others, while other participants recognized personal downsides but unequivocally supported work requirements for other program beneficiaries. As a matter of theory, this Article suggests that heterogeneous interpretations can complicate expressive theories of law, and that biases such as confirmation bias, fundamental attribution bias, and prior views of the regulated population may shape how people understand legal rules as signals. Finally, as a practical matter, this Article has explored the implications of findings for behavior, with implications for access and equity; specifically, participants who view the expressive content of work requirements to be personally threatening or insulting may experience more compliance challenges, while participants who viewed the requirements as targeting *other* beneficiaries may be somewhat protected from these reactions.

The issue of work requirements in means-tested public programs is not resolved. Work requirements are a structural feature of many public assistance programs already, including SNAP, TANF, and unemployment insurance benefits. The interaction between public benefits and work motivation continues to be a matter of interest for conservative lawmakers, demonstrated most recently in public discussion regarding COVID-19 relief benefits.[218] Interest in work requirements persists for the Medicaid expansion population, and although these requirements are presently unlawful, shifts in political power may bring renewed interest in future years. The descriptive findings of this work with Medicaid beneficiaries, therefore, can help to explain public perceptions and acceptability of program conditions in future years.

This study has also yielded a new way to understand the expressive impacts of law. In short, law does not produce a unilateral communication from state to

217 This study is not without limitations. Like all qualitative studies, it is vulnerable to social desirability bias. It may not generalize beyond the Commonwealth of Kentucky, or, given ongoing public discussion of Medicaid conditions, beyond the moment in time when data were collected. But this work also has numerous strengths, including the triangulation of qualitative and survey findings, the collection of a statewide representative sample for both types of data collection, and the use of trained, unbiased interviewers to collect primary data.

218 Sarah Jones, *The Return of the Welfare Queen Myth*, N.Y. MAG (May 11, 2021), https://nymag.com/intelligencer/2021/05/biden-unemployment-benefits-and-the-welfare-queen-myth.html.

subject—instead, the message carried by law is co-produced between the state and the listener, and it is understood against the deep context of the listener's prior beliefs. Here, participants' views reflected their personal identity choices compared to others enrolled in Medicaid (e.g., as taxpayers vs. beneficiaries; as contextually motivated vs. character-motivated; as like vs. unlike other beneficiaries). These choices, in turn, drove support or opposition for the waiver policies. This can result in views that at first seem incongruous (e.g., support for a waiver that would make personal access to Medicaid more difficult), but on a closer look make sense given how participants interpret the message behind the policy. It is daunting to confront questions of expressive law in a way that accommodates heterogeneous signals, but this approach opens exciting questions of how we interact with law as subjects, observers, and lawmakers.