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The Political Economy of the Opioid Epidemic

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Public health problems have a political economy rooted largely in public and private laws that both reflect the distribution of power in society and shape its policy responses. In this Article, we apply this perspective to the U.S. opioid crisis, which was triggered by a quadrupling of opioid prescribing beginning in the mid-1990s. Such staggering increases in opioid use are impossible to understand without unpacking the incentives and institutional pressures associated with the distribution and use of addictive legal drugs, particularly how those pressures can dilute the substantive goals and efficacy of regulatory governance. The policy response to the explosion of opioid use, addiction, and overdose contrasts sharply with the swift and punitive response to illicit drug markets in the 1980s and early 1990s, which involved harsh sentences, increased policing, and stricter border controls. Subsequently, as Americans increased their unlawful use of legally available drugs—products nominally subject to controls but often distributed in large quantities by actors with major incentives to encourage their use—pharmaceutical companies encountered, for the most part, a combination of legislatively created regulatory loopholes as well as patterns of lax state and federal enforcement. Doctors also encountered regulatory loopholes and lax enforcement, despite some efforts to develop databases in order to track

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prescriptions. Pain clinics and prescription “pill mills” proliferated. For drug companies, the ability to market addictive drugs by leveraging close relationships with doctors was facilitated by a variety of legal strategies that allowed for willful blindness on the part of physicians, which limited their risk of regulatory and criminal liability. The contrast relative to the enforcement strategies associated with use of traditional illicit drugs has been described as stemming in part from the presence of many white, middle-class users and the relatively minor amount of violence and crime compared to the cocaine and methamphetamine epidemics. We add to that the influence of a large industry with a prominent role in the legal economy—an industry that encountered diluted regulatory governance over a product that has numerous legal and beneficial uses as well as the potential to be extremely destructive. Tort law still casts a shadow over some aspects of the opioid epidemic, but its reach and consequences in this context depend at least as much on the constraints affecting tort litigation and access to courts (including limits on class actions and remedies) as on the content of tort law doctrine.

Over time, jurisdictions came to pursue civil remedies, prosecutors expanded the use of criminal sanctions, and policymakers began supporting stricter constraints on opioid production, distribution, and prescription. Yet these responses have been slow in coming and continue to face practical and political barriers. Although these observations do not yield a straightforward solution, they illuminate how institutional 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.

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I. INTRODUCTION

Since the start of this century, more Americans died from drug overdose than in World Wars I and II combined.¹ Although the full extent

1. Keith Humphreys et al., *Opioids of the Masses: Stopping an American Epidemic From Going Global*, FOREIGN AFF. (May/June 2018), <https://www.foreignaffairs.com/articles/world/2018-04-16/opioids->

of the opioid crisis may have been exacerbated by a range of economic, social, and health factors, there is little doubt about what triggered it: a four-fold increase in opioid prescribing that began in the 1990s.² The U.S. opioid crisis—the deadliest epidemic in the past 60 years, including HIV/AIDS—has been the subject of extensive public and policy discussion. Yet a mystery concerning the current problem remains to be explained.

Unregulated opioid drugs have existed throughout U.S. history and have been the cause of multiple epidemics of addiction and overdose, including “patent medicines” (e.g., laudanum) in the late 1800s and heroin in the 1970s.³ Yet the worst opioid epidemic is occurring right now and was started by legally chartered companies, marketing products approved by the federal government and distributed by the putatively well-regulated medical profession. Hence the mystery: with an unprecedented level of governmental control over an opioid drug—at least on paper—how did the current epidemic become substantially worse than prior ones where essentially no regulatory powers were in place?

To resolve this puzzle, we must understand a critical aspect of the context for the opioid crisis: how legal and political institutions shape public health problems. Public health phenomena, such as epidemics of drug addiction, have a political economy rooted largely in public and private law and in the constellation of interests that seek to shape the content and application of law.⁴ While these dynamics are likely to affect

masses [<https://perma.cc/3HQS-BPPF>]; see also *Overdose Death Rates*, NAT'L INST. ON DRUG ABUSE (Jan. 2019), <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates> [<https://perma.cc/77AL-DXXL>].

2. See Nat'l Ctr. for Injury Prevention & Control, *Prescription Painkiller Overdoses in the US*, CTRS. FOR DISEASE CONTROL & PREVENTION (Nov. 2011), <https://www.cdc.gov/vitalsigns/painkilleroverdoses/index.html>. [<https://perma.cc/34WL-YFTV>].
3. See generally DAVID T. COURTWRIGHT, *DARK PARADISE: A HISTORY OF OPIATE ADDICTION IN AMERICA* (2001).
4. For another analysis of public health phenomena focused on interests and institutions, see, for example, Mariano-Florentino Cuéllar, *Modeling Partial Agency Autonomy in Public-Health Policymaking*, 15 *THEORETICAL INQUIRIES L.* 471 (2014). Although this perspective is not entirely unique, many analyses of public health phenomena often play up the scientific and technical challenges without devoting sufficient attention to how political and institutional factors affect the legal context and, in turn, help explain why particular public health problems arise or persist in some circumstances and not in others.

most systematic, national efforts to improve public health—from reducing risks of foodborne illness to improving air quality—they are particularly acute in the case of legal-drug epidemics. When legal products are at issue, regulators must find ways to balance the positive, legal uses of such drugs (e.g., for pain relief) and their destructive effects, a process that in principal—if not necessarily in practice—ought to bring to the table not only drug manufacturers and distributors but also health care funders and insurers, patients, doctors, and the larger public. Further, drug addiction impairs human capacities that normally help constrain the development of public health problems. All humans are inherently shaped by a variety of biological and psychological realities that often raise legal and policy challenges, such as the willingness to pursue short-term rewards at long-term cost, self-interested behavior in the face of collective costs, and cognitive limitations in risk appraisal. Humans who are addicted to drugs are even more vulnerable to these tendencies.⁵

The extent to which these realities generate public health challenges is inherently affected by the legal and regulatory environment and by the political and economic forces that affect human behavior through their impact on the legal system. In such a world, we can reliably expect major public health consequences to arise from the substance and implementation of laws relating to criminal enforcement and investigation (e.g., affecting law enforcement responses, substantive offenses, and monitoring), regulation, and compensation for injury. Despite the extent of the opioid crisis and its long gestation, serious limitations arising from pluralist politics, organizational challenges and institutional fragmentation, and longstanding substantive and procedural characteristics have diluted the relevance and efficacy of legal and regulatory constraints, such as more robust monitoring of pill distribution, that could have mitigated the crisis. By understanding those constraints, we can appreciate both the consequences of diluted legal adaptation in public health and other regulatory domains and how society can overcome these dynamics in certain contexts.

In this particular context, staggering increases in opioid use are impossible to understand without unpacking the incentives and institutional pressures associated with the distribution and use of nominally legal drugs. Today the United States makes up approximately 4.4% of the world's population but consumes one-third of the world's

5. See generally Keith Humphreys et al., *Brains, Environments and Policy Responses to Addiction*, 356 *SCIENCE* 1237 (2017).

opioid supply.⁶ And as population exposure rises, so does the rate of addiction.

While law enforcement was focused on illegal drugs such as methamphetamine in the 1990s, legal drugs manufactured by the pharmaceutical industry began to be prescribed and used more regularly. The most famous of these was Oxycontin, a long-acting opioid marketed by Purdue Pharma.⁷ A combination of aggressive marketing by pharmaceutical companies and unfettered prescribing by trusted health care providers led to surging opioid use, addiction, and overdose over the next fifteen years. These facilitators of demand were further enhanced by the demand-generating effects of addiction itself: as people become physically tolerant to drugs, they need more to sustain the same effects. The financial crisis of 2007 to 2008 likely exacerbated these trends both by tempting some financially desperate people into dealing diverted pharmaceutical opioids and by making emotionally and physically suffering people in deprived areas (e.g., Appalachia) more prone to addiction.

Drug companies encountered, for the most part, a combination of legislatively created regulatory loopholes as well as patterns of lax state and federal enforcement. The same was true for doctors, despite some efforts to develop databases tracking prescriptions. “Pain clinics” and prescription “drug mills” proliferated. Changing the nature of the drugs in question, for example, by creating “tamper-resistant” formulations to reduce the risk of misuse, was costly and sometimes backfired.

For drug companies, the incentives to market drugs widely by leveraging close relationships with doctors played out against a backdrop where a variety of legal strategies were available to achieve forms of willful blindness, limiting risks of regulatory and criminal liability. The contrast with the enforcement strategies associated with spiking drug use in the 1980s and 1990s is remarkable—reflecting, among other things, already strained capacity within prisons, lower levels of violence associated with opioid provision and use, and the influence of a large industry with a prominent role in the legal economy. The significant representation of white, middle-class people among those addicted to pharmaceutical opioids also likely led to a softening of police responses,

6. See Gary Garrison, *Claire McCaskill Cites Disproven Figure on Opioid Use*, POLITIFACT: MO. (May 10, 2017, 10:32 AM), <https://www.politifact.com/missouri/statements/2017/may/10/claire-mccaskill/mccaskill-cites-long-disproven-figure-opioid-use/> [https://perma.cc/Y5TD-B5X4].

7. See *infra* Section III.F.

relative to the epidemics of crack cocaine (which was concentrated among low-income African Americans) and methamphetamine (which was concentrated among low-income, rural whites).

The political economy of the crisis also implicated civil society. Backlash against the brutality of the response to crack cocaine eventually contributed to the conclusion among many policymakers and opinion leaders that drugs could be more effectively handled if the criminal justice system backed off and allowed market participants to rely on voluntary efforts.⁸ This created a cultural space for the pharmaceutical industry and its allies (witting or unwitting) to delegitimize concern about the sharp rise of prescribing opioids as stemming from a “drug war mentality.” In some cases, legal entities and leaders in the industry were also able to enhance their reputation and influence through donations to universities, museums, civic organizations, and political causes. These trends likely contributed to a government response starkly different from those involving drugs distributed through illicit markets.

In Part II of this Article, we provide some of the crucial public health context for understanding the social policy challenges and legal dilemmas associated with opioid use, misuse, and addiction. We start with a description of some of the properties and characteristics of opioids. We do this in order to emphasize why challenges associated with diluted regulatory governance are especially pronounced when society encounters particularly difficult implementation problems in the regulation of substances that are highly addictive or rife with possibilities for misuse, yet also have a useful role and are therefore made legally available. Because both the economic benefits derived from selling opioids and many legal strategies to mitigate misuse depend on the process of drug distribution, we begin by explaining how an opioid dose gets to a user and how licit and illicit opioid use has changed in the United States in the last few decades.

Given that opioid-related public health problems are driven to a considerable extent by misuse of products that are legal for some individuals to use under certain conditions, Part III turns to the mechanics of how American society regulates the availability of those opioid-based products that have contingent lawful health uses. The relevant legal tools here include not only conventional regulatory rules directly governing the manufacture or distribution of opioids, but also tort and criminal law, which play a quasi-regulatory function mediated by legal doctrine and the market for litigation in the civil context. Whether or not agencies

8. See *infra* Section III.C.

implement regulatory rules explicitly focused on opioids or pharmaceutical products more generally, in principle drug company officials, distributors, and doctors should care about the risk that their actions may land them in prison or lead to a costly tort suit. Jurisdictions' civil and criminal strategies, along with other policies affecting the market for litigation, in turn can strengthen or weaken the power of these deterrents.

Although our primary focus here is on how the lawful market for opioids is regulated, the picture of disaggregated responsibilities sprawling across a variety of state and federal organizations also tells a larger story about the challenges of regulating "dual-use" products, those products that can be lawful or unlawful depending on the circumstances. As we discuss generally and with specific examples involving a major pharmaceutical company and drug distributors, criminal and civil actions have become an important part of the response. Yet because of limitations in the infrastructure to gathering information about opioid use (in some cases as a result of opposition to legislative and regulatory measures) as well as understandable constraints built into the relevant law, responses have been slow in coming and have had, up to now, mixed results. Tort law still casts a shadow over some aspects of the opioid epidemic, but its reach and consequences in this context depend at least as much on the constraints affecting tort litigation, access to courts (including limits on class actions, and remedies), and the decisions of jurisdictions to pursue such remedies over time as on the content of tort law doctrine.⁹

Part IV then connects insights about the political economy of public health regulation—including the role of organizational rigidity, risk aversion, and lack of capacity—to the problems of opioid misuse and addiction. We explain why the mix of forces affecting the legal context governing opioid-related issues results in a kind of "diluted regulatory governance." We draw examples not only from battles over opioid policy but also from the American approach to other addictive products, such as cigarettes. We conclude by reflecting on tentative lessons that can be drawn from a more nuanced understanding of the political economy of public health law.

More specifically, we contend that these political economy pressures affect the realities of implementation shaping legal responses to certain public health problems. The result is what we call diluted regulatory governance: regulatory responses to govern the public health crisis still occur, but they are delayed and constrained in ways that perhaps would, in

9. See *infra* Section III.E.

retrospect, surprise the public. Diluted regulatory governance does not mean that there is no meaningful regulation. It means that it takes longer, sometimes contradicts itself, and often has a milder effect than what one would expect given the extent of the harm involved (and how it compares to other harms), the level of putative concern among the public, and the level of interest from policymakers. Understanding the disconnect requires attention to all the forces that fragment power, limit policy change, and impede the use of existing legal tools.¹⁰ While some degree of “dilution” can be expected whenever a pluralist system with imperfect implementation confronts public health and related risks, the challenge is especially acute in circumstances akin to those that spawned the opioid crisis. Yet where the possibilities for addiction or misuse are pronounced, the economic stakes are enormous, the possibilities for evading responsibility are substantial (because of a lack of accountability within organizations), and the means of constraining policy change are available.

In advancing this analysis, we recognize that prescription opioids have legitimate—and in some cases enormous—benefits. Indeed, that is a key reason why governance over them is so frequently diluted as opposed to governance of drugs that are solely harmful. But if the optimal societal response calls for some degree of surveillance and accountability, we want to underscore the magnitude of the challenges institutions will tend to face in achieving even that measured response. Overcoming these challenges requires more than sensible policy analyses, data, legal arguments, and some measure of widespread public concern. What is crucial is a mix of public concern; a coalition of actors within and outside government to mobilize public action; and parties able to seek legal recourse that can generate information about key actors, which can further the public’s understanding and establish a reliable narrative of the costs to individuals and society.

Although our account does not yield a straightforward solution, it illuminates how institutional 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. They also highlight the risks of

10. Although we discuss in Part IV a number of legal and policy changes with the potential to improve the situation, we do not argue that simple solutions are easily available through unified governance in a single agency, facilitation of civil litigation, or enhancement of government enforcement powers. Instead we argue that, while a variety of the legal and policy changes we discuss may better align private incentives with the public interest, the more fundamental reality is that political economy shapes the nature of public health problems.

romanticizing the capacity of legal and regulatory arrangements to rein in multinational corporations that legally produce addictive products. Without taking those realities seriously, narrow interventions focused on a single area of law or isolated technical changes in treatment may prove mostly beside the point.

II. PLACING OPIOIDS IN CONTEXT AND UNDERSTANDING HOW AN OPIOID DOSE GETS TO A USER

The fountainhead of all opioids is a flower that human beings have cultivated for over five-thousand years: the opium poppy. When cut, the seed pod of the plant releases a milky latex that is called raw opium when collected and dried. With the rise of modern chemistry in the 18th and 19th centuries, more potent and pure opioids were refined from raw opium and the husk of the poppy seed pod (“poppy straw”), including morphine and heroin. In recent decades, other opioids, such as fentanyl, have been produced through entirely synthetic means.¹¹

Opioids of all forms bind to receptors in the brain. This produces multiple effects on users, including euphoria (i.e., emotions of joy, well-being, and relaxation), analgesia (i.e., relief from physical pain), and depression of multiple basic biological functions (e.g., slowed breathing, sleepiness, constipation, disrupted hormonal regulation).¹² The euphoria most users experience from taking opioids, as well as the analgesia for the subset who are in pain, make taking opioids rewarding for most users. The depression of basic biological functions makes them dangerous: breathing can slow to the point that the brain and other vital organs are fatally deprived of oxygen, and sleepiness can result in serious accidents (for example, if a user nods off while driving).

Repeated opioid use can result in tolerance, dependence, and/or addiction. The human brain becomes *tolerant* to the repeated administration of opioids such that the same dose does not continue to produce the same effect. In pursuit of the marked euphoria/analgesia experienced early on, many users raise their dose, thereby exposing themselves to increased risk of harm. *Dependent* users experience withdrawal in the absence of opioids, which is typically characterized by flu-like physical symptoms coupled with an inverse of the drug’s effects (e.g., emotional misery, sleeplessness). Desire to avoid these symptoms

11. See generally COURTWRIGHT, *supra* note 3; Humphreys et al., *supra* note 1.

12. See Anna Lembke et al., *Weighing the Risks and Benefits of Chronic Opioid Therapy*, 93 AM. FAM. PHYSICIAN 982 (2016).

motivates some individuals to keep using opioids. Being dependent is not the same as being disabled by an addiction. Some long-term pain patients as well as patients in methadone maintenance clinics are dependent on opioids but are highly functional in their daily lives, indeed often more so than they would be without opioids. Opioids can also produce *addiction*, such that the individual continues to engage in opioid use despite destructive consequences. Addiction produces other brain adaptations over time including decreased reward from non-drug sources (e.g., food, warmth, sex, social interaction) and greater difficulty exerting self-control over impulses to use the drug.¹³

A. HOW OPIOIDS GET TO USERS

To understand how these characteristics of this product and the people who consume it have affected the United States in recent years, we need to understand how opioids—including legally prescribed ones—get to users, and how patterns of opioid use have changed over the years.

Licit prescriptions. The near-quadrupling of opioid prescriptions that began in the mid-1990s resulted in the per capita opioid consumption in the United States outstripping every other country in the world by a huge margin (see Figure 1).¹⁴ There is nothing per se illegal about this situation; producing and distributing pharmaceutical opioids under license is legal under U.S. law as well as international treaties to which the United States is a signatory. Subject to Drug Enforcement Administration (DEA) quotas, manufacturers produce opioids using domestically produced or imported raw materials or by synthesizing them directly.¹⁵ Drug distribution companies operate as middlemen, purchasing large quantities of opioids wholesale from manufacturers and then delivering them at a markup to local distribution points (e.g., pharmacies).

13. See Nora D. Volkow et al., *Neurobiologic Advances from the Brain Disease Model of Addiction*, 374 *NEW ENG. J. MED.* 363 (2016).

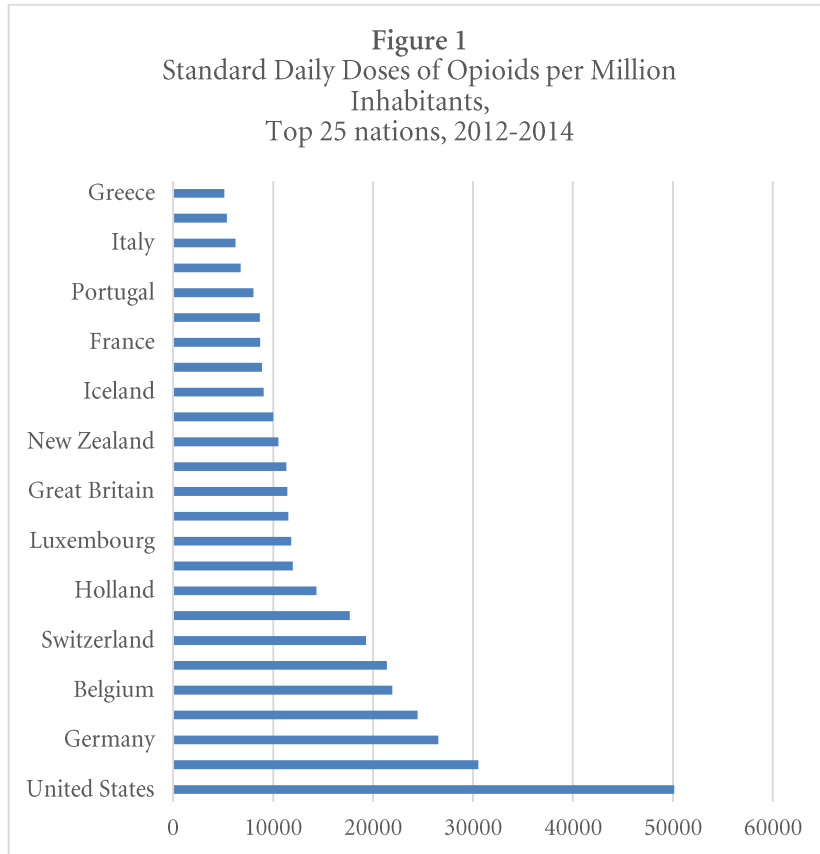
14. Int'l Narcotics Control Board, *Narcotic Drugs 2015: Estimated World Requirements for 2016, Statistics for 2014*, UNITED NATIONS 224 tbl.xiv.1.a (2016), https://www.incb.org/documents/Narcotic-Drugs/Technical-Publications/2015/NAR-tech_pub_2015.pdf [https://perma.cc/4DRM-2S9U].

15. See Established Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2019, 83 *Fed. Reg.* 67, 348 (Dec. 28, 2018).

Medical professionals who hold a DEA-issued controlled substance license are allowed to prescribe opioids for patients. In some limited circumstances, the prescriber will possess and administer the opioids directly, such as hospital staff using opioids to medicate the pain of an inpatient recovering from surgery. But most licit use occurs when patients are given a prescription and fill it themselves by submitting it to a licensed pharmacy.¹⁶ Prescriptions specify the type of opioid, its dose, how often the patient is to take it, and whether it is one-time-only or refillable. Under the Controlled Substances Act, all opioids are assigned a place on a “schedule” that runs from I to V. Opioids that have a medical use are on Schedules II-V. Somewhat counterintuitively, drugs scheduled with lower numbers are more potent and hence subject to more restrictive rules regarding the circumstances under which they can be prescribed and refilled.¹⁷

Opioids carry an unusual amount of risk relative to other widely prescribed medicines, and many individuals become addicted to them or overdose on them even when they have followed their prescription to the letter. At the same time, however, the legal availability of pharmaceutical opioids through the health care system also prevents enormous human suffering, such as in the palliative care of the terminally ill, the treatment of cancer, and the conduct of and recovery from most surgeries.

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16. See NAT'L ACADS. OF SCI., ENG'G & MED., PAIN MANAGEMENT AND THE OPIOID EPIDEMIC: BALANCING SOCIETAL AND INDIVIDUAL BENEFITS AND RISKS OF PRESCRIPTION OPIOID USE 187-267 (Richard J. Bonnie et al. eds., 2017), <http://nationalacademies.org/hmd/Reports/2017/pain-management-and-the-opioid-epidemic.aspx> [<https://perma.cc/XGA9-H6ZN>] (describing trends in opioid use and misuse).
 17. For some of the factors considered when a drug is scheduled, see *The Controlled Substances Act*, DRUG ENFORCEMENT ADMIN., <https://www.dea.gov/controlled-substances-act> [<https://perma.cc/9UM7-SEJZ>].



More thoroughly illicit channels also provide a steady supply of opioids. Criminal organizations produce and sell fake prescription opioids just as they do heroin.¹⁸ This Article, however, will focus on legally manufactured opioids and how these legal substances are illegally obtained and used.

Acts of theft. A small amount of prescription opioids enters the illegal market through discrete criminal acts, e.g., a patient filches a doctor’s prescription pad, an armed robber steals a pharmacy’s supply of Oxycontin, or a gang successfully diverts an opioid shipment from a

18. Press Release, Gulfport Police Dep’t, Public Notice—Oxycodone/Fentanyl (May 7, 2018), <http://www.gulfportpolice.net/notices/public-notice-oxycodone-fentanyl> [https://perma.cc/3LVA-USJA]; Sumathi Reddy, *The Uphill Fight Against Fake Prescription Drugs*, WALL ST. J. (Oct. 8, 2018, 10:35 AM EST), <https://www.wsj.com/articles/the-uphill-fight-against-fake-prescription-drugs-1539009351> [https://perma.cc/3TGW-6D64].

wholesaler.¹⁹ But these rather dramatic events are a sideshow to the far more systemic ways in which prescription opioids are supplied and used illegally.²⁰

Diversion of excess opioids. Most patients do not take all the opioids they are prescribed. For just one class of medical procedures—surgery—this excess of pills is estimated at over three billion per year.²¹ If all were sold on the black market, the revenues from just those pills would well exceed the size of the black market for any one of the three major, purely illegal drugs (heroin, cocaine/crack, and methamphetamine). The licit market thus has the effect of creating an enormous reservoir of pills which may be tapped into by addicted individuals, curious teens, and drug dealers who engage in theft. The excess also allows legitimate patients to innocently (though still illegally) share opioids with co-workers, family, and friends. Many people addicted to prescription opioids report getting them through a prescription held by someone else (e.g., “my knee is really acting up and I left my pills at home, would you mind if . . . ?”).²²

Patients also sometimes sell excess opioids that were legitimately prescribed. An individual who has taken, say, only ten pills out of a bottle of thirty 7.5mg Percocet tablets after a wisdom tooth surgery has an asset worth at least \$100 on the black market.²³ A chronic-pain patient who consistently needs less opioids than prescribed with each refill can supplement income by thousands or tens of thousands of dollars a year.²⁴

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19. See, e.g., Katherin Eban, *Drug Theft Goes Big*, FORTUNE (Mar. 31, 2011), <https://fortune.com/2011/03/31/drug-theft-goes-big> [perma.cc/DM7B-ZATX].
 20. See generally THOMAS BABOR ET AL., DRUG POLICY AND THE PUBLIC GOOD (2d ed. 2018).
 21. See Fred Muench, *We Must Stop Opioid Overprescribing—Now*, U.S. NEWS & WORLD REP.: HEALTH (Sept. 6, 2018, 6:00 AM), <https://health.usnews.com/health-care/for-better/articles/2018-09-06/we-must-stop-opioid-overprescribing-now> [https://perma.cc/4X3X-9UP7].
 22. Rachel N. Lipari & Arthur Hughes, *How People Obtain the Prescription Pain Relievers They Misuse*, SUBSTANCE ABUSE & MENTAL HEALTH SERV. ADMIN.: CBHSQ REP. (Jan. 12, 2017), https://www.samhsa.gov/data/sites/default/files/report_2686/ShortReport-2686.html [https://perma.cc/6B4X-NKCU].
 23. Nabarun Dasgupta et al., *Crowdsourcing Black Market Prices For Prescription Opioids*, 15 J. MED. INTERNET RES. e178 (Aug. 16, 2013), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3758048> [https://perma.cc/7HPY-8GN9].
 24. See Humphreys et al., *supra* note 1.

Patient deception. There is no objective test for pain, making it an easy condition to fake. Many degrees of flummery are possible. A person with no pain can invent a condition, or a patient with some real pain can exaggerate their suffering in the hopes of being prescribed more potent opioids.²⁵ A person can repeatedly con a single prescriber or a whole group of prescribers who do not know of each other's existence.²⁶ Patient deception can be driven by the desire to obtain opioids in order to feed an addiction, to sell on the black market, or both.

Prescriber criminality. A very small but very destructive proportion of prescribers use their license to function outright as drug dealers, such as the "pill mill doctors" who were once prevalent in South Florida.²⁷ These prescribers advertised same day exams, did not require patient identification, operated entirely with cash, and both prescribed opioids and filled their own prescriptions on site. These were lucrative criminal operations netting hundreds of thousands to millions of dollars a year, and all involved a knowing physician participant. Prescribers may also engage in illegal conduct because of their own addictions rather than out of pure avarice.

As legal opioids become widely available for misuse, individuals and communities can be affected by the interaction of lawful and illicit opioid markets. Addicted individuals often become tolerant to the effects of prescription opioids to the point that they consume more pills per day than they can afford. This leads some of them to engage in behavior they would not have contemplated initially, namely using relatively cheaper illegal drugs, including heroin. Other prescription-opioid-addicted individuals may transition to heroin because the prescriber discovers their

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25. See generally SAM QUINONES, *DREAMLAND: THE TRUE TALE OF AMERICA'S OPIOID EPIDEMIC* (2015).
26. See Randy A. Sansone & Lori A. Sansone, *Doctor Shopping: A Phenomenon of Many Themes*, 9 *INNOVATIONS CLINICAL NEUROSCIENCE* 42, 43-44 (2012); John M. Stogner et al., *Deception for Drugs: Self-Reported "Doctor Shopping" Among Young Adults*, 27 *J. AM. BOARD FAM. MED.* 583, 590-91 (2014); *Although Relatively Few, "Doctor Shoppers" Skew Opioid Prescribing*, NAT'L INST. ON DRUG ABUSE (May 27, 2014), <https://archives.drugabuse.gov/news-events/nida-notes/2014/05/although-relatively-few-doctor-shoppers-skew-opioid-prescribing> [<https://perma.cc/84DE-7YD3>].
27. Press Release, Drug Enforcement Admin., DEA-Led Operation Pill Nation Targets Rogue Pain Clinics in South Florida (Feb. 24, 2011), <https://www.dea.gov/press-releases/2011/02/24/dea-led-operation-pill-nation-targets-rogue-pain-clinics-south-florida> [<https://perma.cc/K9XK-VAY9>].

addiction and refuses to continue providing them opioids.²⁸ At least in the short term, switching from diverted prescription opioids to heroin can lower a person's daily expenditure substantially (until, of course, their need for more heroin takes hold).²⁹

The increasing numbers of Americans addicted to prescription opioids was correctly identified as a marketing opportunity by Mexican criminal organizations who began dealing heroin in regions of the country where heroin markets had long been small or non-existent.³⁰ The legal opioid epidemic thus revived illicit opioid markets, which in turn made heroin available to individuals who initiated heroin use first rather than after a period of prescription opioid addiction. As a result, contrary to the claim by pharmaceutical industry advocates that they cannot be held responsible for heroin deaths, the increase in opioid prescriptions played a role in heroin use even for individuals who never used prescribed products.³¹

B. Patterns of Use in the United States over Time

Modern U.S. medicine and its associated regulatory structures (e.g., the Food and Drug Administration) emerged in the early 20th century. For the first nine decades of that century, opioids were used sparingly, mainly for surgery and cancer care.³² In the 1990s, many physicians and patient advocates became concerned that pain was often poorly managed, which was factually correct then and still is today.³³ The pharmaceutical industry seized on this moment to promote its products in a broad range of settings

28. Allison L. Pitt et al., *Modeling Health Benefits and Harms of Public Policy Responses to the US Opioid Epidemic*, 108 AM. J. PUB. HEALTH 1394, 1394 (2018).

29. See Humphreys et al., *supra* note 1, at 122.

30. See, e.g., QUINONES, *supra* note 25, at 40-46.

31. Keith Humphreys, *How Legal Drug Companies Helped Revive the Heroin Trade*, WASH. POST (June 15, 2018), https://www.washingtonpost.com/news/wonk/wp/2018/06/15/how-legal-drug-companies-helped-revive-the-heroin-trade/?noredirect=on&utm_term=.adf67c658534 [https://perma.cc/ETG2-34PG].

32. For a discussion of the transformation in opioid use in the late 20th century, see BARRY MEIER, *PAIN KILLER: AN EMPIRE OF DECEIT AND THE ORIGIN OF AMERICA'S OPIOID EPIDEMIC* (2018).

33. For an extended treatment of pain management, see NAT'L ACADS. OF SCI., ENG'G & MED., *supra* note 16.

and ways that have no historical parallel: the industry contributed financially to multiple professional societies that wrote clinical practice guidelines favoring opioids; funded continuing medical education programs (often with no acknowledgement of the funding source) that encouraged doctors to prescribe opioids more liberally; spent hundreds of millions of dollars lobbying legislators to loosen regulatory controls; made donations to many regulators (e.g., state medical boards, The Joint Commission), and established putatively patient-led advocacy groups who supported the industry agenda without revealing the industry's bankrolling of their work.³⁴ Opioid manufacturers, most notably Purdue Pharma, unleashed an army of “detailers” who visited doctors' offices and encouraged the prescribing of opioids—as well as gave gifts to physicians, which is a legal practice.³⁵

Purdue Pharma and the broader opioid industry's campaign was spectacularly successful at increasing U.S. opioid prescribing, which rose to about a quarter of a billion prescriptions per year.³⁶ This was enough for every adult in the country to have their own prescription or to medicate the entire population of the country twenty-four hours a day for a month. Not surprisingly, as opioid prescribing soared over the last few years, the negative consequences of opioids rose as well. Importantly, because opioids are not always recorded either on death certificates or in emergency room records, the official overdose data understate the horrible reality by 20-35%.³⁷

In analyzing the origins of the U.S. opioid crisis, the obvious explanation is the best one: society was flooded with an unprecedented number of pharmaceutical opioids, leading many people to become

34. See generally ANNA LEMBKE, *DRUG DEALER, MD: HOW DOCTORS WERE DUPED, PATIENTS GOT HOOKED, AND WHY IT'S SO HARD TO STOP* (2016); MEIER, *supra* note 32. For an intriguing account of how the pharmaceutical companies' incentives in the opioid crisis were exacerbated by intellectual property protections, see Daniel J. Hemel & Lisa Larrimore Ouellette, *Innovation Institutions and the Opioid Crisis* (May 5, 2019) (unpublished draft) (on file with author).

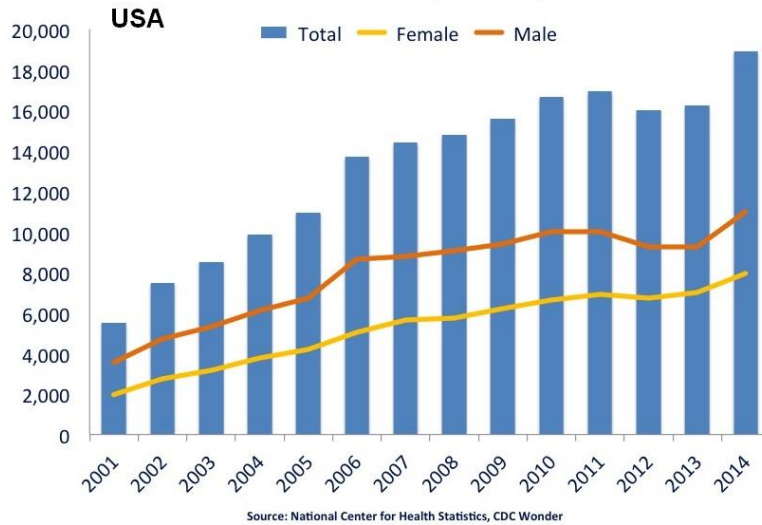
35. MEIER, *supra* note 32, at 68.

36. *U.S. Opioid Prescribing Rate Maps*, CTRS. FOR DISEASE CONTROL & PREVENTION (Oct. 3, 2018), <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> [<https://perma.cc/KP2H-G4SX>].

37. Christopher J. Ruhm, *Corrected US Opioid-Involved Drug Poisoning Deaths and Mortality Rates, 1999–2015*, 113 *ADDICTION* 1339, 1339 (2018).

addicted. Other factors that may have operated in concord with vastly increased exposure have been proposed.

Number of Deaths from Prescription Opioid Pain Relievers



Some observers argue that the opioid epidemic was caused by the financial crisis of 2007 to 2008, which deprived many people of their economic livelihood and created understandable emotional strain on individuals and communities. But the opioid epidemic began ten years before the economic crisis, and there was no opioid epidemic to speak of during the Great Depression.³⁸ Further, another deadly addiction—to cigarettes—declined before, during, and after the 2007 to 2008 financial meltdown.³⁹ Moreover, by itself poverty cannot cause addiction in any simple sense. To become addicted to a substance a person must first use it, and lower-income people have higher abstention rates (usually for religious or cultural reasons) than do middle- and higher-income individuals.⁴⁰

38. For more on the argument that the opioid crisis was driven in part by social and economic factors, see Nabarun Dasgupta et al., *Opioid Crisis: No Easy Fix to Its Social and Economic Determinants*, 108 AM. J. PUB. HEALTH 182 (2018).

39. *Current Cigarette Smoking Among Adults in the United States*, CTRS. FOR DISEASE CONTROL & PREVENTION (Feb. 4, 2019), https://www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/cig_smoking/index.htm [<https://perma.cc/23T8-JANW>].

40. See Keith Humphreys & Elizabeth Gifford, *Religion, Spirituality and the Troublesome Use of Substances*, in *RETHINKING SUBSTANCE ABUSE: WHAT THE*

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All that said, a modified, more plausible, version of the economic determinants hypothesis would be that, when access to an addictive substance is rapidly rising (as opioids, but not tobacco, was during the financial crisis), those users of that substance who live in economically difficult circumstances are more likely to progress from use to addiction. There can be multiple mechanisms behind this: fewer competing rewards in the environments of lower-income people; greater subjective relief from relatively higher life stress upon drug administration; more temptation for economic reasons to deal pills; and selection into social class effects.⁴¹

III. GOVERNING OPIOIDS: WHAT IT MEANS TO REGULATE A LEGALLY AVAILABLE, ADDICTIVE SUBSTANCE WHICH CAN BE BENEFICIAL OR HARMFUL

When American society eventually responds to public health challenges such as the opioid crisis, policymakers can use a variety of tools with a range of effects. Criminal law enforcement, regulatory policy and enforcement, private insurance practices, and civil liability all have the capacity to influence public health and the practice of medicine. All these domains may be implicated in society's approach to the prescription of opioids—an issue affecting a variety of economic and societal interests. Consider, for example, how opioid prescribing is “supposed to work.” In other words, who is in a position to affect access to a contingently lawful, addictive product? What are the forces that are intended to help doctors prescribe opioids safely and effectively such that criminal law need not get involved because no public safety threat is created?

SCIENCE SHOWS, AND WHAT WE SHOULD DO ABOUT IT 257 (William R. Miller & Kathleen M. Carroll eds., 2006).

41. People with mental health problems, for example, may be both more likely to fall into poverty and to find opioids particularly reinforcing. See Mary C. Acri et al., *The Intersection of Extreme Poverty and Familial Mental Health in the United States*, 15 SOC. WORK MENTAL HEALTH 677 (2017); David A. Brent et al., *Association Between Parental Medical Claims for Opioid Prescriptions and Risk of Suicide Attempt by Their Children*, 76 JAMA PSYCHIATRY 941 (2019); Jeffrey F. Scherrer et al., *Prescription Opioid Duration, Dose, and Increased Risk of Depression in 3 Large Patient Populations*, 14 ANNALS FAM. MED. 54, 58-60 (2016); Mark D. Sullivan et al., *Association Between Mental Health Disorders, Problem Drug Use, and Regular Prescription Opioid Use*, 166 ARCHIVES INTERNAL MED. 2087, 2089-92 (2006).

A. Overview of the Key Players and Legal Arrangements

The benefits and costs of drug use have spurred the creation of a variety of federal and state legal arrangements to regulate the supply of products available to the public. At the federal level, the Controlled Substances Act gives authority to the DEA and the FDA to regulate the use of pharmaceuticals, subject to congressional oversight.⁴² DEA regulation covers manufacturers, distributors, and pharmacies as well as physicians, who must be registered with the DEA in order to prescribe controlled substances. Physician registration usually requires state licensing. The Food, Drug, and Cosmetic Act also gives the FDA power to consider the potential for misuse (“abuse liability”) at the stage of new drug approval. Moreover, the Food and Drug Administration Amendments Act of 2007 gave the Administration power to put in place risk-minimization plans that restrict prescriptions, dispensing, or use of a drug and require manufacturers to advise prescribers and patients on proper use. The Department of Justice, primarily through U.S. Attorney’s Offices, also regulates the misuse of pharmaceutical products through criminal and civil actions.

These statutes are implemented by an alphabet soup of federal administrative bodies with overlapping authority and different agendas. The Centers for Disease Control and Prevention (CDC) establishes voluntary clinical practice treatment guidelines for physicians. The Department of Defense (DOD) and Veterans Affairs (VA) also produce clinical practice guidelines as well as operate large health care systems that effectively make them regulators of access to pharmaceuticals for present or former members of the military, respectively. The Centers for Medicare and Medicaid Services (CMS) regulate access through setting reimbursement rates. The Substance Abuse and Mental Health Services Administration (SAMHSA) within the U.S. Department of Health and Human Services (HHS) provides information about best practices and funding for, among other things, state efforts to provide addiction treatment. SAMHSA also collaborates with the FDA, DEA, and White House Office of National Drug Control Policy (ONDCP) on programs providing safe disposal options for prescription drugs and on prescription drug monitoring programs.

42. For a discussion of the regulatory transformation effected by the CSA, see Joseph Spillane & William B. McAllister, *Keeping the Lid On: A Century of Drug Regulation and Control*, 70 *DRUG & ALCOHOL DEPENDENCE* 5 (2003).

State boards of pharmacy regulate pharmacists, usually controlling licensing and establishing professional standards as well as, in some cases, promulgating regulations. Improper prescription practices may also implicate hospital pharmacy licensure or other providers.⁴³ Medical licensure boards establish standards and regulate the practice of physicians but are limited, in most cases, to responding to complaints rather than proactively seeking out improper prescribing habits.⁴⁴ The Federation of State Medical Boards has also established a model policy for the use of controlled substances.⁴⁵ An increasing number of states have prescriber-use mandates that require providers to check a state database under specific circumstances to make sure their prescriptions do not facilitate, misuse, or create risk of drug-drug interaction⁴⁶ (e.g., even taken as directed, simultaneous prescriptions of opioids and benzodiazepines carry risk of overdose).⁴⁷ As discussed below, these monitoring programs have been a domain of particular growth—though not without difficulty—in addressing opioid misuse across all fifty states.

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43. *See generally* RICHARD R. ABOOD, PHARMACY PRACTICE AND THE LAW 381-91 (2012).
44. *See* Jeanne M. Manubay et al., *Prescription Drug Abuse: Epidemiology, Regulatory Issues, Chronic Pain Management with Narcotic Analgesics*, 38 PRIMARY CARE 71, 76 (2011).
45. *Model Policy for the Use of Controlled Substances for the Treatment of Pain*, FED’N STATE MED. BOARDS (May 2004), https://dprfiles.delaware.gov/medicalpractice/Model_Policy_Treatment_Pain.pdf [<https://perma.cc/P4NX-76N3>].
46. *See* Prescription Drug Monitoring Program Training & Tech. Assistance Ctr., *Prescription Drug Monitoring Program: Legislative Update 2019 Second Quarter*, BRANDEIS U. (July 1, 2019), https://www.pdmpassist.org/pdf/PDMP_Legislative_Update_2019_Second_Quarter_Final.pdf [<https://perma.cc/3PGN-RJZ2>]; *see also* *When Are Prescribers Required to Use Prescription Drug Monitoring Programs?: Data Show Mandates Vary Across States*, PEW CHARITABLE TRUSTS (Jan. 24, 2018), <https://www.pewtrusts.org/en/research-and-analysis/data-visualizations/2018/when-are-prescribers-required-to-use-prescription-drug-monitoring-programs> [<https://perma.cc/BA3M-2KGR>].
47. *See* Rebecca L. Haffajee et al., *Mandatory Use of Prescription Drug Monitoring Programs*, 313 J. AM. MED. ASS’N 891 (2015); Eric C. Sun et al., *Association Between Concurrent Use of Prescription Opioids and Benzodiazepines and Overdose: Retrospective Analysis*, 356 BMJ j760 (2017).

B. Forces Shaping Opioid Prescription Practices

The preceding description underscores how critical actors' medical professionals are in this system, given that many of the other actors and institutions in a position to influence access to opioids operate only indirectly by affecting prescriber practices. Moreover, prescribers who are determined to evade legal or ethical requirements—or who have an incentive to engage in some kind of willful blindness—are likely to complicate even the most carefully designed regulatory goals.

In many respects, physicians are like any other group of workers: they have preferences for how to do their jobs but also have to respond to externally-established demands and expectations. Sometimes those internal and external forces are in alignment, and sometimes they compete. Among the most important internally generated goals within medicine are doctors' desire for beneficence, trust, and responsible autonomy. The most important external forces shaping doctors are non-physician regulators, payors, and patients. This Section describes each of these forces in turn.

1. Forces Internal to the Medical Profession: Beneficence, Trust, Responsible Autonomy

Beneficence. “To cure sometimes, to relieve often, to comfort always” is a medical aphorism that captures the aspiration of the profession and those in it to do good or, failing that, to invoke a different aphorism, *primum non nocere*. Doctors tend to want their actions to benefit patients – – sometimes out of empathy, sometimes out of professionalism, sometimes out of vanity, and sometimes out of a mix of the three. The critical point is that it is quite likely that the overwhelming majority of doctors who increased their issuance of opioid prescriptions to harmful levels were convinced that they were helping their patients.

Trust. Physicians want to be trusted by patients so that they can provide them informed care, and they want to be trusted by the broader society because that trust underlies the grant of status and autonomy. Although most Americans continue to trust physicians,⁴⁸ the opioid epidemic has almost certainly damaged that trust for some segments of the public because some patients became addicted to opioids by following their doctor's instructions. This helps explain why a previously

48. Robert J. Blendon et al., *Public Trust in Physicians—U.S. Medicine in International Perspective*, 371 *NEW ENG. J. MED.* 1570, 1570-71 (2014).

unthinkable intrusion on doctors' autonomy in 2017— states and a major pharmaceutical chain limiting opioid prescriptions for certain conditions to 7 days⁴⁹—resulted in far less public backlash than would have been the case twenty years ago.

Responsible autonomy. Relative to other occupations, even professionalized ones, physicians have a high level of autonomy in their decision-making. When organized medicine emerged in the late 19th century, this autonomy was virtually limitless.⁵⁰ Indeed, no less a figure than William James argued that even state licensing of physicians was an unreasonable encroachment on professional freedom.⁵¹ Half a century later, the American Medical Association helped torpedo President Truman's proposal for national health insurance because it feared (accurately) that third-party payors would intrude on physician autonomy.⁵² Modern physicians have high autonomy, but within informal constraints designed to promote responsible practice. These include a desire to follow scientific evidence and a tradition of valuing the opinions of their peers.

2. Forces External to Medicine: Non-Physician Regulators, Payors, and Patients—"Trust But Verify"

Non-physician regulators. Reflecting its historical success at preserving its autonomy, medicine is to a significant extent self-regulated. State medical boards, for example, are run primarily by physicians. However, there are non-physician regulators, the most important of which for opioid prescribing is the Federal Drug Enforcement Administration. To

49. Susan Scutti & Nadia Kounang, *CVS Will Limit Opioid Prescriptions to 7 Days*, ABC 57 (Sept. 22, 2017, 8:51 PM EST), <https://abc57.com/news/cvs-will-limit-opioid-prescriptions-to-7-days> [<https://perma.cc/H5DQ-MM66>].

50. For a description of the transformation of medical practice, see PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* 79-144, 420-49 (rev. ed. 2017); see also Stefan Timmermans, *From Autonomy to Accountability: The Role of Clinical Practice Guidelines in Professional Power*, 48 *PERSP. BIOLOGY & MED.* 490 (2005) (discussing how modern clinical guidelines affect medical professional autonomy); Stefan Timmermans & Hyeyoung Oh, *The Continued Social Transformation of the Medical Profession*, 51 *J. HEALTH & SOC. BEHAV.* S94 (2010) (discussing the modern sociological history of the medical profession).

51. STARR, *supra* note 50, at 105.

52. STARR, *supra* note 50, at 282.

prescribe controlled substances, a physician needs a DEA license and must submit to the possibility of DEA inspections. It is extremely rare for the DEA to withdraw a physician's prescribing license, but the possibility is frightening enough to cause concern (and some resentment). The other key non-physician regulators to whom physicians must be responsive are organizations that accredit health care organizations. The best-known example is The Joint Commission, which at one point put significant pressure on hospitals to be more responsive to patient pain.⁵³

Payors. Payors always shape prescribing. Examples of how they exert control include, for instance, a Medicaid program refusing or agreeing to reimburse non-opioid pain management services (e.g., physical therapy), a private insurance company expanding or contracting its level of utilization review, and a pharmacy-benefits management company negotiating generic drug coverage for an employer-provided health insurance plan. Payors also affect opioid prescribing indirectly, through economic incentives: physicians in the United States (and Canada, which also has an opioid epidemic) are generally paid by volume of services provided, and writing a prescription takes little time compared to other medical procedures such as clinical observations.

Patients. Outside of a hospital setting in which opioids might be administered under close supervision and with complete control over access, doctors have to share control of prescribing with patients. That is, patients can refuse to fill a prescription or fill it but not follow it (e.g., take pills more often than directed). Patients may also have strong preferences regarding different medications, which doctors must negotiate.

Despite patients' formal right to sue doctors, a patient is quite unlikely to prevail merely because she disagrees with her doctor about whether the patient merits an opioid prescription. They could conceivably sue if the physician deviated from the custom of the profession and that deviation caused a cognizable injury—but patient retaliation in the event of a disagreement with the patient's doctor is easier today even in the absence of litigation. Many hospitals and clinics survey patients about their experience, some of which then feeds back into financial incentives, such as by influencing doctors' annual bonuses.⁵⁴ Moreover, digital platforms

53. See David W. Baker, *History of the Joint Commission's Pain Standards: Lessons for Today's Prescription Opioid Epidemic*, 317 J. AM. MED. ASS'N 1117, 1117-18 (2017).

54. See James D. Reschovsky et al., *Effects of Compensation Methods and Physician Group Structure on Physicians' Perceived Incentives to Alter Services to Patients*, 41 HEALTH SERVS. RES. 1200, 1205, 1208 (2006); Aleksandra Zgierska et al., *Patient Satisfaction, Prescription Drug Abuse, and Potential*

for aggregating reviews, such as Yelp.com, allow angry patients to complain about doctors, leaving reputational consequences even if there is no direct financial effect.⁵⁵

The internal and external forces just described are imperfect in many respects. Yet at the same time they created guardrails that historically made it less likely that the health care system would create an epidemic with massive public harm. These forces failed as never before during the opioid epidemic, opening the question of whether criminal law was required to enter the breach.

C. The Strengths and Limitations of Criminal Enforcement

As a general matter, criminal enforcement plays an important role in regulating undesirable conduct, including the illicit distribution and use of opioids. But public health problems are not guaranteed to trigger appropriate criminal justice responses. Moreover, questions about the role of criminal enforcement in addressing public health problems inevitably raise broader issues associated with the longer-term use of the criminal justice system to affect drug consumption. Efforts to describe, or eventually to confine, criminal enforcement to a narrow “malum in se” category—involving offenses such as murder or fraud, for example—tend not to fit closely with how American society actually uses criminal law.⁵⁶ Indeed, the fact that white-collar regulatory enforcement is possible (in domains such as environmental regulation and finance) illustrates the breadth of criminal law. Similarly, the drug enforcement infrastructure has criminal law at its core, including provisions to address complex, group-enabled criminal schemes.

This framework as it currently exists is obviously not without its costs. But it applies, or can be made to apply, to many individual and collective behaviors associated with the opioid crisis. As we shall see, one of the most

Unintended Consequences, 307 J. AM. MED. ASS'N 1377, 1377-78 (2012); see also Bruce Japsen, *More Doctor Pay Tied to Patient Satisfaction and Outcomes*, Forbes (June 18, 2018, 8:35 AM), <https://www.forbes.com/sites/brucejapsen/2018/06/18/more-doctor-pay-tied-to-patient-satisfaction-and-outcomes/#78628410504a> [https://perma.cc/2GDK-CSA3].

55. See Anna Lembke, *Why Doctors Prescribe Opioids to Known Opioid Abusers*, 367 NEW ENG. J. MED. 1580 (2012).

56. See generally Mariano-Florentino Cuéllar, *The Political Economies of Criminal Justice*, 75 U. CHI. L. REV. 941 (2008).

important and timely questions involving the role of criminal enforcement in opioid-related enforcement concerns the apparently different response to the present crisis in contrast to the vigorous law enforcement response to drug problems in the 1980s and 1990s. Calibrating the appropriate level and type of criminal justice response remains a challenge and underscores the complexity of understanding how the legal system more generally affects the behavior of the different actors that shape the availability of opioids.

1. Criminal Enforcement Tools to Target Opioid-Related Offenses

In pursuing physicians, pharmacists, and nurses involved in allegedly overprescribing opioids, U.S. attorneys have charged, both directly and using aiding and abetting theories under 18 U.S.C. § 2, distribution of controlled substances resulting in death in violation of 21 U.S.C. § 841; conspiracy to distribute in violation of 21 U.S.C. § 846; and health care fraud in violation of 18 U.S.C. § 1347.⁵⁷ The federal government has also brought cases against physicians, nurses, and pharmaceutical representatives running “pill mills” for conspiracy to commit healthcare fraud, distribute controlled substances, commit mail and wire fraud, defraud the United States as well as for racketeering and RICO violations.⁵⁸ Prosecutors have also brought money laundering charges against physicians and pharmacists alleged to have run “pill mills.”⁵⁹

States and the federal government have also used the threat of criminal prosecution to curb the sale of opioids from internet-based pharmacies. A prominent example is FDA warning letters sent to online pharmacies marketing non-approved opioids or selling prescription

57. *See, e.g.*, Indictment, United States v. Robison, No. 5:18-cr-00163-M (W.D. Okla. June 20, 2018).

58. *See, e.g.*, Indictment, United States v. Couch, No. 40-9999 (S.D. Ala. Apr. 30, 2015). The case is sealed, but the Department of Justice put out a press release summarizing the charges, available at <https://bit.ly/2sbttwO>. *See also* Janelle Lawrence & Jef Feeley, *Ivy League Doctor Gets 4 Years in Prison for Insys Opioid Kickbacks*, BLOOMBERG (Mar. 9, 2018, 2:24 PM EST), <https://bloom.bg/2Hld0Kx> (summarizing several cases related to Insys’s malfeasance) [<https://perma.cc/N9PY-WJLZ>].

59. *See* Second Superseding Indictment, United States v. Ilonzo, No. 1:12-CR-00276-SCJ-GGB (N.D. Ga. Sept. 5, 2013).

opioids to individuals without a prescription.⁶⁰ Because even the sketchiest of internet prescription drug sales typically involve legal intermediaries, such as banks that issue credit cards and process transactions or shipping companies that deliver drugs, this provides another venue for potential federal prosecution. For example, United Parcel Service recently avoided DOJ prosecution by forgoing \$40 million in internet drug sale revenue and agreeing to stop delivering suspicious shipments from internet pharmacies.⁶¹

Recently, the Department of Justice formed a task force to fight the prescription opioid crisis, targeting misconduct at all levels from manufacturers to pharmacies to healthcare providers.⁶² The Department of Justice has brought criminal charges against high-level executives at Insys Pharmaceuticals, which produced and promoted potent legal opioids. The initial indictment alleged racketeering conspiracy (18 U.S.C. § 1962(d)), mail and wire fraud conspiracy (18 U.S.C. § 1349), and conspiracy (18 U.S.C. § 371) to violate the Anti-Kickback Statute (42 U.S.C. § 1320a-7b).⁶³ At the urging of Judge Burroughs, prosecutors have narrowed the indictment to just the racketeering conspiracy.⁶⁴

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60. *Internet Pharmacy Warning Letters*, U.S. FOOD & DRUG ADMIN. (Jan. 23, 2019), <https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm348680.htm> [<https://perma.cc/EFN9-PEC7>].
61. Press Release, U.S. Dep't of Justice, UPS Agrees to Forfeit \$40 Million in Payments from Illicit Online Pharmacies for Shipping Services (Mar. 29, 2013), <https://www.justice.gov/usao-ndca/pr/ups-agrees-forfeit-40-million-payments-illicit-online-pharmacies-shipping-services> [<https://perma.cc/4SJ4-3BWG>].
62. *See* Press Release, U.S. Dep't of Justice, Attorney General Sessions Announces New Prescription Interdiction & Litigation Task Force (Feb. 27, 2018), <https://bit.ly/2GQrwtH> [<https://perma.cc/EJ5U-WFE3>]; *see also* Press Release, U.S. Dep't of Justice, Attorney General Sessions Announces Opioid Fraud and Abuse Detection Unit (Aug. 2, 2017), <https://bit.ly/2ukVRdf> [<https://perma.cc/JR9C-JS9B>]. *See generally* Rachel L. Rothberg & Kate Stith, *The Opioid Crisis and Federal Criminal Prosecution*, 46 J. L. MED. & ETHICS 292 (2018).
63. Indictment, *United States v. Babich*, No. 1:16-cr-10343-ADB (D. Mass. Dec. 6, 2016).
64. *See* Second Superseding Indictment, *United States v. Babich*, No. 1:16-cr-10343-ADB (D. Mass. Sept. 11, 2018).

2. Criminal Enforcement in Broader Context

The preceding example underscores the distinction between the extent of criminal enforcement tools available and the more complex mix of aggressive and limited enforcement actually pursued. Indeed, one of the common threads in the law-related commentary on the opioid crisis is the tension between treating the epidemic as a criminal versus public health issue. This prevalent framing of the policy choice obscures the important distinction between how society deals with traffickers versus users. If two drug dealers are shooting it out over a particular street corner, no one thinks the best solution is to call a psychiatrist. The split in philosophy is about responses to drug users, particularly addicted ones. The point of view associated with the War on Drugs is that such users should be arrested and punished whereas the public health perspective views addicted individuals as ill and in need of rehabilitation rather than punishment.⁶⁵

The Obama Administration (in which both authors served), sought to combat the opioid crisis through “targeted activities, funding new and unprecedented networks of law enforcement and public health partnerships to address the heroin threat; targeting heroin and prescription opioid traffickers and the illegal opioid supply chain; and

65. See, e.g., OFFICE OF THE SURGEON GEN., U.S. DEP’T OF HEALTH & HUMAN SERVS., FACING ADDICTION IN AMERICA: THE SURGEON GENERAL’S REPORT ON ALCOHOL, DRUGS, AND HEALTH 7-1 to 7-17 (2016); Howard K. Koh et al., *A Smarter War on Drugs*, 320 J. AM. MED. ASS’N 2301, 2301-02 (2018); Jeffrey A. Singer, *Harm Reduction: Shifting from a War on Drugs to a War on Drug-Related Deaths*, CATO INST. (Dec. 13, 2018), <https://www.cato.org/publications/policy-analysis/harm-reduction-shifting-war-drugs-war-drug-related-deaths> [<https://perma.cc/72PA-3Q7Y>]; Betsy Pearl & Maritza Perez, *Ending the War on Drugs*, CTR. AM. PROGRESS (June 27, 2018, 9:00 AM), <https://www.americanprogress.org/issues/criminal-justice/reports/2018/06/27/452786/ending-war-drugs> [<https://perma.cc/XG89-XD5D>]; see also Lisa D. Moore & Amy Elkavich, *Who’s Using and Who’s Doing Time: Incarceration, the War on Drugs, and Public Health*, 98 AM. J. PUB. HEALTH 782 (2008). But see German Lopez, *The New War on Drugs*, VOX (Sept. 13, 2017), <https://www.vox.com/policy-and-politics/2017/9/5/16135848/drug-war-opioid-epidemic> [<https://perma.cc/K326-W3HD>]; Sejal Singh & Alisha Jarwala, *Nuisance Ordinances: The New Frontier in Social Control*, CURRENT AFF. (Aug. 6, 2019), <https://www.currentaffairs.org/2019/08/nuisance-ordinances-the-new-frontier-in-social-control> [<https://perma.cc/L8T8-SD58>].

thwarting doctor-shopping and disrupting so-called ‘pill mills.’⁶⁶ At the same time, the Administration emphasized that opioid addiction was “a public health problem that requires a public health response.”⁶⁷ This included “working with law enforcement to help people get into treatment instead of into jail,” “expand[ing] access to substance use disorder treatment through the Affordable Care Act,” getting first responders to carry the overdose rescue drug naloxone, and “chang[ing] the rules to allow more types of health care providers to provide evidence-based opioid treatment.”⁶⁸ The Trump Administration’s President’s Commission on Combatting Drug Addiction and the Opioid Crisis has similarly emphasized the “public health crisis” of opioids.⁶⁹ Yet the President himself and his first attorney general, Jeff Sessions, have advocated a 1980s-style enforcement approach, including longer sentences and expansive use of capital punishment.⁷⁰

Law-related commentary on the opioid crisis is overwhelmingly focused on discrete legal issues, including the burdens to the legal system created by opioid misuse and addiction. Few if any scholars have offered a critical analysis of the mix of civil litigation, criminal enforcement, and regulatory tools that comprise the national response to the opioid crisis.⁷¹

66. Barack Obama, Commentary, *Advancing Criminal Justice Reform*, 130 HARV. L. REV. 811, 859 (2017).

67. *Id.*

68. *Id.* at 859-60.

69. *See, e.g.*, Exec. Order No. 13,784, 82 Fed. Reg. 16,283 (Mar. 29, 2017) (“It shall be the policy of the executive branch to combat the scourge of drug abuse, addiction, and overdose (drug addiction), including opioid abuse, addiction, and overdose (opioid crisis). This public health crisis was responsible for more than 50,000 deaths in 2015 alone, most of which involved an opioid, and has caused families and communities across America to endure significant pain, suffering, and financial harm.”).

70. *See, e.g.*, Eli Rosenberg, *Trump Is ‘Most Excited’ About Death Penalty for Drug Dealers. Rights Groups Say It’s a Terrible Idea*, WASH. POST (Feb. 15, 2019), <https://www.washingtonpost.com/politics/2019/02/15/trump-again-praises-strongmen-who-execute-drug-dealers-rights-groups-say-its-terrible-idea/> [<https://perma.cc/TU8Y-WG58>].

71. *See, though*, the pieces collected in the Summer 2018 issue of the *Journal of Law, Medicine and Ethics*. *E.g.*, Andrew W. Parker et al., *State Responses to the Opioid Crisis*, 46 J.L. MED. & ETHICS 367 (2018); Rachel L. Rothberg & Kate Stith, *The Opioid Crisis and Federal Criminal Prosecution*, 46 J.L. MED. & ETHICS 292 (2018); Alex Wang & Aaron S. Kesselheim, *Government Patent Use to*

Rather than focusing on the systemic interactions between different legal tools, or on how legal arrangements affect root causes, much of the law-related commentary treats law as a dependent rather than independent variable, focusing on ways to address the epidemic's strain on the legal system.

For instance, scholars have chronicled a variety of specific strategies currently employed against the opioid crisis. As one example, the DEA's "360 Strategy" unsurprisingly focuses on law enforcement efforts. The DEA employs a "three-pronged approach to combating the epidemic through: (1) coordinated Law Enforcement actions against drug cartels and traffickers in specific communities; (2) Diversion Control actions against DEA registrants operating outside the law and long-term engagement with pharmaceutical drug manufacturers, wholesalers, pharmacies, and practitioners; and, (3) Community Outreach through local partnerships that empower communities to take back affected neighborhoods."⁷² The DEA rolled out this strategy in Pittsburgh, St. Louis, Milwaukee, and other affected communities.⁷³ The Department of Justice has elsewhere invested in evaluating various law enforcement strategies to combat the epidemic, such as prescription-drug monitoring programs,⁷⁴ forensic analysis of drug ledgers,⁷⁵ and enhanced sentencing requirements for drug trafficking that results in death.⁷⁶

Don Stemen has placed the federal and state response to the opioid epidemic in the larger historical context of U.S. drug policy, noting that despite some signs that drug addiction is increasingly viewed as a public health problem, it remains unclear whether the country will

Address the Rising Cost of Naloxone: 28 U.S.C. § 1498 and Evzio, 46 J.L. MED. & ETHICS 472 (2018).

72. Mike Gill et al., *DEA's 360 Strategy: Attacking the Opioid Crisis on Three Fronts*, U.S. ATT'YS BULL., Sept. 2016, at 55 (emphasis removed).

73. *Id.*

74. See Tara Kunkel, *Data-Driven Approaches to Responding to the Opioid Epidemic*, U.S. ATT'YS BULL., Sept. 2016, at 79, 79-82.

75. See Jessica L. Affeldt, *Drug Ledge Analysis Capabilities of the FBI's Cryptanalysis and Racketeering Records Unit*, U.S. ATT'YS BULL., Sept. 2016, at 83-86.

76. See 21 U.S.C. § 841(a)(1), (b)(1)(A)-(C) (2016); William J. Ihlenfeld II, *"Death Results" Prosecutions Remain Effective Tool Post-Burrage*, U.S. ATT'YS BULL., Sept. 2016, at 45-52.

fundamentally alter its approach to drug policy.⁷⁷ Ameet Sarpatwari et al. have argued that policymakers should probe the root cause of the overuse of opioids. They propose several ways to solve the legal and regulatory problems, such as having the federal government challenge patents, imposing time restrictions on citizen petitions filed by opioid manufacturers to protect their commercial interests, requiring sample sharing for bioequivalence studies, and promoting cost-effectiveness research and dissemination.⁷⁸ Timothy S. Coyne has noted that in stark contrast to the crack-cocaine epidemic, the legislative reaction to the current opioid epidemic “has generally been far more treatment-oriented, with some exceptions.”⁷⁹

3. Contrasting Responses to the Opioid Epidemic and the “Drug War” of the 1980s and 1990s

The extent of enforcement-related action—or lack of action—regarding opioid issues in the last decade contrasts with the more punitive response associated with drug enforcement during the 1980s and 1990s. One possible explanation is that the severity of the epidemic “has worn down historic Republican resistance to public health driven drug policy.”⁸⁰ Another proffered explanation is the demographics of prescription drug users: the epidemics of the 1980s and 1990s affected mainly low-income African Americans (crack cocaine) and low-income, rural whites (methamphetamine), whereas the opioid epidemic includes a large representation of middle-class, white individuals with more political and social capital. Indeed, whites accounted for eighty-five percent of all opioid overdose deaths in 2014.⁸¹ There is also the unique nature of the crisis:

As patients continue to seek pain relief, the rise of opioid abuse calls into question medicine’s approach to pain management and creates new conflicts in United States approaches to illegal drug use. Indeed, the question of how to address prescription drug

77. Don Stemen, *Beyond the War: The Evolving Nature of the U.S. Approach to Drugs*, 11 HARV. L. & POL’Y REV. 375, 379 (2017).

78. Ameet Sarpatwari et al., *The Opioid Epidemic: Fixing a Broken Pharmaceutical Market*, 11 HARV. L. & POL’Y REV. 463, 481-84 (2017).

79. Timothy S. Coyne, *The Resurgence of Heroin: Benefitting from the Current Political Climate*, 20 RICH. PUB. INT. L. REV. 185, 190 (2017).

80. Stemen, *supra* note 77, at 415.

81. *Id.*

misuse falls to both health care professionals and criminal justice system actors and creates conflicts between legitimate approaches for treating pain and the punishment for engaging in the illegal use of drugs. Moreover, because the illegal use of drugs in this context often begins from a legitimate, legal use of such drugs, the response has been more focused on treatment than punishment, marking a significant change in both national rhetoric and practice around drug abuse.⁸²

Although we acknowledge the importance of these distinctions, and particularly the complicated impact of a drug's licit uses, one should not presume that a public health approach to opioid addiction is now triumphant. The opioid crisis is pervasive in rural areas, which often lack adequate social and health care services, leaving jail as the default option for many addicted individuals who commit low-level offenses. Anderson and Reinsmith-Jones touch briefly on this issue and note how lessons from the past war on drugs drive criminal justice approaches to the opioid epidemic today.⁸³ As drug-related incarceration in rural areas rises, it has been dropping in urban areas. These patterns likely reflect a mix of factors, including growing public concern over opioid-related crime in rural areas and changing criminal justice priorities in urban areas.

An interesting perspective on the opioid crisis—and the prosecutions that could have happened but did not—is described in *A Prosecutor's Perspective on a Public Health Crisis*, by the Commonwealth's Attorney for the County of Henrico:

It is unrealistic to think that those of us in Public Safety (law-enforcement and prosecutors) would simply turn our backs on people who break the law. It is unrealistic to think that Public Safety and the Courts do not have a role to play in this opioid epidemic, but the definition of that role is delicate—the attempt to balance the interests of a public health crisis revolving around a

82. *Id.* at 414.

83. James F. Anderson & Kelley Reinsmith-Jones, *Opioid Addiction in Rural North Carolina: A Criminal Justice and Public Health Issue*, 5 INT'L J. SOC. SCI. STUD., July 2017, 42, 47-49, <https://doi.org/10.11114/ijsss.v5i7.2495> [<https://perma.cc/T95K-VWS5>]. While this analysis correctly recognizes that some recalibration in the use of criminal enforcement has occurred since the height of the 1980s drug war, it does not fully explore the socially optimal role of criminal enforcement in addressing the role or responsibility of drug manufacturers, distributors, and doctors in the opioid crisis.

criminal activity. Yet, that is what I—an elected official, a prosecutor—am asked to do.⁸⁴

Another factor shaping the response to the opioid crisis is the remarkable lack of violence associated with it relative to the methamphetamine and crack cocaine epidemics. This may in part be pharmacological: opioids are soporific, whereas stimulants such as methamphetamine and crack cocaine increase agitation and aggression. It is also in part due to opioids being distributed by people who wear white coats and carry stethoscopes rather than people who wear gang colors and carry guns. Violence tends to draw strong cries from voters of all classes and races for more punitive responses to drugs, and the lack of violence around opioids has not created this political pressure.

Some of the nuances and tradeoffs associated with the role of criminal enforcement in addressing the opioid crisis are not lost on observers of and participants in the criminal justice system.⁸⁵ An example comes from Tim Coyne, a public defender in Virginia:

In our community, it really started with law enforcement—our task force came forward and said we cannot arrest our way out of this problem. We have a problem, our deaths are rising, people are overdosing on our streets. We have to look about it and treat it differently. So with law enforcement, our public health system we have one hospital that serves our area, our region, they contributed—we have the court system, commonwealth attorneys, defense attorneys, private community providers, our community started meeting together to try and address it, which ultimately developed into the Northern Shenandoah Valley Substance Abuse Coalition. We were able to get some funding from the localities—Winchester City, Frederick County, Clark County, and Valley Health. It enabled us to start a drug treatment court, which our first docket was held August 16th. Drug courts aren't anything new And a lot of what we experienced was trying to change the mindset and peoples' approach in what they thought about addicts. It wasn't the junkie in the alley that it used to be. It was now fathers, sons, mothers, daughters, peoples' children. They

84. Shannon Taylor, *A Prosecutor's Perspective on a Public Health Crisis*, 20 RICH. PUB. INT. L. REV. 182, 182 (2017).

85. *See, e.g.*, Symposium, *Virginia's Opioid Epidemic: Treatment and Policy in the 21st Century*, 20 RICH. PUB. INT. L. REV. 128, 133 (2017).

could put a different face on it and that's really what has changed.⁸⁶

Adding further gloss to these insights, one study evaluated how the mainstream news media has described the phenomenon of opioid addiction. According to the study, the news media more often frame the problem as a criminal justice issue—despite the fact that prevention-oriented approaches, such as prescription-drug monitoring programs, were mentioned more frequently in the latter years of the study.⁸⁷

Ultimately, prosecutors could have deployed a broad range of criminal justice-related tools to focus on opioid-related issues early in the epidemic. As with all criminal enforcement strategies, any criminal prosecution or related forfeiture would face—by design—procedural and substantive limitations. To the extent public officials might have sought strategies with fewer procedural and substantive limitations, such as expanding regulatory measures limiting access to opioids and giving public officials the ability to pursue enforcement, these measures were likely to have faced opposition from the pharmaceutical industry.

D. Challenges Associated with Civil Regulatory Enforcement

Criminal and civil regulatory enforcement are both substitutes and complements. Regulatory policy can make use of various levers for controlling the prescription, distribution, and misuse of opioids that may be available in light of the organization of medical care and pharmaceutical distribution in the United States. The government may regulate by imposing civil penalties or constraints for violating health-protecting rules grounded in statutory requirements. Jurisdictions can also enact new statutes and rules requiring compliance with some administrative scheme to limit availability of some drug (as with nominally legalized marijuana), changing tax policy, or allowing the public to pursue private rights of action.

Regulatory rules can address substantive conduct directly capable of affecting health (e.g., prescriptions) or can involve compliance with monitoring mechanisms designed to gather information about possible criminal or regulatory violations. Violations of federal regulatory

86. *Id.* at 135.

87. Emma E. McGinty et al., *Criminal Activity or Treatable Health Condition? News Media Framing of Opioid Analgesic Abuse in the United States, 1998-2012*, 67 *PSYCHIATRIC SERVS.* 405 (2016).

requirements can trigger civil penalties or criminal prosecution. A variety of state laws also apply.⁸⁸ Together with the federal efforts, these civil regulatory actions demonstrate a high degree of law-enforcement interest in the problem. Nonetheless, as discussed below, enforcement efforts face a variety of challenges—in part because of the difficulty of gathering data and the challenges (by design) of proving the relevant criminal statutes’ intent requirements. But political economy can also dilute how regulatory policies emerge, the breadth of their scope, and, particularly, their enforcement.

1. A Legislative Example: DEA Pharmaceutical Manufacturers’ Registrations

A recent legislative example involving the DEA and the Ensuring Patient Access and Effective Drug Enforcement Act of 2016 (the “Act”) illustrates how difficult it is to achieve meaningful changes in the regulatory environment. The Act was enacted “[t]o improve enforcement efforts related to prescription drug diversion and abuse” and has two major parts: (1) revisions to the Controlled Substance Act’s registration process and (2) the commissioning of a report to Congress on the opioid crisis.⁸⁹ It made three major changes to the Controlled Substances Act. First, the Act amended the Controlled Substances Act’s registration requirements under section 303, 21 U.S.C. § 823, to define the phrase

88. State civil suits against manufacturers, distributors, or pharmacies have generally alleged some common law-related causes of action, discussed below, such as public nuisance, common law fraud, and negligent misrepresentation, negligence, as well as violation of state unfair business practices statutes (e.g., MASS. GEN. LAWS ch. 93A, § 11 (2019)), unjust enrichment, and civil conspiracy. Violations of state law negligence have alleged that distributors’ failure to comply with federal regulatory requirements goes to negligence. *See* 21 C.F.R. § 1301.71(a). State attorneys general have also brought cases against drug representatives who participated in kickback schemes. *See, e.g.*, Bill Wichert, *Insys Sales Rep Pleads Guilty to Opioid Kickback Scheme*, LAW360 (May 30, 2018, 6:52 PM), <https://www.law360.com/articles/1048620/insys-sales-rep-pleads-guilty-to-opioid-kickback-scheme> [<https://perma.cc/KSF7-MEQU>] (reporting a guilty plea by a drug representative in New Jersey). *See generally* Andrew M. Parker et al., *State Responses to the Opioid Crisis*, 46 J.L. MED. & ETHICS 367 (2018).

89. Ensuring Patient Access and Effective Drug Enforcement Act of 2016, Pub. L. No. 114-145, 130 Stat. 354 (codified at 21 U.S.C. §§ 801 et seq.).

“factors as may be relevant to and consistent with public health and safety.” According to the Act, the phrase means “factors that are relevant to and consistent with the findings contained in section 101 [21 U.S.C. § 801].”⁹⁰ Section 101 of the Controlled Substances Act contains congressional findings and declarations regarding controlled substances.⁹¹

Second, the Act defined the standard required to immediately suspend pharmaceutical manufacturers’ registrations. Section 304(d) of the Controlled Substances Act⁹² allows the Attorney General, at his or her discretion, to revoke a registration to manufacture, distribute, or dispense a controlled substance “in cases where he finds that there is an imminent danger to the public health and safety.” The Act added a definition for the phrase “imminent danger to the public health or safety,” which now means, “due to the failure of the registrant to maintain effective controls against diversion or otherwise comply with the obligations of a registrant under this title or title III, there is a *substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration.*”⁹³ Although the Attorney General could previously interpret “imminent danger to the public health or safety” under his or her own terms, the law now requires a “substantial likelihood of an immediate threat” before the Attorney General can revoke a pharmaceutical company’s registration.

Third, the Act establishes requirements for an order to show cause under the Controlled Substances Act, in situations other than the “imminent danger” provision in section 304(d) of the Controlled Substances Act. Before the Attorney General revokes a registration in instances where there is no imminent danger, the Attorney General “shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended.”⁹⁴ The Controlled Substances Act previously stated that “[a] failure to comply with section 823(g)(1) of this title [regarding the heightened registration requirements for practitioners dispensing narcotic drugs for narcotic treatment] may be treated . . . as grounds for immediate suspension of a

90. *Id.* at § 2(a)(1).

91. *See* 21 U.S.C. § 801 (2018).

92. *See* 21 U.S.C. § 824(d) (2018).

93. Pub. L. No. 114-145, § 2(a)(2), 130 Stat. 354, 354 (emphasis added).

94. 21 U.S.C. § 824(c) (2018).

registration.”⁹⁵ The Act deleted this provision, allowing for immediate suspension of registrations for narcotic drugs. The Act also instituted a number of requirements for the order to show cause. Any order to show cause must contain a statement of the basis for the denial, revocation, or suspension of a corrective action plan; direct the applicant or registrant to appear before the attorney general at a time and place stated in the order; and notify the applicant or registrant of the opportunity to submit a corrective action plan.⁹⁶ The Attorney General must consider the registrant’s corrective action plan before taking action.⁹⁷

Finally, the Act directs a variety of agencies within HHS, along with the DEA Administrator and the Secretary of Defense and Secretary of Veterans Affairs, to submit a report to Congress that identifies, among other things, “obstacles to legitimate patient access to controlled substances”; “issues with diversion of controlled substances”; and “how collaboration between federal, state, local, and tribal law enforcement agencies and the pharmaceutical industry can benefit patients and prevent diversion and abuse of controlled substances.”⁹⁸ The Act requires the agencies to consult with a variety of stakeholders in preparing the report, including law enforcement, pharmacies, drug manufacturers, healthcare providers, insurance companies, and wholesale drug distributors.⁹⁹

In combination, these changes remove discretion from the DEA to suspend the registrations of pharmaceutical companies under the Controlled Substance Act and heighten the level of proof required to pursue immediate enforcement action against pharmaceutical companies.

The statute had its origins in a May 2014 bill introduced by Representative Tom Marino (R-PA).¹⁰⁰ H.R. 4709 had many of the same provisions as the eventually passed Act: it defined “factors as may be relevant to and consistent with the public health and safety,” added requirements for orders to show cause, and called for a report to

95. See 21 U.S.C. § 824(d) (2015), amended by Pub. L. 114-145, § 2(a)(2), (b), 130 Stat. 354 (Apr. 19, 2016).

96. *Id.* at § 2(b)(3).

97. *Id.*

98. Ensuring Patient Access and Effective Drug Enforcement Act of 2016, Pub. L. No. 114-145, § 3, 130 Stat. 354, 355-56.

99. *Id.*, at § 3(b).

100. See H.R. 4709, 113th Cong. (as referred to S. Comm. on Health, Education, Labor and Pensions, July 30, 2014).

Congress.¹⁰¹ H.R. 4709, however, had an even more specific definition of “imminent danger to the public health or safety” as meaning that controlled substances:

- (A) will continue to be intentionally distributed or dispensed—
 - (i) outside the usual course of professional practice; or
 - (ii) in a manner that poses a present or foreseeable risk of serious adverse health consequences or death; or
- (B) will continue to be intentionally diverted outside of legitimate distribution channels.¹⁰²

The bill passed the House, but stalled in the Senate.¹⁰³ The DEA “mobilized to defeat Marino’s measure,” and an internal DEA memo “noted that the bill essentially [would] eliminate[] the agency’s power to file immediate suspension orders of drug shipments.”¹⁰⁴

The following year, Representative Marino introduced a second version of his bill, H.R. 471.¹⁰⁵ H.R. 471 again mirrored the Act’s provisions but proffered a new definition of “imminent danger to the public health or safety” as meaning:

in the absence of an immediate suspension order, controlled substances will continue to be distributed or dispensed by a registrant who knows or should know through fulfilling the obligations of the registrant under this Act—

- (A) the dispensing is outside the usual course of professional practice;
- (B) the distribution or dispensing poses a present or foreseeable risk of adverse health consequences or death due to the abuse or misuse of the controlled substances; or
- (C) the controlled substances will continue to be diverted outside of legitimate distribution channels.¹⁰⁶

101. *Id.* at § 2.

102. *Id.*

103. *See* H.R. 4709, CONGRESS.GOV, <https://www.congress.gov/bill/113th-congress/house-bill/4709> [<https://perma.cc/X3MV-QPF3>].

104. 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/?utm_term=.89cd8b888db9 [<https://perma.cc/3QG5-YSCE>].

105. H.R. 471, 114th Cong. (as referred to S. Comm. on the Judiciary, April 22, 2015).

106. *Id.* at § 2.

H.R. 471 was received in the Senate and referred to the Committee on the Judiciary.¹⁰⁷ The DEA was reportedly in negotiations with the staff of Senator Orrin Hatch (R-UT) to amend the bill for the Senate's consideration.¹⁰⁸ The eventually enacted bill was introduced by Senator Hatch as S. 483 on February 12, 2015.¹⁰⁹ The bill changed the definition of "imminent danger" to require the DEA to show that a company's conduct posed a "substantial likelihood of an immediate threat" of death, serious bodily harm, or drug abuse before the agency could seek a suspension order.¹¹⁰ The bill also required the DEA to consider a company's corrective action plan before taking action.¹¹¹ Senators Sheldon Whitehouse (D-RI), Marco Rubio (R-FL), David Vitter (R-LA), and Bill Cassidy (R-LA) joined as cosponsors.¹¹²

The bill was supported by Senator Charles Grassley (R-IA) and reported out of the Committee on the Judiciary on February 11, 2016, without an accompanying written report.¹¹³ It passed in the Senate by unanimous consent on March 17, 2016.¹¹⁴ It then passed in the House without objection on April 12, 2016, and was signed by the President on April 19, 2016.¹¹⁵

Though the Senate bill did not generate any written committee report, its early version in the House, H.R. 471, did include a report. The House Report stated H.R. 471 "would help prevent prescription drug abuse, while ensuring that patients have access to needed medications by fostering better collaboration between drug manufacturers, wholesalers, pharmacies, the Drug Enforcement Administration (DEA), and the Food and Drug Administration (FDA)."¹¹⁶ The report characterized the bill as

107. *Id.*

108. Higham & Bernstein, *supra* note 104.

109. S. 483, 114th Cong. (as introduced in Senate, February 12, 2015).

110. S. 483, 114th Cong. § 2 (2016) (enacted).

111. Ensuring Patient Access and Effective Drug Enforcement Act of 2016, Pub. L. No. 114-145, § 2, 130 Stat. 354, 354-55.

112. *See* S. 483, 114th Cong. (as introduced in Senate, February 12, 2015).

113. S. 483, 114th Cong. (as reported to Senate, February 11, 2016).

114. S. 483, 114th Cong. (as engrossed in Senate, March 17, 2016).

115. S. 483, 114th Cong. § 2 (2016) (enacted); 162 CONG. REC. H1618 (daily ed. Apr. 12, 2016) (Ensuring Patient Access and Effective Drug Enforcement Act of 2016).

116. H.R. REP. NO. 114-85, pt. 1, at 2 (2015).

clarifying “rules for enforcement agencies and for providers... by providing certainty with how Federal authorities will apply the law when undertaking enforcement actions, and by increasing the investment that private industry must make to ensure the integrity of the system.”¹¹⁷

The passage of the Act illustrates the kind of regulatory-capture-related pressures associated with prescription opioid legislation. As revealed by investigative journalists at the *Washington Post* and *60 Minutes*, the DEA had been pressuring opioid distribution companies who shipped millions of pills to very small towns and did not fulfill their responsibility to halt and report such suspicious shipments.¹¹⁸ Those distributors donated heavily to politicians, including Congressman Marino, who essentially prevented the DEA from holding them responsible. When this was revealed, the public outcry forced Congressman Marino to withdraw from consideration for serving as President Trump’s Director of the White House Office of National Drug Control Policy. But the fact that he was nominated for such a post in the first place is a tribute to the industry’s political clout.

The Act has had other consequences as well. At oral argument during a D.C. Circuit case against Walgreens,¹¹⁹ the panel appeared to question the legality of the DEA’s suspension of Walgreens’s narcotics shipments from a Florida warehouse in September 2012.¹²⁰ No public written decision ever resulted from the case, however, as an order was filed under seal on April 24, 2013 and the parties stipulated to a dismissal on June 11, 2013.¹²¹ Linden Barber, a former DEA lawyer and executive at Cardinal Health, cited to the *Walgreens* case in arguing about the need for a clearer legal definition of the DEA’s imminent danger standard.¹²²

117. *Id.* at 2-3.

118. *See, e.g.*, Higham & Bernstein, *supra* note 104; Jeff Fager & Martin Baron, *How the DEA’s Efforts to Crack Down on the Opioid Epidemic Were Derailed*, 60 MINUTES (2018), <https://www.cbsnews.com/news/60-minutes-how-the-dea-efforts-to-crack-down-on-the-opioid-epidemic-were-derailed/> [<https://perma.cc/CX7B-UL49>].

119. *See* Transcript of Oral Argument, *Walgreen Co. v. DEA*, (D.C. Cir. 2013) (No. 12-1397).

120. *See* Higham & Bernstein, *supra* note 104; *see also* Erica Telchert, *DC Circ. Blasts DEA Shipping Ban on Walgreen Facility*, LAW360 (Mar. 21, 2013), <https://www.law360.com/articles/426175/dc-circ-blasts-dea-shipping-ban-on-walgreen-facility> [<https://perma.cc/USD6-AWTP>].

121. *See Walgreen Co. v. DEA*, No. 12-1397 (D.C. Cir. 2013), ECF No. 49, 53.

122. Higham & Bernstein, *supra* note 104.

Depending on how the FDA interprets the FDCA, the scope of safety regulation may or may not encompass addiction risk. A “satisficing” strategy may focus safety on simply assessing whether a product incorporates a mechanism to slow down the release of a psychoactive compound affecting the brain, and not on, say, how easy to defeat such a safety mechanism is, or what risk may be associated with addiction that later triggers interest in illicit products such as heroin.

E. Tort Law and Civil Litigation

In March 2019, the State of Oklahoma settled a tort lawsuit against Purdue Pharma and the Sackler family on the eve of trial. The suit targeted Purdue, the Sacklers, and several other defendants for actions associated with the development, promotion, and sale of OxyContin. As part of the \$270 million settlement, some of the defendants agreed to fund a new center for addiction and treatment at Oklahoma State University.¹²³ In May of 2019, Teva Pharmaceuticals also settled with Oklahoma for \$85 million; the state’s case against Johnson & Johnson just resulted in a \$465 million judgment. Earlier in the year, documents released in a Massachusetts lawsuit brought by the state Attorney General revealed how—when evidence of OxyContin abuse mounted in 2001, nineteen years before Oklahoma settled—one of the members of the family that owned Purdue Pharma sought to encourage the company to blame the individuals who were becoming addicted.¹²⁴ These examples highlight why any model of public health policy must account for the continuing relevance of civil lawsuits, and particularly tort remedies, in structuring incentives and generating information shaping the public’s ability to understand how the legal system confronts public health crises. What the lawsuits in Oklahoma, Massachusetts, and other states also reveal—as we explain below—are all the contingencies that model would also need to include given the many delays, procedural constraints, and practical limitations that also characterize the role of civil lawsuits in the political economy of public health law.

123. See Jan Hoffman, *Purdue Pharma and Sacklers Reach \$270 Million in Opioid Lawsuit*, N.Y. TIMES (March 26, 2016), <https://www.nytimes.com/2019/03/26/health/opioids-purdue-pharma-oklahoma.html> [<https://perma.cc/A38C-4FXV>].

124. Barry Meier, *Sacklers Directed Efforts to Mislead Public About OxyContin, Court Filing Claims*, N.Y. TIMES (Jan. 15, 2019), <https://www.nytimes.com/2019/01/15/health/sacklers-purdue-oxycontin-opioids.html> [<https://perma.cc/5PP8-7X6P>].

Tort law forces wrongdoers to compensate victims of harm as defined by common law concepts such as (for negligence) whether a duty exists between the victim and the alleged wrongdoer, whether the duty was breached, and whether the breach proximately harmed the victim. Although tort law appears on its face to concern itself with what recourse individuals have for harms already sustained, its consequences can obviously cause changes in tortfeasors' calculations of the costs and benefits of their actions, resulting in downstream consequences for individuals who might have been victims in the future (and for those who may face higher costs or lower benefits as a result of the tortfeasor internalizing the harm that can lead to liability). The regulatory space also includes entry regulation of pharmaceutical products. Obviously, tort law depends not only on the substantive nature of the claim, but on the incentives for lawyers to represent clients with potential tort cases—and in particular, the rules governing how lawyers may use class actions and other means to aggregate claims.

1. Tort Law: Preliminary Observations

The complaint in *Eastern Band of Cherokee Indians v. Amerisourcebergen Drug Corp.* illustrates some of the legal arguments advanced in the context of multi-district litigation (MDL) targeting opioid manufacturers.¹²⁵

First, the plaintiffs made the case that the manufacturers engaged in false, deceptive, and unfair marketing of opioids. The manufacturers spent an alleged \$14 million on medical journal advertising of opioids in 2011, for example, which is nearly triple of what they spent in 2001.¹²⁶ Advertisements focused on the benefits of opioids for chronic pain. They also promoted the use of opioids through sales representatives, spending “in excess of \$168 million in 2014 alone on detailing branded opioids to doctors, more than twice of what they spent in 2000.”¹²⁷

The complaint also contends that industry leaders have used indirect marketing strategies. The manufacturers indirectly marketed their opioids using “unbranded advertising, paid speakers and ‘key opinion leaders’ (‘KOLs’), and industry-funded organizations.”¹²⁸ One key opinion leader

125. Complaint, *Eastern Band of Cherokee Indians v. Amerisourcebergen Drug Corp.*, No. 1:19-op-45098 (N.D. Ohio, Jan. 4, 2018), ECF No. 1.

126. *Id.* at 26.

127. *Id.*

128. *Id.* at 27.

was heavily funded by the manufacturers and created the Opioid Risk Tool, a five-question, one-minute screening tool relying on patient self-reports which purportedly allowed doctors to predict the risk that their patients will become addicted to or misuse opioids, but was in fact inaccurate in many cases.¹²⁹ Another notable case is presented by the American Pain Foundation (APF), which billed itself as the independent voice of pain patients while it advocated for increased opioid prescribing. APF issued education guides, engaged in a significant multimedia campaign to educate patients about their “right” to pain medications, and launched a campaign to promote opioids for veterans.¹³⁰ When an investigation by ProPublica revealed that nearly ninety percent of APF’s budget came from opioid manufacturers and that its board included many individuals with extensive financial ties with the industry, APF’s credibility was destroyed and it closed its doors soon afterwards.¹³¹

The manufacturers’ marketing scheme misrepresented the risks and benefits of opioids. Janssen, for example, reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as “myth” the claim that opioids are addictive, and asserted as fact that “[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain.”¹³² As another example, Endo distributed a pamphlet entitled *Living with Someone with Chronic Pain*, which stated that “[m]ost healthcare providers who treat people with pain agree that most people do not develop an addiction problem.”¹³³ These claims are contrary to longstanding scientific evidence.¹³⁴ A peer-reviewed, systematic analysis of studies of patients prescribed opioids for chronic back pain concluded that “up to one quarter of patients who are receiving these

129. See *id.* at 32; Lisa R. Witkin et al., *Usefulness of the Opioid Risk Tool to Predict Aberrant Drug-Related Behavior in Patients Receiving Opioids for the Treatment of Chronic Pain*, 9 J. OPIOID MGMT. 177 (2013).

130. See Complaint, *supra* note 125, at 34.

131. See Charles Ornstein & Tracy Webber, *The Champion of Pain Killers*, PRO PUBLICA (Dec. 23, 2011), <https://www.propublica.org/article/the-champion-of-painkillers> [<https://perma.cc/L7JQ-ZHKV>].

132. Complaint, *supra* note 125, at 40.

133. *Id.*

134. See Wilson M. Compton & Nora D. Volkow, *Major Increases in Opioid Analgesic Abuse in the United States: Concerns and Strategies*, 81 DRUG & ALCOHOL DEPENDENCE 103 (2006).

medications exhibit aberrant medication-taking behaviors that may be interpreted as signs of abuse.”¹³⁵

Second, the lawsuits also emphasize how manufacturers and distributors unlawfully distributed opioids. The manufacturers and distributors have a duty under federal and state law to guard against and report unlawful diversion and to report and prevent suspicious orders. The sheer volume of prescription opioids distributed to pharmacies was excessive for the community’s medical need and facially suspicious. In a 2017 agreement between McKesson and the DEA, McKesson admitted that, at various times between 2009 and 2017, it did not identify or report to the DEA certain orders that should have been detected as suspicious.¹³⁶ McKesson was fined \$150 million.¹³⁷

Purdue Pharma and a variety of other companies conducted their business through legitimate and illegitimate means in the form of an association-in-fact enterprise and/or a legal entity enterprise (the “Opioid Diversion Enterprise”). Finding it impossible to legally achieve their sales goals, the Opioid Diversion Enterprise systematically and fraudulently violated their statutory duty to maintain effective controls against diversion of the drugs, to design and operate a system to identify suspicious orders, and to notify the DEA of suspicious orders.¹³⁸ The illegal scheme was allegedly hatched by an association-in-fact enterprise between the manufacturers and the distributors. The scheme enabled the companies to extract billions of dollars in revenue. Underscoring the connection between regulatory strategies and the tort system, the plaintiffs hope to use the DEA’s Automation of Reports and Consolidated Orders Systems (ARCOS) to build cases that distributors knowingly shipped millions of pills to outlets where there was an unreasonable risk of diversion to addicts.¹³⁹

135. Bridget A. Martell et al., *Systematic Review: Opioid Treatment for Chronic Back Pain: Prevalence, Efficacy, and Association with Addiction*, 146 ANNALS OF INTERNAL MED. 116, 123 (2007).

136. *Id.* at 78; see also ADMINISTRATIVE MEMORANDUM OF AGREEMENT BETWEEN THE U.S. DEP’T OF JUSTICE, THE DRUG ENF’T ADMIN., AND THE MCKESSON CORP., DEP’T JUST. (Jan. 17, 2017), <https://www.justice.gov/opa/press-release/file/928476/download> [<https://perma.cc/UP8M-PBH4>].

137. Complaint, *supra* note 125, at 79.

138. *Id.* at 109-40.

139. Daniel Fisher, *Plaintiff Lawyers See Nationwide Settlement as Only End for Opioid Lawsuits*, FORBES: LEGAL NEWSLINE (Mar. 6, 2018), <https://www.forbes.com/sites/legalnewsline/2018/03/06/plaintiff->

Third, plaintiffs and commentators argue that opioid manufacturers and distributors created a public nuisance by lulling prescribing physicians into believing drugs like OxyContin were safe and non-addictive. One article draws parallels to the lead paint litigation in California, where cities argued that paint manufacturers created a “public nuisance” by selling lead paint despite knowing that lead is dangerous.¹⁴⁰

With respect to discerning the defendants’ legal theory of the case, few of the cases against the pharmaceutical companies appear to have advanced to motions for summary judgment. As expected, some defendants have argued that a number of the plaintiffs’ arguments are preempted by federal law and Food and Drug Administration regulations.¹⁴¹ On the public nuisance claims, defendants will argue that opioids were distributed through tightly regulated channels and were prescribed by physicians.¹⁴²

As far as the adequacy of the pleadings, at least one court has dismissed a number of claims against the manufacturers and distributors in a case brought by the City of Chicago. In the Northern District of Illinois, the court dismissed the City’s claims alleging unfair practices, false statements, civil conspiracy, false claims, insurance fraud, recovery of city costs, and unjust enrichment, but upheld its claims for deceptive practices.¹⁴³

Civil liability has spillover effects in related domains. The MDL cases have triggered legal and policy responses that are difficult to envision occurring if litigation had not been commenced. One of the major developments since the creation of the MDL has been an agreement by the federal government to release data. After previously releasing data for manufacturers only for 2012 and 2013, the DEA recently agreed to provide the identities of manufacturers and distributors that sold ninety-five

lawyers-see-nationwide-settlement-as-only-end-for-opioid-lawsuits/
[<https://perma.cc/VZ35-WD7D>].

140. *Id.*

141. *See, e.g., In re Nat’l Prescription Opiate Litigation*, No. 17-2804, 2018 WL 4895856, at *22-27 (N.D. Ohio Oct. 5, 2018) [hereinafter *In re Nat’l Prescription Opiate Litigation Oct.*]; *see also In re Nat’l Prescription Opiate Litigation*, No. 17-2804, 2018 WL 6628898, at *1 (N.D. Ohio Dec. 19, 2018) [hereinafter *In re Nat’l Prescription Opiate Litigation Dec.*] (adopting Report and Recommendation, 2018 WL 4895856, regarding preemption).

142. *See, e.g., In re Nat’l Prescription Opiate Litigation Oct.*, *supra* note 141, at *38; *In re Nat’l Prescription Opiate Litigation Dec.*, *supra* note 141, at *6.

143. *City of Chicago v. Purdue Pharma LP*, 211 F. Supp. 3d 1058 (N.D. Ill. 2016).

percent of opioids in every state from 2006 through 2014.¹⁴⁴ The DEA had previously voiced objections to a broad disclosure of records.¹⁴⁵ The data comes from ARCOS, which receives roughly 80 million reports annually from drug companies about transactions involving controlled substances.¹⁴⁶ Information will include a state-by-state breakdown and will show the “aggregate amount of pills sold and the *market* shares of each manufacturer and distributor.”¹⁴⁷ The DEA has stated it would be willing to apply this opioid sales data to other legal challengers.¹⁴⁸

There are at least two-dozen counties, cities, and towns pursuing lawsuits in state court.¹⁴⁹ There has also been some recent action bringing lawsuits against pharmacy benefit managers (third-party administrators of prescription drug programs for health plans), including Express Scripts, CVSHealth, and OptumRx.¹⁵⁰

2. Tort Law and Civil Litigation: Prospects for a Global Settlement and Comparisons to Tobacco Litigation

The opioid-related multidistrict litigation has also sparked discussions about whether a global settlement could resolve all opioid-related litigation, as occurred with tobacco. One challenge would be figuring out

144. Jeff Overley, *DEA Agrees to Large Data Release in Opioid MDL*, LAW360 (Mar. 5, 2018).

145. In explaining why this data was not used earlier to identify the diversion of opioids, Acting DEA Head Richard Patterson recently suggested at a congressional hearing that it would have been difficult to use ARCOS to flag large amounts of opioid shipments to single pharmacies ten years ago since, pre-2010, data collection was an extremely manual process. See Emily Field, *More Sharing of Opioid Sales Data Possible, DEA Chief Says*, LAW360 (Mar. 20, 2018) <https://www.law360.com/articles/1022074/more-sharing-of-opioid-sales-data-possible-dea-chief-says> [<https://perma.cc/U8W7-MP4F>].

146. Overley, *supra* note 144.

147. *Id.*

148. Field, *supra* note 145.

149. Andrew Joseph, *Why Houston and Other Cities Want Nothing to Do with the Massive National Opioid Lawsuit*, STAT (Mar. 27, 2018), <https://www.statnews.com/2018/03/27/houston-national-opioid-lawsuit/> [<https://perma.cc/H33M-XLQ2>].

150. Casey Ross, *A South Texas County Drags PBMS into Nationwide Lawsuit over Opioids*, STAT (Feb. 26, 2018), <https://www.statnews.com/2018/02/26/texas-pbm-opioid-lawsuit/> [<https://perma.cc/A9HE-PLVW>].

how to spread cash evenly across the country, including to local, state, and federal entities.¹⁵¹ Some of the plaintiff municipalities are represented by plaintiffs' lawyers under contingency-fee contracts.¹⁵² Plaintiffs' lawyers might be more interested in reaching a financial settlement, whereas states might be more interested in injunctive relief, such as reforms in the ways drugs are distributed and more robust systems for preventing diversion.¹⁵³ Amanda Pustilnik points out that unless any settlement imposes enduring incentives on the industry to reduce the incidence of opioid addiction, the likely effect will be that a large check is written and then the industry continues on largely as before. Pending state court litigation—which continues outside of the MDL—also makes it difficult to provide closure in order to reach global peace.¹⁵⁴

Judge Polster seems interested in hammering out a global settlement between parties. He stated at a January hearing that he would like a global settlement that would “do something meaningful to abate this crisis and do it in 2018.”¹⁵⁵ The Justice Department has asked to be allowed to participate in settlement talks—not as a party, but as an amicus with the opportunity to provide information on the opioid crisis and how any potential settlement could be crafted to combat the growing number of overdoses.¹⁵⁶

151. Daniel Fisher, *Plaintiff Lawyers See Nationwide Settlement as Only End for Opioid Lawsuits*, FORBES: LEGAL NEWSLINE (Mar. 6, 2018), <https://www.forbes.com/sites/legalnewsline/2018/03/06/plaintiff-lawyers-see-nationwide-settlement-as-only-end-for-opioid-lawsuits/> [https://perma.cc/AH9G-28MW].

152. *Id.*

153. *Id.*

154. Amanda Pustilnik, *The Law's Response to the Opioid Epidemic: Legal Solutions to a Unique Public Health, Criminal Law, and Market-Related Crisis*, in CONFRONTING OUR NATION'S OPIOID CRISIS 93, 113 (Alan R. Weil & Rachel Dolan eds., Aspen Health Strategy Group, 2017); see also Barry Meier, *Opinion, Opioid makers are the big winners in lawsuit settlements*, N.Y. TIMES (Dec. 26, 2018), <https://www.nytimes.com/2018/12/26/opinion/opioids-lawsuits-purdue-pharma.html> [https://perma.cc/62SN-J532].

155. Fisher, *supra* note 151.

156. Jeff Mordock, *Justice Department Seeks to Join Opioid Settlement Talks*, WASH. TIMES (Apr. 2, 2018), <https://www.washingtontimes.com/news/2018/apr/2/justice-department-seeks-join-opioid-settlement-ta> [https://perma.cc/Q734-L3T7].

The landmark tobacco litigation that played out over decades serves as an interesting case with which to compare and contrast. For most of the twentieth century, the tobacco industry reigned supreme in the marketplace, in the culture, and in politics. No industry returned more per dollar invested over the twentieth century than tobacco; few convinced so much of the public to romanticize their product; and generations of state and federal officials learned to their pain that crossing the industry was usually fruitless at best, perilous at worst.¹⁵⁷ The tobacco industry fought tooth and nail to maintain this situation because, unlike the pharmaceutical industry, it had only one product. The industry therefore regarded any effort to limit the sale or document the harms of tobacco as an existential threat, justifying any tactic and any resource investment. Yet the situation changed in the last third of the century, with the industry becoming loathed by the public, seeing its political capital dwindle, and its profits and practices crimped by laws and lawsuits.¹⁵⁸

How did this change happen, and could something similar happen with opioid manufacturers? At least three factors merit analysis. First, scholars and other researchers pursued major research efforts yielding an enormous body of evidence to rebut the cigarette manufacturers' claims.

157. See generally ROBERT PROCTOR, *GOLDEN HOLOCAUST: ORIGINS OF THE CIGARETTE CATASTROPHE AND THE CASE FOR ABOLITION* (2012).

158. See W. Kip Viscusi & Joni Hersch, *Tobacco Regulation Through Litigation: The Master Settlement Agreement*, in *REGULATION VS. LITIGATION: PERSPECTIVES FROM ECON. AND L. 71* (Daniel P. Kessler ed., 2010); Walter J. Jones & Gerald A. Silvestri, *The Master Settlement Agreement and Its Impact on Tobacco Use 10 Years Later*, 137 *CHEST* 692 (2010); Michael Givel & Stanton A. Glantz, *The "Global Settlement" with the Tobacco Industry: 6 Years Later*, 94 *AM. J. PUB. HEALTH* 218 (2004); see also *15 Years Later, Where Did All the Cigarette Money Go?*, NPR (Oct. 13, 2013), <https://www.npr.org/2013/10/13/233449505/15-years-later-where-did-all-the-cigarette-money-go> [<https://perma.cc/S4AF-UZQG>] (surveying the effects of the Master Settlement Agreement). But see Jennifer Maloney & Saabira Chaudhuri, *Against All Odds, the U.S. Tobacco Industry Is Rolling in Money*, *WALL STREET J.* (Apr. 13, 2017); Jeremy Bulow, *The Tobacco Settlement*, *MILKEN INSTITUTE REV.* 41 (2006); F.A. Sloan et al., *Impacts of the Master Settlement Agreement on the Tobacco Industry*, 13 *TOBACCO CONTROL* 356, 358-59 (2004) ("Overall, from 1999 through 2002, participating manufacturers maintained or improved performance in terms of investor stock returns and profit from domestic tobacco sales. However, these companies lost market share to [subsequent participating manufacturers] and [non-participating manufacturers]. Also, the decline in exports was not anticipated based on incentives of the [Master Settlement Agreement].").

Cigarettes were advertised as healthy and indeed physician-recommended for most of the twentieth century; a 1946 advertising campaign claimed (on slim evidence) that Camels were the favorite cigarette of American doctors.¹⁵⁹ For decades after the 1964 U.S. Surgeon's General report announcing to the country that cigarette smoking was harmful to health, the tobacco industry's spokespeople continued to maintain—even under oath at congressional hearings—that cigarettes were not addictive.¹⁶⁰

Such assertions and others raising related arguments about the relative safety of “light” and “low-tar” cigarettes were undermined by decades of careful scientific work conducted by legions of researchers around the world.¹⁶¹ The findings of these researchers did not languish in obscure journals but were disseminated by advocacy groups and used by lawyers in court.¹⁶²

Second, lawsuits, legislative hearings, and whistleblowers revealed the extent to which the industry had engaged in destructive conduct. A plausible defense against false claims for the industry was that no one knew the risks of smoking. Nonetheless, the release of the Tobacco Papers showed that the industry had indeed long known of the risks and suppressed the evidence.¹⁶³ They had also conducted extensive research on how to make cigarettes more addictive, how to market to children and other vulnerable groups, and how to defeat safety measures and regulatory checks. These revelations put the industry in an indefensible

159. Martha Gardner & Allan Brandt, *The Doctors' Choice is America's Choice: The Physician in US Cigarette Advertisements, 1930–1953*, 96 AM. J. PUB. HEALTH 96, 222-32 (2006).

160. See PROCTOR, *supra* note 157.

161. See, e.g., Schwab v. Philip Morris USA, Inc., 449 F. Supp. 2d 992, 1028-31 (E.D.N.Y. 2006), *rev'd in part sub nom.* McLaughlin v. Am. Tobacco Co., 522 F.3d 215 (2d Cir. 2008); United States v. Philip Morris USA, Inc., 449 F. Supp. 2d 1, 430-561 (D.D.C. 2006); Nadine-Rae Leavell, *The Low Tar Lie*, 8 TOBACCO CONTROL 433, 434 (1999); see also Evans v. Lorillard Tobacco Co., 990 N.E.2d 997, 1014-16 (Mass. 2013) (describing Lorillard's efforts to defeat a products liability suit by arguing that low-tar, low-nicotine cigarettes were not a feasible alternative design because ordinary cigarettes inherently have carcinogenic levels of tar and addictive levels of nicotine).

162. See PROCTOR, *supra* note 157.

163. See STANTON A. GLANTZ ET AL., THE CIGARETTE PAPERS 171-99 (1996). The papers themselves are available through an online repository maintained by the UCSF library at <https://www.industrydocuments.ucsf.edu/tobacco/> [<https://perma.cc/QN9Q-437Q>]. See also Philip Morris USA, Inc., 449 F. Supp. 2d at 34-839 (D.D.C. 2006).

position in court cases. They also destroyed its once-positive image with the public. Wayne McLaren, the iconic Marlboro Man, appearing in anti-smoking ads after he was diagnosed with lung cancer, epitomized the irony at the heart of the tobacco industry's efforts to shape public perceptions over the decades.¹⁶⁴

Third, generational turnover took its toll on the industry, particularly as younger generations were exposed to different norms and practices reflecting changes in public health-policy motivated restrictions on smoking. The exposure of the tobacco industry's conduct certainly changed some minds among those who were alive at the time, but broader changes in attitudes driven by generational turnover also played a part. Americans became more health conscious, which aided some industries (e.g., health clubs, organic food stores) and hurt others (e.g., tobacco).¹⁶⁵ Also, the country came to contain many millions of people who had buried grandparents, parents, uncles, and aunts they had lost to smoking-related illnesses.¹⁶⁶ This created a constituency that was responsive rather than resistant when, for example, legislators imposed high taxes on tobacco and greater restrictions on tobacco advertising.

All three of these factors are present in the example of opioids, and indeed the third should come into play even more quickly because opioid addiction typically does visible harm to the user much faster than does cigarette addiction. Nonetheless, two factors differentiate the cases in ways that may make it more difficult to impose public health-oriented laws on the opioid industry.

First, whereas there is no safe, healthful way to consume a cigarette, opioids are essential medicines that when prescribed judiciously can dramatically relieve human suffering. The explosion of prescribing thus helped at least some patients and continues to do so, even though it also caused widespread addiction and death. This situation spurs the involvement of multiple regulators in the policy debate—with potentially competing priorities in terms of facilitating pain treatment relative to limiting misuse—and dilutes the influence of any one decision maker. The possible benefits of opioids may also create a more ambiguous situation than obtained with respect to tobacco, ambiguities that could cause hesitation in the mind of a disinterested judge, juror, or legislator, and could be exploited in argument by an advocate of the industry.

164. See PROCTOR, *supra* note 157, at 111.

165. *Id.*

166. *Id.*

Second, because cigarettes existed prior to federal consumer protection laws such as the 1906 Pure Food and Drug Act, they were never reviewed and sanctioned for sale in advance by the federal government. In contrast, every pharmaceutical opioid on the market was approved by the Food and Drug Administration. Opioid manufacturers thus may adopt a particular line of defense against lawsuit: How can the government blame us for manufacturing and selling a substance that the government itself verified as safe and effective? In contrast, this is not a line of reasoning that could be used by distribution companies that knowingly shipped huge numbers of opioids to addiction hotspots and failed to intervene in or even report such deliveries. The conduct of these distribution companies was not approved in advance by the federal government and indeed violates the spirit and probably the letter of relevant federal law.

Decades after the legal and political landscape changed for the industry, tobacco still kills over 450,000 Americans a year and seven million worldwide. Even as the tobacco industry has been forced to live with new domestic regulatory constraints, the industry has reacted to tightened regulation in developed countries by expanding activities in developing nations, much as the opioid industry has begun to do.¹⁶⁷ Thus even if a similar revolution in regulation occurred for prescription opioids as has for tobacco, the best scenario is a lessened death toll rather than an eliminated one.

Both the tobacco and opioid cases underscore how substantive and procedural content of law plainly matters, but how that substantive law is implemented, enforced, and adapted to changing circumstances also matters. By turning our attention to those issues, we begin to see a more complicated picture, where policy goals must be translated into specific criminal and regulatory enforcement strategies, and where tort law and its implementation must strike a balance between addressing a sprawling array of potentially valid claims and administrative feasibility.

3. Challenges and Constraints Affecting Civil Litigation in the Opioid Context

Tort law is premised on the prospect that individuals and organizations anticipating liability will have reason to alter their behavior—for example, by internalizing the costs associated with a product or activity that society would bear alone absent the imposition of tort liability on the entity. At least some of the arguments advocates

167. Humphreys, *supra* note 1.

advanced in the tobacco context underscored this premise. And indeed, some commentators suggest that present and prospective opioid-related litigation has begun to affect the behavior of pharmaceutical companies and other market participants. Litigation may contribute to the reduced prescribing of opioids and self-imposed marketing limitations by the major manufacturers.¹⁶⁸ Distributors may become increasingly concerned about their potential liability due to their role in exacerbating opioid abuse.¹⁶⁹

Nonetheless, civil litigation often faces a host of constraints as a means of addressing public health challenges.¹⁷⁰ Some of these challenges bedevil complex tort suits across a variety of substantive domains, including familiar and sometimes understandable limitations on class action certification, arbitration clauses, and contending claims from experts that are difficult to disentangle. Tort suits involving pharmaceutical products pose even further challenges.

One complexity in the opioid context is the highly regulated nature of the drug industry. Unlike cigarettes at the time of the tobacco litigation, for instance, opioids are regulated by the FDA.¹⁷¹ Judges and juries may defer to the agency's approval of the opioid products as safe and effective for treating pain and the drugs' warning labels that disclose addiction-related

168. Abbe R. Gluck et al., *Civil Litigation and the Opioid Epidemic: The Role of Courts in a National Health Crisis*, 46 J.L., MED. & ETHICS 351, 352 (2018) (discussing reduced prescriptions and Purdue Pharma's decision to cease marketing OxyContin to doctors).

169. *Id.* at 354.

170. *See, e.g.*, David Marcus, *The Short Life and Long Afterlife of the Mass Tort Class Action*, 165 U. PA. L. REV. 1565, 1572-75, 1592-97 (2017) (describing early challenges in certifying high profile mass tort class actions and increase of settlement activity following appellate courts' policing of class certification); Myriam Gilles, *The Day Doctrine Died: Private Arbitration and the End of Law*, 2016 U. ILL. L. REV. 371 (2016); Paul S. Miller & Bert W. Rein, *Whither Daubert? Reliable Resolution of Scientifically-Based Causality Issues in Toxic Tort Cases*, 50 RUTGERS L. REV. 563, 565-67 (1998) (discussing liability for toxic substance exposure theories and challenges that arise in judges' decisions on the admissibility of scientific evidence).

171. Nate Raymond, *U.S. State, Local Government Lawsuits Over Opioids Face Uphill Battle*, REUTERS (June 2, 2017), <https://www.reuters.com/article/us-ohio-opioids-lawsuit-analysis/u-s-state-local-government-lawsuits-over-opioids-face-uphill-battle-idUSKBN18T1H4> [<https://perma.cc/AGK2-TTCK>].

risks.¹⁷² As a general matter, an entity's compliance with federal laws or regulation provides a complete defense to liability, where federal law is held to preempt state law. In other settings, compliance with federal law is merely admissible but not conclusive (since at common law, compliance with the law does not provide a defense to negligence).¹⁷³ Some states have explicitly made evidence of compliance admissible, and at least one state—Oregon—has gone further by eliminating punitive damages where prescription drugs comply with FDA regulations.¹⁷⁴

In the many civil liability settings where regulatory compliance is considered at least admissible, compliance is most relevant in cases proceeding under the somewhat novel theory of design defect.¹⁷⁵ In one such case, the court held that, under such a theory that the drug was not effective for any class of patients, plaintiffs had a heavy burden to prove “an articulable basis for disregarding the FDA’s determination that the drug should be available.”¹⁷⁶ By contrast, in another case where the defective design theory turned on “whether an ordinarily prudent manufacturer, being fully aware of the risks, would have placed the product on the market,” the court, in upholding a verdict for plaintiffs, discussed the basis for disregarding the FDA’s finding of efficacy.¹⁷⁷

Early suits alleging design defects or failure to warn generally foundered on defenses of FDA approval, despite the possibility that arguably adequate warnings to prescribers may not have been conveyed

172. A host of scholarship addresses the relevance of regulatory compliance in tort actions, especially in the 1990s around the Third Restatement. Mark A. Geistfeld, *Tort Law in the Age of Statutes*, 99 IOWA L. REV. 957 (2014), provides a useful summary. See also Carl Tobias, *FDA Regulatory Compliance Reconsidered*, 93 CORNELL L. REV. 1003 (2008); Robert L. Rabin, Keynote Paper, *Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049 (2000); and Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. MICH. J.L. REFORM 461 (1997).

173. See Dan B. Dobbs et al., *THE LAW OF TORTS* § 474 (2d updated ed. 2018).

174. See Or. Rev. Stats. § 30.927 (2015).

175. For the traditional disfavoring of design defect claims related to prescription drugs, see RESTATEMENT (THIRD) OF THE LAW OF TORTS: PRODUCT LIABILITY § 6 (AM. LAW INST. 1998); see also *Shanks v. Upjohn Co.*, 835 P.2d 1189 (Alaska 1992).

176. *Williams v. Ciba-Geigy Corp.*, 686 F. Supp. 573, 577 (W.D. La. 1988).

177. *Tobin v. Astra Pharmaceutical Prods., Inc.* 993 F.2d 528, 536, 537-40 (6th Cir. 1993).

to patients.¹⁷⁸ In fact, holding drug makers responsible was difficult on any viable theory of liability where “the prescriber’s decisions and the patient’s behavior contributed to the harm” or where “[s]ome individuals [did] not take opioids as prescribed or purchase them illegally.”¹⁷⁹ These early suits also faced difficulties in obtaining class certification, thus avoiding defenses based on individual conduct, but with changing social attitudes it may be easier to establish the necessary elements, as in the case of the Neonatal Abstinence Syndrome classes.¹⁸⁰ Although claims of public nuisance and lax monitoring brought by state and local governments may avoid the problems of unsympathetic plaintiffs and challenges of the earlier strategies, claims of deceptive business practices may be difficult to prove without whistleblower evidence such as was available in the tobacco litigation.¹⁸¹ Plaintiffs have attempted to fill that void with information that has emerged in prior settlements, government investigations, investigative reporting, and continuing marketing practices.¹⁸² Unjust enrichment claims may be hard to make out where courts insist on a showing that the state or municipality conferred a direct benefit on the company, but public insurance payments contributing to company profits may help make out the claim.¹⁸³

What’s more, the range of defendants targeted in the more recent litigation may threaten to confuse the chain of causation and undermine plaintiffs’ ability to hold anyone responsible. Criminal distributors are plausible intervening actors in claims against both manufacturers and distributors.¹⁸⁴ As the use of interrogatories in tobacco and some opioid litigation suggests, defendants may also try to argue that no one

178. R.L. Haffajee & M.M. Mello, *Drug Companies’ Liability for the Opioid Epidemic*, 377 N. ENGL. J. MED. 2301, 2301 (2017).

179. *Id.*

180. *Id.* at 2304; *see also* Robert L. Rabin, *The Third Wave of Tobacco Tort Litigation*, in *REGULATING TOBACCO* 176, 179-83 (Stephen D. Sugarman ed., 2001) (discussing the importance of class aggregation in the successful litigation of the 1990s, especially in the wake of the Supreme Court’s decision on preemption of failure to warn claims).

181. Haffajee & Mello, *supra* note 178, at 2304.

182. *Id.* at 2305; *see also* First Amended Complaint, *Massachusetts v. Purdue Pharma L.P.*, No. 1884-1808 (Mass. Sup. Ct. Jan. 31, 2019), <https://bit.ly/2GRLkjin> [<https://perma.cc/LWL4-EAE4>].

183. Haffajee & Mello, *supra* note 178, at 2305.

184. *See* Gluck et al., *supra* note 168, at 357.

distributor is aware of what other distributors are doing and that plaintiffs cannot show that any particular distributor's product was diverted into the black market.¹⁸⁵ The multiplicity of defendants highlights a crucial difference from the tobacco litigation—there are many more links in the chain in the case of opioids as compared with tobacco companies where the same company would produce, distribute, and market the product.¹⁸⁶

In addition, although plaintiffs in the federal MDL have so far managed to survive preemption claims, the pharmaceutical manufacturers seem likely to continue to assert them and, whatever success they have in trial courts, may continue to press these arguments before appellate courts.

A final complexity may arise from parallel civil and criminal proceedings, which can complicate tort actions and civil regulatory enforcement. Such situations arise not infrequently in white collar criminal enforcement, such as in investigations of suspected violations of securities law. Such proceedings raise a variety of concerns, particularly in relation to the use of materials obtained through discovery in one proceeding and used in connection with the other. Civil defendants, for instance, may be able to bolster their criminal case against the government through civil discovery, while the government's use of civil discovery materials in criminal proceedings may raise self-incrimination issues under the Fifth Amendment. No formal or pervasively-followed informal rules structure precisely how courts should proceed. In the past, the lack of agreement sometimes led to courts attempting to issue injunctions against other courts.¹⁸⁷ In recent years, some courts have resolved potential problems by staying proceedings, usually the civil proceedings, on the motion of the parties.¹⁸⁸ Where courts perceive a stay motion to be excessively strategic, especially on the part of the government, they may deny the motion.¹⁸⁹

185. *Id.*

186. *See id.* at 358.

187. *See Note, Concurrent Civil and Criminal Proceedings*, 67 COLUM. L. REV. 1277 (1967).

188. Judge Milton Pollack helpfully summarized some of the factors to be considered in ruling on such stay motions. Milton Pollack, *Parallel Civil and Criminal Proceedings*, 129 F.R.D. 201 (1990); *see also* *State ex rel. Stovall v. Meneley*, 22 P.3d 124, 136-37 (Kan. 2001) (discussing federal and state precedents for issuing stays in civil trials during the pendency of parallel criminal proceedings).

189. *See SEC v. Saad*, 229 F.R.D. 90 (S.D.N.Y. 2005). Courts may be willing to impose protective orders in civil proceedings, but here too decisions seem to

F. Cases Against Purdue Pharma and Drug Distributors: Examples of Criminal and Regulatory Enforcement, Legal Remedies, and Constraints

The treatment of Purdue Pharma and drug distributors offers an illustration of both the delayed nature of enforcement in the opioid context as well as the interplay of procedural and substantive constraints affecting criminal and civil liability. If these developments showcase how criminal enforcement and civil liability have been a slow-moving, uncertain process in this context, they also underscore the interplay between litigation and public awareness, particularly given how litigation can result in the release of information concerning the economic context and organizational choices affecting the opioid crisis or spur legislative investigations. Because of the relatively slow nature of much of the civil litigation and criminal enforcement response in this domain, the dilution of the more conventional regulatory response given resistance to legislative and regulatory action has almost certainly had even more pronounced consequences.

1. Purdue Pharma

In the late 1990s, Purdue Pharma argued that OxyContin, because of its time-release formulation, posed a lower threat of misuse and addiction to patients than traditional painkillers like Percocet or Vicodin.¹⁹⁰ Purdue Pharma heavily promoted OxyContin, particularly to primary care doctors, who typically have little training in the treatment of serious pain or in recognizing signs of addiction in patients.¹⁹¹ The extraordinary amount of money spent promoting OxyContin was unprecedented: during its first six years on the market, Purdue spent approximately six-to-twelve times more on promoting it than did the two other competing manufacturers on

be made on a case-by-case basis. *Compare* *Minpeco S.A. v. Conticommodity Services, Inc.*, 832 F.2d 739 (2d Cir. 1987) (finding protective order appropriate), *with* *In re Grand Jury Subpoena*, 62 F.3d 1222 (9th Cir. 1995) (holding that grand jury subpoena takes precedence over protective order for civil discovery).

190. See Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 AM. J. PUB. HEALTH 221, 221-23 (2009), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/pdf/221.pdf> [<https://perma.cc/FUM6-7X39>].

191. *Id.* at 222.

their sustained-release opioids.¹⁹² By 2001, OxyContin was the most frequently prescribed brand-name opioid in the United States for treating moderate-to-severe pain.¹⁹³

In 2007, Purdue Pharma paid \$600 million in fines and other payments to resolve criminal and civil charges related to the “misbranding” of the narcotic painkiller OxyContin.¹⁹⁴ Three current and former executives of Purdue Pharma also pleaded guilty to criminal charges that they misled regulators, doctors, and patients about the drug’s risk of addiction and its potential to be abused.¹⁹⁵ Their pleas covered conduct from late 1995, when OxyContin received FDA approval, to mid-2001, when Purdue Pharma dropped its initial marketing claims for the drug.¹⁹⁶ The executives agreed to pay a total of \$34.5 million in fines.¹⁹⁷ If the executives had trafficked \$3,000 worth of heroin, they would have faced a mandatory five-year federal prison sentence, but their role in generating an estimated \$30 billion in revenue from OxyContin did not result in them spending even a single day behind bars.

After the 2007 fine, Purdue funded some diversion prevention programs, such as those to prevent pharmacy robberies or to prevent other family members from stealing relatives’ pills.¹⁹⁸ The company eventually rolled out a tamper-resistant version of the painkiller that was somewhat harder to crush and snort, but Purdue apparently failed to address the problem of the drug wearing off early.¹⁹⁹ An investigation by the *Los Angeles Times* found that Purdue representatives had discovered that doctors were prescribing more frequent doses of OxyContin; these concerns came in tension with the heavy emphasis on sales and lucrative

192. *Id.* at 225.

193. *Id.*

194. See Barry Meier, *In Guilty Plea, OxyContin Maker to Pay \$600 Million*, N.Y. TIMES (May 10, 2007), <http://www.nytimes.com/2007/05/10/business/11drug-web.html> [<https://perma.cc/S6TC-PE53>].

195. *Id.*

196. *Id.*

197. *Id.*

198. Harriet Ryan et al., *‘You Want a Description of Hell?’: OxyContin’s 12-Hour Problem*, L.A. TIMES (May 5, 2016), <http://www.latimes.com/projects/oxycontin-part1/> [<https://perma.cc/DY9F-P4WT>].

199. *Id.*

bonuses available to pharmaceutical sales representatives who could convince doctors to write prescriptions for higher dosage strength.²⁰⁰

These practices garnered attention from potential plaintiffs and their lawyers. Following the 2007 enforcement action, plaintiffs filed a number of separate lawsuits against Purdue Pharma (and its owners, the Sackler family) and other pharmaceutical companies alleging that the companies spent millions on marketing that trivialized the risks of opioids, and lobbied doctors to influence their opinions.²⁰¹ These lawsuits include, among others, actions by attorneys general in Ohio, Illinois, and Mississippi; actions by four counties in New York; and actions by Santa Clara and Orange Counties in California.²⁰²

The Massachusetts Attorney General, for example, has alleged that Purdue Pharma retained McKinsey & Co., which advised the company how to increase sales, how to counter drug enforcement efforts to reduce opioid use, and how to counter emotional messages from mothers with teenagers that overdosed on the drug.²⁰³ The complaint details further efforts to ward off criticism as more attention focused on opioid abuse. According to the complaint, the Sacklers and Purdue attempted to push the media narrative that misuse, not addiction, was the cause of the terrible consequences of opioid profusion; that people who misused opioids, rather than the producers, were the problem—they were “junkies” and “criminals.”²⁰⁴ When those tactics failed, the Sacklers tried to portray themselves as not actively involved in Purdue’s operations and

200. *See id.*

201. *See* Alana Semuels, *Are Pharmaceutical Companies to Blame for the Opioid Epidemic?*, ATLANTIC (June 2, 2017), <https://www.theatlantic.com/business/archive/2017/06/lawsuit-pharmaceutical-companies-opioids/529020/> [<https://perma.cc/V9QV-2NRP>].

202. *Id.*

203. *See* First Amended Complaint, *supra* note 182. As to the last, the Massachusetts complaint alleges that Craig Landau, the Chief Medical Officer and then CEO, developed a strategy to position extended-release and long-acting opioids as safer than immediate release opioids; and to identify pain patients to imply the extended-release technology was more effective even though he knew that it was no more effective and that abuse of oxycodone was worse than comparable pain medications. *Id.* ¶¶ 799-802. Landau also oversaw a marketing campaign for a purportedly abuse-deterrent formulation he knew would have no such effect and that was in fact expected to have a “balloon effect” on the market for Purdue’s products. *Id.* ¶¶ 806-07.

204. *Id.* ¶¶ 38-48

management, despite employee trepidation about such boldfaced lies.²⁰⁵ The Sacklers also sought to expand their business and improve their image by purchasing a company that treated opioid addiction.²⁰⁶

Although some of the aforementioned enforcement actions and recent lawsuits appear to have had an impact, litigation against the pharmaceutical company has also faced a variety of constraints arising from the nature of the procedures and substantive provisions at issue. Purdue has attempted to ward off suits by indicating that they may seek bankruptcy protection and subsequently made a settlement offer which the plaintiffs are debating internally as of this writing. It is hardly surprising that a company in Purdue's position may be eager to settle if they can do so reasonably. The Massachusetts complaint further alleges that Craig Landau ascended to the CEO position by pitching a strategy of managing the company's loss of R&D capacity and loss of credibility with the FDA by doubling down on its focus on opioids and attempting to dominate that market as other participants fled in the face of bad publicity.²⁰⁷ In recent public statements, Landau has indicated that the company may seek bankruptcy protection, "depend[ing] on what unfolds in the weeks and months ahead," apparently referencing pending trials.²⁰⁸

In earlier litigation, plaintiffs have had difficulties establishing a causal connection between pharmaceutical company practices and injuries to plaintiff states or municipalities. In *Koenig v. Purdue Pharma Co.*, 435 F. Supp. 2d 551 (N.D. Tex. 2006), for example, the court held that the plaintiff had not established that his addiction and adverse health consequences

205. *Id.* ¶¶ 476-77, 480-481.

206. *Id.* ¶ 482.

207. *Id.* ¶¶ 817-820.

208. Katie Zezima, *Purdue Pharma CEO Says Bankruptcy Is 'An Option' as Company Faces Opioid Lawsuits*, WASH. POST (Mar. 13, 2019), <https://wapo.st/2PxQaVz> [<https://perma.cc/4R49-RDGV>]. After the Sacklers and Purdue Pharma avoided a trial in the suit brought by Oklahoma, settling for \$270 million, Mary Jo White, who is representing members of the Sackler family, suggested that while the family and Purdue believed that the litigation was unfounded, they were interested in a global settlement. See Alison Frankel, *Purdue's Sackler Family Wants Global Opioids Settlement: Sackler Lawyer Mary Jo White*, REUTERS (Apr. 22, 2019), <https://reut.rs/2IluZiQ> [<https://perma.cc/L8RH-T5TL>]; Lenny Bernstein & Katie Zezima, *Purdue Pharma, State of Oklahoma Reach Settlement in Landmark Opioid Lawsuit*, WASH. POST (Mar. 26, 2019), <https://wapo.st/2DATiLr> [<https://perma.cc/BM2Q-JKFH>].

were causally related to Purdue's and its partners' marketing practices. Purdue has also regularly been able to defeat class certification.²⁰⁹

Purdue Pharma has also sometimes been able to avail itself of defenses involving individual plaintiffs' wrongful conduct—a defense neutralized in lawsuits from states and cities. Where plaintiffs crushed oxycontin pills and eliminated the time-release function, for example, and where plaintiffs procured pills through illegal means, some courts have found plaintiffs were barred from recovery.²¹⁰ Where plaintiffs have attempted to allege design-defect claims based on the ease of bypassing the time-release mechanism by crushing pills, Purdue has been able to raise a misuse or alteration defense.²¹¹ And similarly, where plaintiffs have brought failure to warn claims, courts have found that inserts indicating that crushing OxyContin could yield a deadly dose and that it could be addictive and a target for drug abusers and addicts were sufficient to insulate Purdue, under comment *k* to Restatement; (Second) of Torts, § 402A, from strict liability because the product was unavoidably unsafe.²¹² The probability that Kentucky would adopt the learned intermediary rule was also held to insulate Purdue in that case.²¹³ In cases bringing implied warranty of

209. *See* Campbell v. Purdue Pharma L.P., No. 02-163, 2004 WL 5840206 (E.D. Mo. 2004) (commonality, typicality, adequacy); Harris v. Purdue Pharma L.P., 218 F.R.D. 590 (S.D. Ohio 2003) (commonality); Wethington v. Purdue Pharma L.P., 218 F.R.D. 577 (S.D. Ohio 2003) (commonality); Gevedon v. Purdue Pharma, 212 F.R.D. 338 (E.D. Ky. 2002) (commonality, typicality, adequacy). Courts have also held that the amount in controversy is determined by aggregating class members claims, thus making it more difficult to keep class actions in state court. *See* DaWalt v. Purdue Pharma L.P., 397 F.3d 392 (6th Cir. 2005) (holding that the class satisfied the amount-in-controversy requirement for diversity jurisdiction but that appellate court lacked jurisdiction to review the decision to remand to state court).

210. *See* Price v. Purdue Pharma Co., 920 So. 2d 479 (Miss. 2006); Foister v. Purdue Pharma L.P., 295 F. Supp. 2d 693, 705 (E.D. Ky. 2003); *see also* Labzda v. Purdue Pharma L.P., 292 F. Supp. 2d 1346 (S.D. Fla. 2003).

211. *See* Richard C. Ausness, *The Role of Litigation in the Fight Against Prescription Drug Abuse*, 116 W. VA. L. REV. 1117, 1124 (2014) (citing *Labzda*, 292 F. Supp. 2d at 1356).

212. *Foister*, 295 F. Supp. 2d at 705-07.

213. *Id.* at 706; *see also* *Labzda*, 292 F. Supp. 2d at 1353-55 (holding that Purdue did not have a duty to control overprescribing or report overprescribing physician to authorities).

merchantability claims, Purdue has sometimes been able to successfully argue that the statute of limitations had run.²¹⁴

In many of the cases brought by state attorneys general, Purdue has also managed to settle for comparatively small amounts.²¹⁵ In other cases, litigation over removal to federal court (whether based on the *Grable* standard or CAFA) and consolidation in an MDL has dragged on for years.²¹⁶

2. Drug Distributors

The main civil claim brought against distributors has been that they negligently, knowingly, and recklessly continued to distribute drugs to third parties, despite their knowledge that the drugs would be used for diversion rather than legitimate medical needs.²¹⁷ The claim includes allegations that the distributors failed to satisfy their obligations under the Controlled Substances Act (“CSA”) and its implementing regulations to monitor and report suspicious opioid orders.²¹⁸ In particular, the claim alleges that distributors failed to investigate suspicious orders, document the result of the investigation, and halt the sale if not reasonably satisfied it was for legitimate sale by the retail end user.²¹⁹ The specific causes of action in the Massachusetts cases, for instance, include public nuisance, common-law fraud, negligent misrepresentation, negligence, violation of General Laws c. 93A, § 11 (unfair business practices), unjust enrichment,

214. See *Franz v. Purdue Pharma Co.*, No. 05-201, 2006 WL 455998 (D.N.H. 2006); *Freund v. Purdue Pharma Co.*, No. 04-611, 2006 WL 482382 (E.D. Wis. 2006).

215. See Ausness, *supra* note 211, at 1149, 1156; Joseph B. Prater, *West Virginia’s Painful Settlement: How the Oxycontin Phenomenon and Unconventional Theories of Tort Liability May Make Pharmaceutical Companies Liable for Black Markets*, 100 NW. U. L. REV. 1409, 1433-35 (2006); see also Abbe R. Gluck et al., *Civil Litigation and the Opioid Epidemic: The Role of Courts in a National Health Crisis*, 46 J.L., MED. & ETHICS 351, 353-54 (2018).

216. Ausness, *supra* note 211, at 1149-56.

217. See, e.g., Order Granting Motion to Remand and Denying Motion to Stay at 3, *City of Worcester v. Purdue Pharma, L.P.*, No. 18-119858 (D. Mass. Nov. 21, 2018), ECF No. 36.

218. See 21 C.F.R. § 1301.71(a); *Masters Pharm., Inc. v. DEA*, 861 F.3d 206, 212-13 (D.C. Cir. 2017).

219. *Id.*

and civil conspiracy.²²⁰ New York State's recent supplemented complaint also alleges violations of a state finance law.

Based on the claims brought against the distributors, it is possible that the Department of Justice's large settlement with McKesson for CSA violations in early 2017, coupled with the D.C. Circuit's ruling a few months later on the force of amended reporting regulations, alerted state and local plaintiffs to the possibility of using regulatory compliance as a basis for pursuing negligence actions.²²¹ The D.C. Circuit's ruling was an indication that there was firm legal ground for claims against the distributors. The DOJ settlement was a reminder that McKesson and other distributors have very deep pockets and the resources to satisfy settlements or judgments after Purdue, or other manufacturers whose revenue was more closely tied to opioids, are depleted of resources.²²²

220. First Amended Complaint, *supra* note 182.

Under Massachusetts law, either of two possible causes of action may be called "civil conspiracy." *First*. There is precedent supporting a very limited cause of action in Massachusetts for "civil conspiracy" of a coercive type. In order to state a claim of [this type of] civil conspiracy, plaintiff must allege that defendants, acting in unison, had some peculiar power of coercion over plaintiff that they would not have had if they had been acting independently. . . . Th[e] second type of civil conspiracy is more akin to a theory of common law joint liability in tort. It is explicitly recognized in Massachusetts law.

Aetna Cas. Sur. Co. v. P & B Autobody, 43 F.3d 1546, 1563-64 (1st Cir. 1994) (internal quotations and citations omitted).

221. *See* *Masters Pharmaceutical, Inc. v. DEA*, 861 F.3d 206, 212-13 (D.C. Cir. 2017); Office of Public Affairs, *McKesson Agrees to Pay Record \$150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs*, U.S. DEP'T JUST. (Jan. 17, 2017), <https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders> [<https://perma.cc/SCV7-M58U>]; States had earlier settled claims against the distributors for state law violations. *See* Scott Higham & Lenny Bernstein, *Opioid Distributors Sued by West Virginia Counties Hit By Drug Crisis*, WASH. POST. (Mar. 9, 2017), https://www.washingtonpost.com/national/health-science/lawsuits-filed-against-drug-distributors-in-west-virginia/2017/03/09/f9e3165e-0501-11e7-b1e9-a05d3c21f7cf_story.html [<https://perma.cc/VVX5-R2JY>] (citing Charleston Gazette-Mail's reporting that between 2007 and 2012 distributors shipped 780 million doses of opioids to West Virginia, a state with a population of less than 2 million people).

222. Purdue Pharma was already in a weak market position as of 2017 and indicated that it may seek bankruptcy protection.

The details of how multi-district litigation is managed can play an important role. The drug companies and distributors were uniformly unsuccessful in removing and consolidating with the MDL the actions brought by Massachusetts towns.²²³ The crucial point was that Massachusetts law does not allow proof of per se negligence but only considers a statutory violation as evidence going to negligence, and so alleged violations of the Controlled Substances Act and implementing regulations did not provide a basis for federal court jurisdiction over state-law causes of action.²²⁴ Ultimately, the Massachusetts municipality plaintiffs were able to keep their claims in state court, but they will possibly bear a heavier burden of proof in establishing negligence. Defendants have also attempted to get cases removed under CAFA.²²⁵

Another possibility is that plaintiffs are concerned about statute of limitations issues. Plaintiffs have argued that the distributors are equitably estopped from asserting statute of limitations and laches defenses because they undertook efforts to purposefully conceal their unlawful conduct.²²⁶

Some of the cases against the distributors depend on showing that the distributors should have known better in light of the information they had when they were intensely involved in distributing opioids. The New York Attorney General’s complaint, referenced below, presents extensive evidence to this effect, but also indicates that gathering that evidence must have been quite difficult, as suggested by the volume and detail of the evidence and the redactions in the New York complaint. The redactions, in particular, suggest the resource-intensive nature of law enforcement activity necessary to gather this information. Only in 2019 did a federal prosecutor—in this case, the U.S. Attorney’s Office for the Southern District of New York—bring a federal civil action against the Rochester Drug Co-operative (“RDC”) for failure to comply with its legal duty to

223. *See, e.g.*, Order, *Town of Canton v. Purdue Pharma, L.P.*, No. 19-10167 (D. Mass. Feb. 7, 2019), ECF No. 7.

224. *See* Order Granting Motion to Remand and Denying Motion to Stay at 6-8, *City of Worcester v. Purdue Pharma, L.P.*, No. 18-11958 (D. Mass. Nov. 21, 2018), ECF No. 36.

225. *See* Notice of Removal, *Town of Randolph v. Purdue Pharma L.P.*, No. 19-10813 (D. Mass. Apr. 22, 2019), ECF No. 1; *see also* discussion of Purdue’s response to earlier state suits *infra*.

226. *See* Complaint, *Town of Randolph v. Purdue Pharma L.P.*, No. 19-0400 (Mass. Sup. Ct., Norfolk Dep’t Mar. 27, 2019), ECF No. 1.

report suspicious orders of controlled substances to the DEA.²²⁷ The complaint alleges, among other charges, a violation of 21 U.S.C. § 842(a)(5) and 21 C.F.R. § 1301.74(b) and likewise points to the CSA's implementing regulations as a basis for the action.²²⁸

Meanwhile, in congressional hearings in the spring of 2019, most of the executives of the distribution companies sought to disclaim any responsibility for the opioid epidemic.²²⁹ The executive chairman of Cardinal Health, by contrast, attempted to simultaneously take and downplay responsibility, suggesting that its role simply amounted to imprudent involvement with two West Virginia pharmacies.²³⁰ Cardinal Health sent 10.5 million pills to one pharmacy over an eight-year period,²³¹ and, along with McKesson, sent 12.3 million doses to another pharmacy over the same period.²³²

In addition, in *Masters Pharmaceutical*, a distributor facing the prospect of losing its certification to distribute controlled substances sought to argue that the decision that Masters failed to comply with the suspicious orders management system imposed by settlement effectively amended existing DEA rules in violation of the APA.²³³ More specifically, Masters argued that where a rule is established through notice and

227. Complaint, *United States v. Rochester Drug Co-operative, Inc.*, No. 19-3568 (S.D.N.Y. Apr. 23, 2019), ECF No. 1.

228. See 21 C.F.R. § 1301.71ff. Other charges include conspiracy to distribute controlled substances outside the scope of professional practice, 21 U.S.C. § 846 to violate 21 U.S.C. § 841(a)(1); conspiracy to defraud the United States in connection with the regulatory violations, 18 U.S.C. § 371; and failure to file suspicious order reports, 21 U.S.C. §§ 842(a)(5) and (c)(2)(A), as well as forfeiture allegations. Information, *United States v. Rochester Drug Co-operative*, No. 19-290 (S.D.N.Y. Apr. 23, 2019), ECF No. 2.

229. Katie Zezima & Scott Higham, *Drug Executives Express Regret over Opioid Crisis, One Tells Congress His Company Contributed to the Epidemic*, WASH. POST. (May 8, 2018), <https://wapo.st/2LmZIV5> [<https://perma.cc/H5WK-JQW3>].

230. *Id.*

231. *Id.*

232. Lenny Bernstein & Katie Zezima, *One Small Town, Two Drug Companies and 12.3 Million Doses of Opioids*, WASH. POST (Feb. 15, 2018), <https://wapo.st/2VwA1Fh> [<https://perma.cc/YE7K-FB6T>].

233. *Masters Pharmaceutical, Inc. v. DEA*, 861 F.3d 206, 219 (D.C. Cir. 2017).

comment, it cannot be amended in an adjudication, and the DEA's decision revoking its certification amounted to amending two such rules.²³⁴

3. The Role of Criminal Cases and Civil Litigation in Addressing Misuse of Licit Drugs: Preliminary Observations

It seems quite plausible that criminal cases and civil lawsuits are playing some part in addressing the opioid crisis, particularly by contributing to settlements that sometimes meaningfully change marketing practices; spurring public attention; providing for the release of documents showing how the epidemic unfolded; and, to some extent, exposing key individuals to the prospect of liability they would prefer to avoid. Yet these criminal and civil actions have also coexisted with relatively diluted regulatory governance: civil litigation and white-collar criminal cases are often slow and somewhat uncertain even when key stakeholders clamor for a vigorous response to a crisis. In this context, both civil and criminal responses are to some extent dependent on the regulatory mechanisms like prescription monitoring that have been routinely constrained by interest group pressures. On the criminal side, the investigations and prosecutions were initially slow to get started. Moreover, the conduct targeted is understandably subject to many defenses, particularly because opioids have some legitimate uses. As a result, unlike the penal provisions that apply to substances such as heroin or cocaine, the penal provisions relevant to opioids do not use the mere fact of possession or intent to distribute as a basis for concluding that the defendant is engaged in socially damaging conduct that deserves a severe punishment. On the civil side, the remedies are far more *ex post* relative to measures directly seeking to regulate distribution. In addition, the contingencies of civil litigation, including aspects such as class certification and allegedly contributory conduct from those affected by opioids, complicate recovery. Thus, criminal and civil liability, however delayed or contingent, appear to have begun to shape the policy narrative in ways that may contribute to less diluted regulatory governance over time.

234. *Id.* at 219-20 (holding that there was no need to consider the Administrator's statutory authority because the decision neither created nor imposed any new duties).

IV. DILUTED REGULATORY GOVERNANCE: OPIOIDS AND THE POLITICAL ECONOMY OF PUBLIC HEALTH REGULATION

Compare the publicly conveyed level of concern among policymakers and civil society organizations with the various challenges and limitations associated with the use of the different available legal tools—from prescription monitoring to prosecutions to class actions—to address opioid abuse. The juxtaposition is jarring: virtually every legal mechanism is difficult to use in practice and, in many cases, delayed in effect for years. In addition, these mechanisms are often replete with limitations that have either persisted despite broad public concern, or, in some cases, have been deliberately developed because of political, economic, or bureaucratic agendas, to limit the success and extent of enforcement and civil remedies.

To resolve the puzzle of why nominal government control of a product failed to stem stark increases in use and harm, and why it took so long for public concern about opioid-related damage to public health and safety to translate into legal action and policy change, we must remember the constraints and competing agendas at work in a pluralist system that disperses power over the policymaking, enforcement, and regulatory tools we have described. Even for tobacco, which, unlike opioids, has no licit medical use, no one actor controls the various enforcement, regulatory, legislative, and litigation-related decisions that plausibly shape public health outcomes of this kind.²³⁵ Although coalitions of policymakers, lawyers, and civic leaders can alter the landscape, sophisticated actors with concentrated economic benefits can hold important sway in shaping the policy agenda.²³⁶ Enforcement of existing criminal and regulatory laws can be complicated given a rickety existing infrastructure that collects relevant data. And while civil litigation can contribute to spurring broader action, tort liability takes time and lawyers face a variety of hurdles in advancing their arguments for liability arising from a regulated product.

At a minimum, for years after it became clear there was a public health problem with a serious regulatory dimension, the story associated with regulatory and criminal enforcement showcases what might be called “diluted regulatory governance.” Public officials face a version of this

235. For a discussion of the costs of agency coordination and the competing incentives implicated in enforcing complex criminal-regulatory schemes, see Mariano-Florentino Cuéllar, *The Tenuous Relationship Between the Fight Against Money Laundering and the Disruption of Criminal Finance*, 93 J. CRIM. & CRIMINOLOGY 311, 335-63 (2003).

236. See Cuéllar, *supra* note 4.

challenge when addressing a variety of public health problems, but this problem is even more likely to arise with addictive drugs that can be destructive but are also beneficial under some circumstances.²³⁷ Diluted governance involves limited gathering of information from key actors in the system relative to what is feasible under both existing law and plausible reforms; relatively rare referrals for prosecution from regulators or state authorities (and likely limited action where these do occur); and, more generally, less complementary criminal-regulatory enforcement. Such complementary enforcement epitomizes efforts to target money laundering since the 1980s, where criminal statutes are used to heighten regulatory compliance, including vigorous implementation of suspicious activity reporting requirements and due diligence. And regulatory compliance (by generating the information on which criminal cases are partially based) tends to increase the possibility of successful criminal prosecutions. A closer look reveals both the extent to which competing agendas shape the legal response to the opioid crisis, and also some of the key factors likely to affect the consequences of any effort to address public health through the enforcement of legal provisions or the application of civil remedies.²³⁸

Consider first some of the background political realities affecting legislative or regulatory responses that we have described in the preceding sections. Regulating the flow of a drug that can be legally prescribed but routinely misused depends to some extent on the existence of broad public concern, but such relatively disaggregated concern may prove meager in comparison to the highly concentrated interests of drug companies and pharmacies who could be severely affected by policy changes in this area. Meanwhile, society has fragmented the responsibility for opioid policy and enforcement across state and federal entities, across health and criminal justice policymakers, and across multiple agencies.²³⁹ Across a range of situations, doctors and patients had (and, in many cases, retain) incentives favoring distribution of opioids.²⁴⁰

Nor did legislators or agencies routinely find that substantial, meaningful policy changes were easy to achieve or especially valuable politically in the early days of the crisis. Although individual legislators

237. *Id.*

238. Cuéllar, *supra* note 4.

239. *See generally* Mariano-Florentino Cuéllar, *The Political Economies of Immigration*, 2 U.C. IRVINE L. REV. 1 (2012); Jim Rossi & Jody Freeman, *Agency Coordination in Shared Regulatory Space*, 125 HARV. L. REV. 1131 (2012).

240. *See generally* Lembke, *supra* note 34; Meier, *supra* note 32.

may have increasingly felt their constituents growing concerned about the situation, the pressure to enact administrative, criminal, or enforcement changes was lessened by their range of opportunities to take relatively symbolic positions or to merely support research and treatment. Enforcement agencies sometimes lacked the means to obtain the full range of relevant information useful in developing (civil or criminal) cases. As in a variety of domains involving risk and public health, ranging from vehicle safety to tobacco, tort law played a crucial role as a backstop capable of generating information, public attention, and, eventually, credible risks of penalties and negative publicity that could reshape the incentives of large private organizations. Yet while tort lawsuits were possible and eventually commenced, the lawyers and parties here too encountered familiar challenges involving the aggregation of claims, the complexity of causation questions in this context, and the difficulty of prevailing where the government has explicitly approved a product.

Of course, constraints on regulatory policy and enforcement are familiar in many contexts involving public health, environmental protection, and other domains where the benefits are disaggregated and the costs are concentrated.²⁴¹ The financial regulatory reform effort begun in 2009, for example, culminated in legislation including diluted provisions to manage systemic risks and stark constraints on the regulatory powers it granted to protect consumers.²⁴² This outcome was certainly made more likely given *de jure* and *de facto* legislative veto points triggered by powerful legislators, and subsequent administrative impediments affecting the speed and substance of regulatory rules.²⁴³ The regulation of firearms provides yet another fertile example of conflict over regulatory policy.²⁴⁴

What is important to recognize in the opioid context is that these limitations not only arise, but can be enormously consequential, despite stark changes in health risks and substantial public concern, and despite a variety of settings where public health policymakers leverage their relative insulation and protection rooted in public law to achieve

241. *See generally*, Sean Gailmard et al., *Administrative Procedures as Instruments of Political Control*, in *THE OXFORD HANDBOOK OF CLASSICS IN PUBLIC POLICY AND ADMINISTRATION* 465 (Steven J. Balla et al. eds., 2015).

242. Daniel Carpenter, *Institutional Strangulation: Bureaucratic Politics and Financial Reform in the Obama Administration*, 8 *PERSP. ON POL'Y* 825, 828 (2010).

243. *See id.*

244. *See, e.g.*, ROBERT J. SPITZER, *THE POLITICS OF GUN CONTROL* 214 (7th ed. 2018).

significant innovations.²⁴⁵ That such headwinds can frustrate even a subject capable of generating serious concern among the public and policymakers is an important conclusion we want to emphasize. Although such public concern has certainly had an effect on discrete policy issues, it suggests that legal responses to public health problems cannot depend entirely and perhaps not even primarily on an engaged public. Where collective action problems exist given the vast numbers of affected parties and the difficulty of coordinating meaningful action, change must depend more at the margin on savvy regulatory entrepreneurs within government, such as the FDA officials who led efforts to expand tobacco regulation; partially insulated agency or adjudicatory entities, such as the FTC; and philanthropic efforts to address policy failures that may persist despite public concern, such as funding collaborations currently underway to promote new research, public education, and policy changes involving climate change.

Meanwhile, policy responses affecting the legal mechanisms available to deal with prescription opioid addiction have almost certainly been affected by the industry's efforts to bolster its reputation. Campaign contributions to state legislators by the pharmaceutical industry outpace those of groups trying to fight opioid overprescribing by 220 to 1.²⁴⁶ Less direct forms of influence and stature have been sought through philanthropy. The Sackler Family, for example, which owns Purdue Pharma and has made billions from OxyContin, has donated money to New York's Metropolitan Museum of Art, London's Victoria and Albert Museum, the Louvre, and the Smithsonian, among many other cultural landmarks.²⁴⁷ They have also made high-profile donations to prominent universities.²⁴⁸ Unlike families such as the Fords, Packards, and Johnsons, their name does not grace their main product—OxyContin—but the

245. Cuéllar, *supra* note 4.

246. *Pharma Lobbying Held Deep Influence Over Policies on Opioids*, ASSOCIATED PRESS (Sept. 17, 2016), <https://apnews.com/9b72ea1408f845eaa26638a652df2912> [<https://perma.cc/9AZZ-8PHG>].

247. Christopher Glazek, *The Secretive Family Making Billions from the Opioid Crisis*, ESQUIRE (Oct. 16, 2017), <https://www.esquire.com/news-politics/a12775932/sackler-family-oxycontin/> [<https://perma.cc/YQ5S-6XTE>].

248. *Id.*

Sacklers have been assiduous in ensuring that their name is prominently displayed in association with any donation they make.²⁴⁹

Nor can we assume that all public health regulatory issues are created equal or that the conditions affecting them remain static over time. We earlier discussed changes in the legal arrangements and social policies affecting tobacco consumption in the United States. Major public health changes have also occurred in food safety, occupational and environmental health, and nutrition. We note that changes in these domains often depend on some mix of long-term strategy by public officials, support from civil society and philanthropy, and changing public attitudes. We find few if any examples of far-reaching, successful, public health-related legal or policy change occurring within less than a decade. Nor can we conclude that all drug-related policy problems generate the same response. As discussed earlier, the extent of the law enforcement response targeting illicit drug use in the 1980s and 1990s affected even the most far-flung parts of the federal law enforcement apparatus and fundamentally reshaped key aspects of state criminal law.

The starkest contrast is in the federal criminal justice system, which took over an unprecedented prosecution and incarceration role for drug crimes in the 1980s and 1990s, increasing the number of federal inmates about sixfold.²⁵⁰ Yet as the opioid epidemic rages on, Congress in December 2018 enacted the First Step Act, which reduces federal prison incarceration, including by paving the way for early release of thousands of individuals convicted on drug charges.²⁵¹ This retreat of federal law enforcement regarding the opioid epidemic creates some policy space for expansion of public health approaches such as were embodied in the SUPPORT for Patients and Communities Act passed in October of 2018. At the same time, as emphasized above, both of these federal changes were many years in the making and were of constrained scope when they finally arrived.

None of these observations suggests that it is impossible to adjust American society's legal and policy responses to the opioid crisis. Some progress is possible, and indeed, the last few years reflect a growing

249. Patrick Radden Keefe, *The Family that Built an Empire of Pain*, NEW YORKER (Oct. 30, 2017), <https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain> [<https://perma.cc/EDW3-W2NS>].

250. See Nathan James, CONG. RESEARCH SERV., R42937, THE FEDERAL PRISON POPULATION BUILDUP: OPTIONS FOR CONGRESS 1, 19-20 tbl.A-1 (2016).

251. See Formerly Incarcerated Reenter Society Transformed Safely Transitioning Every Person, or First Step, Act, Pub. L. No. 115-391, 132 Stat. 5193 (2018).

awareness among policymakers that existing legal tools were inadequate to address the situation. The SUPPORT Act of 2018 as well as the Comprehensive Addiction Recovery Act and the 21st Century Cures Act of 2016 provided federal funding for expanded access to opioid addiction treatment and to the opioid overdose rescue drug naloxone, and also provided significant research funds regarding opioid addiction as well as development of alternatives to opioids for pain.²⁵² Even more significantly, the Patient Protection and Affordable Care Act of 2010 defined substance use disorder treatment as an essential health care benefit to be provided at parity with other health benefits in Medicaid and in private insurance plans sold on state exchanges.²⁵³ This policy change substantially increases Americans' access to opioid addiction treatment, although whether that will be sustained is unknown given judicial, legislative, and executive efforts to roll back the Affordable Care Act.

Other policy changes remain within reach despite the more modest progress achieved in regulatory policy as well as criminal and regulatory enforcement. Although these responses are not guaranteed to have an impact in isolation, they are likely to contribute to further progress in combination. They become more feasible after substantial public concern persists for years, and litigation against some large companies begins to gain traction and to produce further information. Federal and state officials, for example, can continue experimenting with new means for monitoring prescriptions and establishing appropriate regulatory oversight for companies involved in drug distribution. Policymakers can also safeguard autonomy, promote appropriate coordination, and providing adequate resources for federal and state regulatory and criminal

252. *See* Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, Pub. L. No. 115-271 §§ 3001-02, 3201-04, 6042, 7041-42, 132 Stat. 3894, 3932-34, 3943-47, 3979-84, 4016-17 (2018); 21st Century Cures Act, Pub. L. No. 114-255 §§ 1001-3093, 9001-10006, 130 Stat. 1033, 1039-1152, 1234-1269 (2016); Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-198 §§ 101-10, 130 Stat. 695, 697-710 (2016).

253. Jeffrey A. Buck, *The Looming Expansion and Transformation of Public Substance Abuse Treatment Under the Affordable Care Act*, 30 HEALTH AFFAIRS 1402, 1402-408 (2011); Keith Humphreys & Richard Frank, *The Affordable Care Act Will Revolutionize the Care of Substance Use Disorders in the United States*, 109 ADDICTION 1957, 1957-958 (2014); Keith Humphreys & A. Thomas McLellan, *Brief Intervention, Treatment and Recovery Support Services for Americans Who Have Substance Use Disorders: An Overview of Policy in the Obama Administration*, 7 PSYCHOL. SERVS. 275, 275-84 (2010).

justice agencies addressing the problem. They can enhance the use of task forces and other mechanisms for coordination, particularly where a legal product that can be abused is at issue. They can provide access to documents helping legislatures, the media, and the public understand the nature of decision-making by private entities in this area and the consequences. They can teach effective use of appropriate databases and monitoring tools to inform public decisions about seeking redress through civil actions or accountability through the criminal justice process.

Learning from the experience with opioids and other products with addictive properties can also spur improvements in the analysis of costs and benefits undertaken by regulatory agencies, including the FDA. Where not prohibited by statute, such analyses can consider the likely difficulties in achieving effective enforcement and regulation arising from concentrated interests with a considerable stake in the continued, more lightly-regulated distribution of potentially hazardous products. It is hard to see how regulatory impact analyses are likely to give a particularly useful description of the world if they fail to consider the institutional realities we've described in this article, including organized resistance to compliance, possible changes in public norms, and the interaction of civil and criminal enforcement. Although it may be analytically difficult to incorporate these factors, public officials and stakeholders can use a variety of techniques to make progress, including simulations, scenario planning, and historical analyses.

Of course, jurisdictions can also invest in making treatment more affordable and training law enforcement officials to manage opioid-related emergencies.²⁵⁴ Public agencies and private distributors such as pharmacies can improve distribution channels for naloxone.²⁵⁵ State governments can enhance regulatory data collection to monitor opioid flows and take corrective action through civil and criminal enforcement, and the federal government can improve its capacity to track opioid use, addiction, and overdose trends.²⁵⁶ Perhaps doctors, researchers, and the

254. Keith Humphreys & Harold Pollack, *How Should the U.S. Respond to the Opioid Addiction and Overdose Epidemic?*, in *THE PALGRAVE HANDBOOK OF AMERICAN MENTAL HEALTH POLICY* (H.H. Goldman, J.P. Morrissey, & R. Frank eds., 2019).

255. Keith Humphreys, *An Overdose Rescue Drug Goes Mainstream*, 34 *HEALTH AFF.* 1624, 1624-27 (2015).

256. Beau Kilmer & Jonathan Caulkins, Opinion, *Hard Drugs Demand Solid Understanding*, USA TODAY (Mar. 8, 2014), <https://www.usatoday.com/story/opinion/2014/03/08/heroin-abuse-hoffman-research-column/6134337> [<https://perma.cc/GBJ6-JAFJ>].

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organizations within which they work can develop alternative approaches for dealing with pain through a mix of public funding and support from other sources.²⁵⁷ But because some key actors have strong reasons to protect their economic and legal interests, the extent of constraints we have described here affect not only the production of legislative or regulatory responses, but also the implementation of them. That is reason for caution—though certainly not for a sense of futility—about the success of any legal or policy change in this area.

CONCLUSION

Powerful political and economic actors can frustrate the normal translation of widespread societal concern into broad changes in law, policy, and enforcement. A variety of governance arrangements are often capable of responding to public concern as a means of forestalling backlash or more dramatic changes in the future. Yet in a pluralist system of institutions with distinct powers, private actors' opposition can stultify changes in enforcement, in the implementation of existing authority, or in policy reform despite widespread public alarm. Some of this disconnection may be socially valuable because initial impulses to make changes in regulation or criminal enforcement may not be the right ones (e.g., a brutal war on drugs policy). In addition, sometimes there is moral panic about a putative problem that proves evanescent, such as a new drug that emerges in a few cities, causes some deaths that receive wide media coverage, and falls out of favor with users almost immediately and stops being a problem.

But there is also a cost. In the opioid context, concern rose well before the various pressures shaping the legal system began to trigger meaningful responses—including regulatory and criminal enforcement. Well after policymakers and the public became aware of the extent of the problem, American institutions remained constrained by the mix of risk aversion, organized legal and political resistance from stakeholders, and limited resources that resulted in diluted regulatory governance. The resulting picture is not without nuances, reflecting some federal, state, and local efforts to move aggressively against opioid abuse even in the early years of the crisis. But for the most part, entities ranging from state legislatures to

257. *National Pain Strategy: A Comprehensive Population Health-Level Strategy for Pain*, NIH INTERAGENCY PAIN RES. COORDINATING COMMITTEE (2016), https://www.iprcc.nih.gov/sites/default/files/HHSNational_Pain_Strategy_508C.pdf [<https://perma.cc/47LF-D79Z>].

the Justice Department and the DEA often stopped short of using all the tools at their disposal to enhance regulatory policies and pursue enforcement targeting opioid abuse. Civil tort lawsuits faced the considerable difficulties that often bedevil aggregate litigation.

As the years since the start of the opioid crisis passed, certain aspects of this picture began to change. The Justice Department began to show more interest in both criminal and regulatory enforcement. It sought changes from Congress to facilitate an expanded DEA role in monitoring and investigation. State attorneys general and local jurisdictions relied on tort law to serve as a crucial backstop for a rickety and slow-to-change regulatory system, generating considerable attention even if it came long after opioid-related morbidity and mortality had spiked. As lawsuits and settlements began to advance, in some cases these proceedings resulted in the release to the public of industry documents describing company strategies to market opioids despite addiction risks. That the response nonetheless has been slow despite the extent of public concern underscores the difficulty of enforcement-oriented policy change involving legally available drugs that are addictive. These difficulties matter because in domains involving parties willingly transacting with each other, the actual imposition of criminal liability often depends heavily on regulatory mechanisms to detect offenses. This is true even if illicit activity generates sufficiently widespread societal concern to justify broad criminal enforcement. These mechanisms allow agencies to gather information, impose prophylactic rules, and levy more serious sanctions (more serious than just routine fines for noncompliance), using criminal liability as a backstop. But in this context, the development and use of regulatory capacity was at times neglected by policymakers and in some cases frustrated by opposition from industry players and their hired help. Balancing that dynamic takes agencies with politically sophisticated leadership prioritizing enforcement, litigants capable of leveraging a civil litigation, and emerging changes in the widespread public salience of the opioid crisis. These factors have taken a considerable amount of time to develop in this context, leaving many missed opportunities to align regulatory and criminal enforcement realities with asserted public health priorities.

The opioid crisis also raises the question of whether, as a general matter, our understanding and implementation of regulation in the United States is adequate when addictive products are at issue. All addictive products, including opioids, pose a challenge to Adam Smith's "invisible hand" thesis, which holds that the pursuit of rational self-interest guides efficient, socially beneficial markets. Because addictive products can induce maladaptive changes in brain circuits affecting learning,

motivation, and decision-making, they can lead to people consuming drugs that destroy their lives rather than advance their self-interest. For this reason, addictive products are not “ordinary commodities.” The intertemporal utility conflicts and negative externalities support a compelling case for tight regulation.²⁵⁸ For tobacco products, the relevant political economy arising from business incentives and societal norms once cut decisively against substantial regulation. Recent conditions tend to be far more supportive of regulation, at least in developed countries.

But in contrast to nominally legal opioids, tobacco is in some sense an easy case in that using it as directed, by definition, harms health and indeed has a high chance of causing premature mortality.²⁵⁹ More akin to opioids are addictive products such as alcohol and electronic slot machines, which for any given user can have a benefit particularly if not used for extended periods; one can safely enjoy a glass of wine with dinner, or risk small amounts of money on slots during a once-a-year trip to Vegas. Even more importantly, opioids are required for the management of certain serious medical conditions. Coupled with an awareness in some quarters of the costs associated with criminal and regulatory enforcement, these public impressions understandably heighten resistance to regulating them more strictly even though the net social welfare benefit of doing so is likely to be positive.

The resulting mix of pressures and institutional constraints is likely to affect any societal effort to implement sensible legal arrangements addressing these health-related challenges, from access to tort-law remedies to monitoring regulations to appropriately enforced criminal sanctions. In a market economy with pluralist political institutions, a critical problem is that the very addictiveness of these products makes them lucrative to produce and sell. When any such product is legalized, a powerful actor is created with significant resources available to achieve a measure of regulatory capture and to exploit the constraints associated with existing criminal enforcement and imposition of civil liability. For these reasons, even as policymakers, lawyers, and scholars consider options to recalibrate policy responses to public health crises involving addictive products, they should be realistic about the constraints governments face and the resistance they are likely to encounter.

258. *See generally* BABOR ET AL., *supra* note 20; Humphreys et al., *supra* note 5.

259. *See* FDA v. Brown & Williamson, 529 U.S. 120, 155 (2000) (quoting FDA officials acknowledging that smoking tobacco products has been “widely recognized as being harmful to human health”).

If jurisdictions learn to take better advantage of the unusual recent extent of public concern, it will save tens of thousands of lives per year and mark one of the first successful forays into regulating addictive products that bring benefit to some but misery or death to others. Yet without overcoming the serious constraints that have delayed and, in some cases, diluted society's response to the opioid crisis, narrow interventions focused on a single area of law or isolated technical changes in treatment will almost certainly fail to address the larger problem. That is reason for caution—though certainly not for a sense of futility—about the prospects for success of any legal or policy change in this area.