Beyond the Prohibition Debate: Thoughts on Federal Drug Laws in an Age of State Reforms

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Nearly forty years after President Richard Nixon first declared a “war on drugs”—calling drugs the “modern curse of the youth, just like the plagues and epidemics of former years”1—it seems the war may finally be coming to an end. In his first interview after being confirmed as the Director of the Office of National Drug Control Policy, Gil Kerlikowske told the Wall Street Journal that he thought it was time to retire the war rhetoric when it comes to addressing drug abuse.2 At the state level, the past year has seen proposals to legalize marijuana introduced in a handful of states with polls showing approximately forty-five percent of Americans nationwide in support of the idea.3 Importantly, these recent developments follow nearly a decade and a half of successful drug reform measures at the state level on issues ranging from medical marijuana, treatment instead of incarceration, asset forfeiture, and marijuana decriminalization. In short, the argument that we should end the war on drugs in favor of a new approach no longer resides in the world of the politically unthinkable, and has quickly become a subject of serious policy and political discussion.

This article considers how we might think about federal drug laws in a post-drug war context, particularly one in which states are increasingly passing laws that are at-odds with federal law. I argue that, when it comes to federal drug law, traditional debates about prohibition, legalization, or decriminalization turn out to

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be surprisingly unimportant. Instead, as states begin to enact new policies, the key question facing federal lawmakers and administration officials will be how to harmonize federal law with state reforms.

My argument proceeds in four Parts. Part I provides a brief overview of the mounting evidence that the war on drugs strategy has proven to be an extremely costly and largely ineffective method for dealing with the problem of drug abuse. Further, this section also looks at how dissatisfaction with the current approach has led to increased interest in decriminalizing or legalizing marijuana, even at the federal level. In Part II, I argue that the focus on debates over legalization or decriminalization at the federal level is misplaced. This is because, even if it wanted to, the federal government would not have the ability to unilaterally “legalize” or “decriminalize” any controlled substances. Using the example of medical marijuana laws as a case study, Part III contends that, just as the federal government does not have the ability to unilaterally decriminalize a drug, it also does not have the power to stop states from reforming their own laws. In Part IV, I consider the implications of Parts II and III and conclude that they counsel in favor of reforming federal drug laws in a way that would respect states’ decisions to innovate in the area of drug policy, while also providing important controls and incentives to prevent against negative externalities in the form of spillover effects in neighboring states.

I. THE EMERGING CONSENSUS FOR REFORM

The central principle of the drug war strategy has been that vigorous enforcement of increasingly strict criminal laws, though expensive, is necessary to reduce drug abuse and related problems.4 This philosophy has had a dramatic effect on our criminal justice system. In 2008, 12.2 percent of all arrests in the United States were for drug offenses—more than any other category of offense5—and 82.3 percent of all drug arrests were for simple possession.6 Meanwhile, nearly one quarter of the 2.3 million Americans behind bars today are there for drug-related offenses.7 Indeed, the number of Americans incarcerated

4 This Part of my article draws heavily from my article Toward a Public Health Approach to Drug Policy, 3 ADVANCE: J. ACS ISSUE GROUPS 43, 43–47 (2009).
6 Id.
7 Kreit, supra note 4, at 43.
for drug offenses today is larger than the *entire* United States prison and jail population was in 1980.\(^8\)

Maintaining this effort has been quite costly to taxpayers. The annual price tag of our drug policies is notoriously difficult to measure, due in large part to the various agencies at the federal, state, and local levels that are involved.\(^9\) As a result, measurements vary. But, while the specific figure is open to debate, there is no doubt that the number is in the tens of billions each year. In one of the more recent and prominent drug war cost-estimates, for example, Harvard economist Jeffrey Miron reported that net annual expenditures, across all levels of government, is approximately $44 billion after subtracting drug law-related revenue from fines and asset forfeitures.\(^10\)

Despite all of this, however, our policies appear to have had little impact on drug abuse. Drug war proponents often cite temporary reductions in use within particular time periods or drug categories, yet as each apparent success has given way to another drug epidemic—from heroin in the 1970s, to crack in the 1980s, to methamphetamine in recent years—it has become increasingly clear that our policies have had, at most, a negligible impact on abuse and overall use. The drug war’s inability to achieve its stated goal of reducing the overall use of illegal drugs along with the continued occurrence of new drug epidemics are due, at least in part, to the substitution effect: “[I]f enforcement increases the price of an illicit drug, consumers often can shift to alternative illegal substances or to new products that have not yet been declared illegal.”\(^11\) In short, while the use of certain drugs have decreased over the life of the drug war, the overall effort to reduce drug use and abuse through law enforcement has not succeeded. Indeed, as vocal drug war supporter Joseph Califano observes in his book *High Society*, the “number of Americans twelve and older who use[d] illicit drugs more than doubled” between 1992 and 2005.\(^12\) Gil Kerlikowske recently

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8 Id.
9 Erik Luna, *The Big Picture, Drug Détente*, 20 FED. SENT’G REP. 304, 305 (2008) (“Frankly, however, calculating the aggregate expense of prohibition may be an impossible task, given the myriad areas of spending and the disinterest of drug warriors in revealing the actual cost of their crusade.”).
summarized the drug war strategy by acknowledging: "In the grand scheme, it has not been successful."\textsuperscript{13}

Perhaps the starkest evidence that our current strategy has failed came in the first comparison of drug use rates across countries, which was undertaken by the World Health Organization. The World Health Organization concluded that despite having the most punitive policies, the United States had the highest rates of illegal drug use of the seventeen countries included in the study.\textsuperscript{14} Among the report's findings: The number of Americans who have used cocaine is approximately four times higher, at 16.2 percent, than any other country.\textsuperscript{16} And more than twice as many Americans have tried marijuana than residents of the Netherlands, where the drug is openly bought and sold in regulated shops. That gap is even wider among adolescents fifteen years and younger, with just under three times as many American teens (twenty percent) having tried the drug than their contemporaries in the Netherlands (seven percent).\textsuperscript{16}

The World Health Organization's findings present a particularly difficult challenge to those who support our current approach to drug policy. This is because, even if we were to assume that the war on drugs has reduced overall substance use and abuse—a questionable premise—the lower usage rates in other countries indicate that we could almost surely be achieving the same or better results at significantly reduced economic and human costs.

Indeed, even when we look at the impact on drug supply, the drug war appears to have been relatively ineffective. While few would dispute that prohibition increases the price of illegal drugs above what they would be in a legal and regulated market, most illegal drugs remain relatively affordable. Moreover, prices for some drugs have actually decreased over the past three decades, even as we have undertaken costly and environmentally questionable efforts, such as crop eradication programs. A 2008 Brookings report on U.S.-Latin American relations found that


\textsuperscript{14} Louisa Degenhardt et al., Toward a Global View of Alcohol, Tobacco, Cannabis and Cocaine Use: Findings from the WHO World Mental Health Surveys, 5 PLoS MED. 1053, 1057 Table 2, 1062 (2008) [hereinafter WHO Survey], available at http://medicine.plosjournals.org/archive/15491676/5/7/pdf/10.1371_journal.pmed.0050141-L.pdf (concluding that the United States "stands out with higher levels of [drug] use ... despite punitive illegal drug policies").

\textsuperscript{15} Id. at 1057.

\textsuperscript{16} Id. at 1057–59.
“the street prices of cocaine and heroin fell steadily and dramatically” between 1980 and 2007, and that “cocaine production in the Andean region is currently at historic highs.”

It is perhaps not surprising, then, that the overwhelming public support for ever-more punitive drug policies during the 1980s and early 1990s has disappeared and we now see substantial majorities in favor of reform measures. According to a 2008 Zogby poll, three quarters of Americans say that they believe the “war on drugs” policy is failing. Similarly, voters have generally embraced proposals to move state and local drug policies away from the drug war strategy. Since California voters passed the first modern state medical marijuana law in 1996, thirteen other states have followed suit. Most recently, proposals to decriminalize or legalize marijuana have begun to attract an especially great deal of attention. In 2008, Massachusetts voters approved a ballot initiative to decriminalize the drug with sixty-five percent in favor. And, within the past year, legislation and ballot initiatives to legalize marijuana have been proposed in California, Nevada, New Hampshire, Oregon, and Washington, with legislators in Rhode Island establishing a panel to study the issue. In California, where the issue will come before voters in a ballot initiative this fall, recent polling has shown that fifty-six percent of residents are in support of taxing and regulating marijuana like alcohol.

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18 The past decade has also seen an emerging consensus among policy analysts and some foreign leaders that the war on drugs has proven to be less effective than lower-cost and more humane policies adopted by other countries. See Kreit, supra note 4, at 45–47.
22 Kreit, supra note 4, at 44.
24 Wyatt Buchanan, Pot Initiative: 700,000 Signatures Gathered, S.F. CHRON., Jan. 29, 2010, at C1 (reporting that backers of a marijuana legalization ballot initiative had gathered the necessary signatures to place the issue before the voters and that a Field Poll had found fifty-six percent of Californians in favor of the idea).
II. Reforming Federal Drug Laws: The Importance of Asking the Right Questions

As this brief overview reveals, after forty years, it is difficult to describe the war on drugs strategy as anything other than a failure. Our effort appears to have had little, if any, sustained success at reducing drug use or abuse. More importantly, to the extent drug war policies may have had an impact on the use of illegal drugs, the experiences of European countries give us every reason to believe that we could have achieved the same or better results at a substantially reduced cost. As a result, there is now a strong consensus among voters that the war on drugs strategy has failed. We have also begun to see substantial support for particular reforms, including some ideas that were viewed as politically unimaginable just a decade ago.

However, as proposals to alter our drug laws have entered the political spotlight, there has been relatively little attention paid to the different roles of the federal government and the states in the area of drug policy. This oversight is not new. Indeed, as Michael O’Hear observes in his authoritative article Federalism and Drug Control, the question of how drug enforcement and policy-making decisions should be distributed between state and federal authorities has been surprisingly under-examined for quite some time.25 The changing political landscape in this area, however, reveals even more clearly why this question is such an important one. When state and federal efforts are closely aligned in the pursuit of the same strategy, as they were for some time during the war on drugs, policy discussions will naturally tend to revolve around the best tactics for implementing the strategy, or about the wisdom of the strategy as a general matter. Perhaps it is not surprising, then, that drug policy questions are typically viewed through the same lens, regardless of whether the context is state or federal law. While this tendency may make sense when state and federal strategies are closely aligned, it becomes problematic when the two diverge.

The example of marijuana law reform, which has started to gain some attention at the federal level, is instructive. In 2008, and again in 2009, Congressman Barney Frank introduced bills to “decriminalize” marijuana, saying that the government should allow people to “make their own choices as long as they are not

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impinging on the rights, freedom or property of others[.]" And, when President Barack Obama held an online town-hall meeting to answer questions submitted and voted on by voters through a White House website, reformers worked to help push a question about marijuana legalization to the top of the list. President Obama offered only a brief response to the question that garnered the most votes, joking, "I don't know what this says about the online audience," before dismissing the idea. Meanwhile, when faced with questions about proposals to tax and regulate marijuana like alcohol, President Obama's "drug czar" Gil Kerlikowske has taken to saying that "[l]egalization isn't in the President's vocabulary, and it certainly isn't in mine."28

Kerlikowske's "vocabulary" line has been a source of frustration among marijuana legalization advocates and has been viewed as a sign that the administration is not willing to engage the question with a serious response, even if it were to ultimately remain opposed to the idea. The criticism is certainly understandable. After all, President Obama gave serious and substantive responses to all of the other questions he received in his online town hall meeting, but only a one-sentence humor-based reply to the question about marijuana policy.29

In an important sense, however, the debate about legalizing or decriminalizing marijuana truly is misplaced in the context of federal drug laws. Indeed, to ask if the federal government should legalize marijuana is to ask an essentially irrelevant question—irrelevant not because it is unimportant or on the political fringe (certainly, if the polling is to be believed, it is not), but because it misunderstands the role of the federal law in shaping drug policy. Whether or not legalizing or decriminalizing marijuana is a good idea, the federal government simply does not have the power to effect such a change.

Imagine, for example, that every federal elected official decided tomorrow that marijuana should be taxed and regulated like alcohol. Even if they were to pass legislation that removed all federal criminal penalties for possessing, manufacturing, or

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26 Bob Egelko, Lee Backs Bill to Ease Pot Laws, S.F. CHRON., July 31, 2008, at B2 (reporting that Frank's bill was "the first marijuana decriminalization measure introduced in Congress since 1978").
28 Donna Leinwand, New Drug Czar Ready to Corral Forces; Putting Focus on Abuse of Prescriptions, USA TODAY, May 21, 2009, at A3.
29 See Aaron Houston, Laws Subsidizing Mexican Drug Gangs Are No Laughing Matter, S.F. CHRON., March 31, 2009, at A18 (criticizing President Obama for failing to take marijuana policy seriously).
selling marijuana, the drug would still be illegal everywhere in
the country because all fifty states have their own laws
criminalizing the sale of marijuana.\textsuperscript{30} To be sure, if the federal
government were to remove criminal penalties for the cultivation
and distribution of marijuana, it would have a substantial impact
on the enforcement of marijuana laws in the United States. That
impact, however, would not be “legalization” of the drug
inasmuch as marijuana would not be legal to buy and sell in any
state unless and until that state also changed its laws. In short,
unless the federal government decided to preempt state law,\textsuperscript{31} it
could not unilaterally “legalize” a controlled substance even if it
wanted to.

To see why this point has important implications for
thinking about federal drug laws, consider Congressman Frank’s
proposed legislation. Congressman Frank and the media framed
the bill, dubbed the “Act to Remove Federal Penalties for
Personal Use of Marijuana by Responsible Adults,” as a proposal
to decriminalize marijuana nationwide.\textsuperscript{32} But, if we think a bit
more about what the bill would actually do, we find that the
question of whether or not our country should decriminalize
marijuana is not particularly relevant to assessing the merits of
Congressman Frank’s proposal.

The Personal Use of Marijuana by Responsible Adults Act
would enact a simple change in federal law by eliminating
federal penalties for “the possession of marijuana for personal
use,” defined as 100 grams or less of marijuana, “or for the not-
for-profit transfer between adults of marijuana for personal
use.”\textsuperscript{33} How would this change in the law impact marijuana
enforcement in the United States? A quick look at the data for

\textsuperscript{30} Though some states have decriminalized possession of personal-use amounts of
marijuana, no state has made the sale or cultivation of marijuana legal other than for
medicinal purposes. See Robert MacCoun et al., \textit{Do Citizens Know Whether Their State
Has Decriminalized Marijuana? Assessing the Perceptual Component of Deterrence
Theory}, 5 REV. OF LAW & ECON. 347, 351–53 (2009) (listing states that have considered
decriminalizing marijuana).

\textsuperscript{31} The likelihood of this happening is, not surprisingly, virtually zero. Indeed, the
federal government has not even sought to preempt state medical marijuana laws despite
fervent efforts to stop their implementation and almost certainly could not, even if it
wanted to. See infra note 79 and accompanying text. \textit{Cf. also}, Whalen v. Roe, 429 U.S.
589, 603 (1977) (noting that “the State no doubt could prohibit entirely the use of
particular Schedule II drugs,” which are legal under federal law).

\textsuperscript{32} See David Knowles, \textit{Barney Frank and Ron Paul Team Up to Decriminalize
barney-frank-and-ron-paul-team-up-to-decriminalize-marijuana. Although the Act has
been called by other names, its official name is the Personal Use of Marijuana by
Responsible Adults Act of 2009. H.R. 2943 111th Cong. § 2 (2009). For purposes of
consistency, I will refer to it by its official name.

\textsuperscript{33} H.R. 2943, 111th Cong. § 2 (2009).
federal prosecutions reveals that the actual effect of the legislation would be quite minimal. In 2008 there were a total of only 626 simple marijuana possession cases disposed of in federal court.\textsuperscript{34} To put this number in perspective, there were approximately 754,223 arrests for marijuana possession nationwide in 2008.\textsuperscript{35} In other words, the bill would impact about 0.0008 percent of all individuals arrested for marijuana possession.

It is also worth noting that the 626 figure is almost certainly larger than the number of individuals who would have been charged with a federal crime based on simple possession of a personal use amount of marijuana alone. This is because, in all likelihood, a number of the 626 defendants were initially charged with a more severe offense but were convicted of marijuana possession as part of a plea deal.\textsuperscript{36} Indeed, of the 370 defendants convicted of federal marijuana possession in 2008, 367 were based on guilty pleas.\textsuperscript{37} And, though data is not available on the number of individuals who were federally charged based on the not-for-profit transfer of personal use amounts of marijuana, there is no reason to believe that it is significantly larger than the number of individuals charged with simple possession.

With this in mind, to say that the Personal Use of Marijuana by Responsible Adults Act would have a negligible impact on marijuana arrests and prosecutions would be an understatement, particularly when one considers that individuals who might avoid federal prosecution under the legislation would not necessarily escape punishment, as they could still be prosecuted at the state level. Far from “decriminalizing” marijuana, then, the direct impact of Congressman Frank’s proposal would be to remove a few hundred defendants from the federal system and leave their cases to local prosecutors. Indeed, even if the proposal were expanded beyond marijuana to take the federal government out of the business of prosecuting simple possession


\textsuperscript{36} See \textsc{Office of Nat’l Drug Control Policy, Who’s Really in Prison for Marijuana? 23} (2005) (arguing that plea bargaining “can distort the statistics on marijuana possession offenders, consequently leading some people to claim that our prisons are overflowing with pot smokers”).

\textsuperscript{37} \textsc{Criminal Justice Statistics, supra} note 34.
for all drugs, the real-world effect would still be surprisingly trivial, as there were only 394 prosecutions for simple possession for all drugs other than marijuana in 2008.38

When viewed in this light, it becomes clear that to discuss a proposal like the Personal Use of Marijuana by Responsible Adults Act primarily by reference to terms like decriminalization and prohibition is really to misstate the relevant issue. A debate over whether to remove federal penalties for small amounts of marijuana or other drugs is not a debate about decriminalization, but about the best use of federal resources and the most sensible role for federal law in addressing the problem of drug abuse. In other words, the policy question posed by Congressman Frank's bill is not whether to criminalize possession of small amounts of marijuana, but rather who is best able to enforce criminal laws against possession of small amounts of marijuana, and whether the activity is one that the federal government can or should concern itself with.

Not only would reframing the debate over federal drug laws on these terms be more accurate, it may also make it easier to bridge the divide between different sides of the debate on drug policy issues and find common ground. For example, even those who are opposed to the idea of decriminalizing drugs as a general matter may nevertheless believe that it is unwise to have a federal law that is so infrequently enforced. As has been observed in other contexts, rarely enforced laws can become problematic on that basis alone because they are especially susceptible to being applied in a discriminatory or arbitrary fashion.39 The potential for arbitrary or discriminatory enforcement may be all the stronger in an area like drug possession, where the overwhelming majority of defendants will find themselves in state court while an unlucky few may face more severe penalties for the same conduct in federal court.40 Meanwhile, others who oppose decriminalization may nonetheless believe that the federal government should not criminalize activity that can be (and already is) much more

38 Id.
39 See, e.g., Cass Sunstein, What Did Lawrence Hold? Of Autonomy, Desuetude, Sexuality, and Marriage, 2003 SUP. CT. REV. 27, 73 (2004) (arguing in the context of laws against sodomy that rarely enforced statutes "are a recipe for unpredictable and discriminatory enforcement . . . [and] do violence to both democratic values and the rule of law").
40 See, e.g., United States v. Clary, 846 F. Supp. 786, 788–91 (E.D. Mo. 1994) (discussing the role of prosecutorial discretion in the enforcement of federal crack cocaine laws); Steven D. Clymer, Unequal Justice: The Federalization of Criminal Law, 70 S. CAL. L. REV. 643, 668–75 (1997) (arguing that the federalization of crimes over which states also have authority results in disparate treatment because defendants fare worse when prosecuted in federal court than in state court).
efficiently dealt with by the states because doing so detracts from federal efforts to police more complex interstate crimes.\textsuperscript{41} State governments are much better equipped than the federal government to investigate and prosecute local, street-level crimes such as drug possession. Perhaps, then, federal law enforcement resources should be reserved for crimes that are more difficult for state officials to detect.\textsuperscript{42}

Whatever one's view about the appropriate role of federal law in drug enforcement, recognizing that a proposal to remove simple drug possession from federal authority is only tangentially related to the idea of "drug decriminalization" is critical if we want to achieve a more rational and constructive dialogue about federal drug laws. So long as every structural change in federal drug laws is viewed within the framework of the debate about prohibition or legalization, there will be little room for agreement and compromise. Likewise, questions that are much more relevant in the context of today's drug policy landscape—in which states are enacting and considering a diverse range of different reforms—like how to most effectively use state and federal law enforcement resources, or which policy decisions should be left to state discretion and which require uniformity across the country, will continue to be pushed to the background.

III. LEARNING FROM THE FEDERAL RESPONSE TO STATE MEDICAL MARIJUANA LAWS

A. Why the Federal Government Has Been Unable to Block State Medical Marijuana Laws

The case for moving beyond the legalization debate when thinking about federal drug laws becomes even stronger when we consider the sort of changes to state drug laws that we are most likely to see over the coming five to ten years. Among the most prominent and viable state reforms that appear to be on the horizon are the continued enactment of state medical marijuana laws and the probability that one or more states will legalize marijuana for recreational purposes. As discussed above, since

\textsuperscript{41} Cf. e.g., Stephen Chippendale, Note, \textit{More Harm than Good: Assessing Federalization of Criminal Law}, 79 MINN. L. REV. 455, 469 (1994) (arguing that "federalization of criminal law dilutes the resources of federal law enforcement agencies . . . as federal prosecutors devote their time and resources to local crimes").

\textsuperscript{42} Cf. Gonzales v. Raich, 545 U.S. 1, 57 (2005) (O'Connor, J., dissenting) ("[I]f I were a California legislator I would not have supported the Compassionate Use Act. But whatever the wisdom of California's experiment with medical marijuana, the federalism principles that have driven our Commerce Clause cases require that room for experiment be protected in this case.").
1996, fourteen states have legalized the use and, in some instances, distribution of marijuana for medicinal purposes. Similar proposals have already been introduced in the legislatures of other states\(^4\) and, unless there is a sudden reversal in public opinion on the issue, it is very likely we will continue to see more states enacting medical marijuana laws. Moreover, with proposals to tax and regulate marijuana like alcohol, and polls showing support for doing so at above fifty percent in parts of the country, a number of political observers believe we may see marijuana legalized for recreational use in one or more states within the near future.\(^4\)

As in the case of the Congressman Frank’s Personal Use of Marijuana by Responsible Adults Act, we find that the debate over prohibition and legalization is only tangentially relevant to how federal law should address these proposed state reforms. A review of the federal response to state medical marijuana laws is particularly useful to help see why this is so.

Perhaps the most significant, though largely underappreciated, lesson to be learned from fourteen years of state medical marijuana laws is that the ability of the federal government to override or interfere with state drug laws is actually quite limited. As Robert A. Mikos persuasively argues in his insightful article, *On the Limits of Supremacy: Medical Marijuana and the States’ Overlooked Power to Legalize Federal Crime*, “states [have] retain[ed] both de jure and de facto power to exempt medical marijuana from criminal sanctions, in spite of Congress’ uncompromising—and clearly constitutional—ban on the drug.”\(^5\) In other words, just as the federal government does not have the power unilaterally to legalize or decriminalize a controlled substance, it also appears unable to prevent states from doing so.

Not long after California voters enacted Proposition 215—also known as the Compassionate Use Act (CUA)—the federal

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\(^5\) See Nate Silver, *Americans Growing Kinder to Bud*, FiveThirtyEight.com, Feb. 22, 2009, http://www.fivethirtyeight.com/2009/02/americans-growing-kinder-to-bud.html (discussing polling trends on the issue of marijuana legalization). I should emphasize, of course, that it is far from certain that these reforms will occur. Predicting political shifts is always a tricky endeavor; indeed, the sudden surge in public opinion support for marijuana legalization has itself taken many political observers by surprise. But guesses at what the future may hold are a necessary part of thinking about the issues that federal officials are most likely to be confronted with in the area of drug enforcement in the coming years.

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\(^4\) See supra note 34, at 1423.
government began a vigorous effort to effectively block implementation of the law. The federal effort targeted both physicians who recommended medical marijuana to their patients and dispensaries that sought to cultivate and distribute the medicine.46 Just months after passage of the CUA, then-drug czar Barry McCaffrey announced that the administration would seek to revoke the DEA registrations of physicians who recommended medical marijuana to their patients, thereby leaving them unable to prescribe other controlled substances.47 The strategy was a smart one: because the ability to prescribe medication is necessary for a doctor to effectively practice medicine, the odds were that very few physicians would do anything that would put their DEA registration at risk.48 In a lawsuit by a group of California doctors and patients, however, the Ninth Circuit found that the DEA’s plan was unconstitutional as an infringement on physicians’ First Amendment rights because it restricted a physician’s ability to speak “frankly and openly” with their patients49 and discriminated based on the viewpoint of physicians’ speech.50 Accordingly, the Ninth Circuit enjoined the federal government “from either revoking a physician’s license to prescribe controlled substances or conducting an investigation of a physician that might lead to such revocation, where the basis for the government’s action is solely the physician’s professional ‘recommendation’ of the use of medical marijuana.”51 The ruling effectively closed the door on the federal government’s least expensive and most promising method for shutting down California’s medical marijuana law.

With its effort to target physicians thwarted, the federal government was left to focus on enforcement efforts against those involved in the medical marijuana market as the only potentially viable avenue for disrupting state medical marijuana laws. As judged by the results of court rulings, the government was far

47 See Administration Response to Arizona Proposition 200 and California Proposition 215, 62 Fed. Reg. 6164, 6164 (Feb. 11, 1997) (stating that the “DEA will seek to revoke the DEA registrations of physicians who recommend or prescribe Schedule I controlled substances”).
48 Conant v. Walters, 309 F.3d 629, 639–40 (9th Cir. 2002) (Kozinski, J., concurring) (noting that the DEA’s planned revocation policy would mean that physicians who spoke “candidly to their patients about the potential benefits of medical marijuana [would] risk losing their license to write prescriptions, which would prevent them from functioning as doctors”).
49 Id. at 636.
50 Id. at 637.
51 Id. at 632.
more successful on this front. In *United States v. Oakland Cannabis Buyers' Cooperative*, brought one year after passage of the CUA, the federal government sought an injunction under the federal Controlled Substances Act against six different medical marijuana cooperatives. The Oakland Cannabis Buyers' Cooperative (OCBC) successfully argued before the Ninth Circuit that the medical necessity defense would likely apply to their activities. This time, however, the Supreme Court reversed and held that medical necessity was not a valid defense for the manufacture and distribution of marijuana because, under the terms of the "Controlled Substance Act, the balance already has been struck against a medical necessity exception." As a result, the government was able to obtain an injunction against the OCBC and the other dispensaries.

Just four years after *OCBC*, California’s medical marijuana law was back before the Supreme Court, this time in the context of a Commerce Clause challenge. In 2002, DEA agents raided the home of Dianne Monson, a California medical marijuana patient, and seized six marijuana plants. Although the government did not bring charges against Monson, Monson, along with fellow patient Angel Raich and her two caregivers, filed suit to enjoin the DEA from enforcing the Controlled Substances Act against them for cultivating medical marijuana. The *Raich* plaintiffs relied on two recent Supreme Court decisions, *United States v. Lopez* and *United States v. Morrison*, which had restricted the federal government’s authority under the Commerce Clause. In essence, *Lopez* and *Morrison* had held that the commerce power did not extend to “noncommercial” activity, placing such activity beyond the reach of federal law. Thus, for example, the Court in *Lopez* struck down a provision of the Gun Free School Zones Act of 1990 that made possession of a gun in a school zone a federal crime on the grounds that it was not commercial activity. Raich and Monson argued that, like possession of a gun in a school zone, the cultivation of marijuana for person medical use was the sort of

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54 532 U.S. at 499 (Stevens, J., concurring).
55 Gonzales v. Raich, 545 U.S. 1, 7 (2005).
59 *Lopez*, 514 U.S. at 567–68.
noncommercial activity that fell outside the federal government's authority under the Commerce Clause.

In a familiar procedural pattern for these cases, the Ninth Circuit ruled in favor of the Raich plaintiffs and, in a 6-3 decision, the Supreme Court reversed. The Court reasoned that the regulation of the possession and noncommercial cultivation of marijuana was a necessary part of Congress' efforts to criminalize the interstate market for the drug under the Controlled Substances Act. This distinguished Raich from Lopez and Morrison, according to the majority, because the regulation of the possession and cultivation for personal use of marijuana was an "essential part of a larger regulation of economic activity, in which the regulatory scheme could be undercut unless the intrastate activity were regulated."60

Between them, OCBC and Raich left little doubt that federal officials could constitutionally prosecute medical marijuana growers, providers, and even patients themselves.61 And, throughout the past decade, the federal government enthusiastically exercised this authority, at least in California.62 It has raided at least 190 medical marijuana collectives and brought criminal charges against medical marijuana growers and collective operators,64 many of whom were operating in strict compliance with California's law. In one high profile prosecution, for example, the federal government obtained a conviction against Charlie Lynch, who operated a medical marijuana collective in Morro Bay, California. Lynch had the backing of town officials and even held a ribbon-cutting ceremony attended by the mayor and members of the city council when he opened up shop.65 At his sentencing, District Court Judge George H. Wu

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60 Id. at 561.
61 On remand, Raich pressed a substantive due process-based argument before the Ninth Circuit, claiming that she had a fundamental right to use marijuana where it could be proven that it was necessary for her life or health. This time, however, the Ninth Circuit held for the government. Raich v. Gonzales, 500 F.3d 850, 866 (2007).

For now, federal law is blind to the wisdom of a future day when the right to use medical marijuana to alleviate excruciating pain may be deemed fundamental. Although that day has not yet dawned, considering that during the last ten years eleven states have legalized the use of medical marijuana, that day may be upon us sooner . . . .

Id.

62 See O'Hear, supra note 20, at 841 (noting that the federal government has only undertaken vigorous efforts to block state medical marijuana laws in California).
63 MARIJUANA POLICY PROJECT, supra note 21, at S-1.
65 John Stossel, Andrew Sullivan & Patrick McMenamin, California Man Jailed for Medical Marijuana: Purveyor Charlie Lynch Gets a Year in Jail Though His Product is
indicated some displeasure with having to impose a one-year jail sentence for Lynch. The *New York Times* reported that Wu “talked at length about what he said were Mr. Lynch’s many efforts to follow California’s laws on marijuana dispensaries” before concluding: “I find I cannot get around the one-year sentence.”

The DEA has even gone after landlords who have knowingly rented their property to medical marijuana collective operators and growers through asset forfeiture proceedings.

Despite all of these efforts, however, the federal government has not succeeded in blocking California’s medical marijuana law. By 2009, there were an estimated 300,000 to 400,000 qualified patients under California’s medical marijuana laws. Even more telling, there were over 700 medical marijuana collectives openly distributing the medicine via storefronts. The majority of these stores, which are organized pursuant to a California statute that permits patients to associate “collectively or cooperatively to cultivate marijuana for medical purposes,” have been operating with the acceptance or even active support of city and county governments. Indeed, over three dozen cities and counties in the state have adopted ordinances to regulate the zoning and land-use permitting of medical marijuana collectives.

Perhaps because it is one of the few medical marijuana states that has allowed a distribution system to develop, California has drawn more attention from the federal government than most of the others. But, despite a dedicated

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69 *Id.*


72 *See* Mikos, *supra* note 34, at 1431–32 (discussing the differences between different states’ medical marijuana laws).

73 O’Hear, *supra* note 20, at 841 ("Except in California, it does not appear that medical marijuana has become a priority for federal enforcers.").
and sustained effort, the federal government has been unable to impede California’s medical marijuana law. Federal officials have been no more successful in stopping other states from implementing their own medical marijuana laws.\textsuperscript{74} Perhaps as a result, after a nearly fifteen year effort to stop state medical marijuana laws, the Obama Administration recently signaled a new course by issuing prosecutorial guidelines advising federal prosecutors that they “should not focus federal resources in [their] States on individuals whose actions are in clear and unambiguous compliance with existing state laws providing for the medical use of marijuana,” in part because doing so “is unlikely to be an efficient use of limited federal resources.”\textsuperscript{75}

As Robert Mikos explains, the federal government’s inability to block state medical marijuana laws results from a few different factors. First, the federal government’s limited law enforcement resources mean that it cannot arrest and prosecute more than a small fraction of collective operators and growers, let alone patients.\textsuperscript{76} Thus, although federal law may make marijuana possession, cultivation, and distribution illegal for any and all purposes, that fact has little deterrent power in states with medical marijuana laws. Unless the federal government was to radically increase both the federal drug control budget as well as the percentage of the budget devoted specifically to the prosecution of medical marijuana cases in states where the drug is legal, it can do little to change this dynamic.\textsuperscript{77} Similarly, Mikos argues that state laws hold greater sway over social norms and personal preferences than federal laws, at least in the area of drug policy.\textsuperscript{78} As a result, the existence of a federal ban does little to alter people’s personal beliefs about medical marijuana. Finally, the federal government is unable to resort to preemption to try to block state medical marijuana laws. This is because

\textsuperscript{74} Mikos, supra note 34, at 1481 (“Though Congress has banned marijuana outright through legislation that has survived constitutional scrutiny, state laws legalizing medical use of marijuana not only remain in effect, they now constitute the de facto governing law in thirteen states.”). Interestingly, federal officials in Colorado have stated an affirmative lack of interest in following the approach that their colleagues in California have taken, indicating that enforcement in this area may have been left largely to the discretion of local federal officers. Stern & DiFonzo, supra note 67, at 730.


\textsuperscript{76} Mikos, supra note 34, at 1463–67. See also supra note 35 and accompanying text (noting that while there were 754,223 arrests for marijuana possession in the United States in 2008, there were only 626 federal prosecutions for marijuana possession that year).

\textsuperscript{77} See O’Hear, supra note 20, at 863 (“Without local cooperation, tough federal policies have more bark than bite.”).

\textsuperscript{78} Mikos, supra note 34, at 1469–79.
Congress does not have the authority to tell a state what activity to make criminal—indeed, doing so would violate the anti-commandeering principle.\(^{79}\) As a result, a state's decision to remove its own sanctions for medical marijuana-related activity cannot be preempted by the federal government.\(^{80}\)

B. The Collateral Consequences of Interference

Though the federal government has not succeeded in preventing states from legalizing marijuana for medicinal use, its effort to do so has not been entirely without effect. First, federal enforcement efforts have resulted in rifts between state and federal officials that, in at least some cases, have undermined existing drug enforcement partnerships focused on issues that all would agree are far more pressing than medical marijuana. Second, every federal enforcement dollar that has been put toward interfering with state medical marijuana laws is one less dollar available for other uses. Finally, to the extent that federal arrests and prosecutions of individuals in compliance with state medical marijuana laws has had an influence on state policy, it has been to make the laws less controlled than they might otherwise be.\(^{81}\)

Federal interference with California's medical marijuana law has needlessly strained relationships between state and federal law enforcement officials. Throughout the past decade, cities across the state have lodged complaints with DEA offices about medical marijuana raids, and the California Senate even went so far as to vote twenty-three to fifteen in favor of a resolution urging the federal government to stop arresting and prosecuting individuals in compliance with the state's law.\(^{82}\) And, in at least a handful of instances, local displeasure with federal actions went beyond strongly worded letters and resulted in concrete action. In 2002, following a handful of high profile raids—including one in which thirty DEA agents burst into a medical marijuana hospice with guns drawn and arrested a wheelchair-bound patient disabled by polio—four California cities adopted "anti-DEA resolutions" to remove their police officers from DEA

\(^{80}\) Mikos, supra note 34, at 1445–60. See also County of San Diego v. San Diego NORML, 81 Cal. Rptr. 3d 461, 468 (Cal. Ct. App. 2008) (holding that federal law does not preempt California's medical marijuana law).
\(^{81}\) Because our concern here is policy effects, this list does not include what is, of course, the most direct impact of the federal government's efforts: the impact on the individuals who have been arrested and prosecuted.
joint-task forces in protest. San Jose Police Chief William Lansdowne, for example, pulled out his officers who had been assigned to the DEA’s High Intensity Drug Trafficking Area task force, saying it was “unfair to put our officers in a position of deciding how they’re going to enforce a law that’s in conflict with local law.”

It is not surprising that state and local officials would respond negatively when the DEA undertakes investigations that are intended to obstruct state and local laws. Because local and federal law enforcement partner on far weightier problems than medical marijuana, damaging that relationship in order to conduct medical marijuana arrests and prosecutions is a short-sighted approach likely to do more harm than good.

Along the same lines, in light of the fact that the federal government is unable to stop state medical marijuana laws, it is difficult to view its effort to do so as anything other than a waste of law enforcement resources. Of course, some would argue that arresting and prosecuting medical marijuana patients and providers is a poor use of law enforcement resources under any circumstance. My point here, however, is different, and should hold regardless of one’s personal views on the wisdom of state laws that permit the medical use of marijuana. Unless the federal government is prepared to marshal enough resources to block, or at least significantly weaken, state medical marijuana laws, it makes little sense to engage in a scattershot series of raids and prosecutions. Because medical marijuana collectives already operate openly and without fear of state prosecution in the states where they are legal, the remote possibility that they will face federal prosecution likely has at best an insignificant impact on the price of the marijuana that they dispense. Joseph Russoniello, the United States Attorney for the Northern District of California, announced in 2008 (prior to the Obama Administration’s memo) that even though he was personally opposed to medical marijuana his office would not be targeting medical marijuana providers for this very reason. “We could spend a lifetime closing dispensaries,” he said, but “[i]t would be terribly unproductive and probably not an efficient use of precious federal resources[.]”

Indeed, this is also the rationale

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84 It is important to note that these task forces have themselves been the subject of well grounded criticism. See, e.g., Sandra Guerra, The Myth of Dual Sovereignty: Multijurisdictional Drug Law Enforcement and Double Jeopardy, 73 N.C. L. REV. 1159 (1995).
that the Obama Administration relied on in crafting its new policy.86

Finally, to the extent that federal interference with state medical marijuana laws has created uncertainty and risk, it has only made the state laws harder to control and easier to abuse. For example, states and localities are likely to refrain from physically inspecting collectives to make sure they are run properly, or testing medical marijuana to guard against adulterants and provide dosage and potency information, out of concern that doing so would run afoul of federal law.87 Since the federal government is unable to stop the implementation of state medical marijuana laws, maintaining barriers to state controls only serves to make it easier for black market profiteers and recreational users to abuse the system.

States and cities that have considered adopting government-run medical marijuana programs provide an especially illuminating example here. New Mexico, Maine, and San Francisco have all publicly discussed the idea of adopting a government-run medical marijuana cultivation and distribution model, though none of them have done so.88 In the case of Maine, at least, the fear that the state officials who implemented the program could be federally prosecuted and the potential loss of federal grant money was central to the decision not to adopt a state-run system.89 While a state-run medical marijuana program might be a tough pill for medical marijuana opponents to swallow, it would seem to be preferable to the alternative system of privately run collectives. A state-run system would be much more closely supervised and monitored than a private system. It could provide certainty that the medical marijuana used in the program was grown by state officials and was not lining the pockets of black-market producers. A state-run system would also likely be much more effective at guarding against diversion of marijuana to recreational users. Though medical marijuana opponents would surely prefer not to have medical marijuana collectives at all, in light of the federal government's inability to stop the implementation of state medical marijuana laws, that does not appear to be an option. And, if the choice is between a state-run system or a private system, a state-run

86 Memorandum from David W. Ogden, supra note 75.
87 For example, most jurisdictions hold that holding a controlled substance in one's hand, even for a brief moment, is sufficient to sustain a conviction for possession. See, e.g., Hawaii v. Hogue, 486 P.2d 403, 406 (1971).
88 Mikos, supra note 34, at 1432 n.46 and accompanying text.
89 Id. at 1459 n.193.
system would appear to be far better from the perspective of those who favor the strictest possible control.90

In sum, the federal effort to block state medical marijuana laws has strained relationships between state and federal officials, drained federal drug enforcement resources from other priorities, and made it more difficult for state and local governments to strictly control medical marijuana operations. If the federal government is unable to stop or seriously disrupt state medical marijuana programs, opponents of medical marijuana should want to incentivize states to enact stricter controls. A system of minimal enforcement, however, produces the opposite result. Absent a Machiavellian hope that poorly regulated state medical marijuana laws will make them less appealing and result in their repeal, it is difficult to see the benefit of putting roadblocks in the way of strict state regulation, particularly from the prohibitionist perspective.

I want to emphasize that my chief goal here is not to persuade the reader that the federal government should not interfere with state medical marijuana laws per se. This discussion is meant to demonstrate why, when thinking about federal responses to state reforms, we must be careful not to view federal drug law as a simple referendum on the state's law. Reducing the problem of how federal law should approach state medical marijuana laws to whether or not one personally supports medical marijuana only makes sense if the federal government is able to block the state laws. And, as the federal response to medical marijuana shows us, the federal government may actually have very little ability to prevent states from implementing laws that are at-odds with federal policy.

IV. THE WAY FORWARD: FOCUS ON CONTROLLING, NOT BLOCKING, STATE POLICY INNOVATIONS

Up until this point, this article has focused primarily on advancing the argument that debates about whether to legalize marijuana or allow the use of medical marijuana do not reflect the considerations that should guide decisions about federal drug laws. This is because the federal government does not have the resources or ability to control state policy when it comes to drug

90 Similarly, while the threat of federal prosecution is too improbable to keep medical marijuana dispensaries from operating openly in storefronts throughout California, it may be sufficiently strong to dissuade some risk-averse and law-abiding people from operating a collective, thereby leaving room for risk-seeking individuals to step in. Of course, this may be counter-balanced by the fact that the collective operators themselves may be patients who are willing to risk prosecution based on their belief in the cause of medical marijuana.
laws. This is true both for proposals to ease the drug laws, such as Barney Frank’s decriminalization bill, and for efforts to block states from reforming their own laws, like the federal effort to undermine California’s medical marijuana law. In this section, I will briefly explore what this insight might mean for how the federal government should approach drug enforcement, and in particular, respond to state reforms. I will argue that the dynamic discussed above counsels in favor of enacting federal laws that respect states’ autonomy to enact their own drug laws—even where state laws conflict with federal preferences—but also provide important controls and incentives to prevent against negative externalities in the form of spillover effects in neighboring states. This outlook is similar to the “competitive alternative” model advanced by Michael O’Hear in Federalism and Drug Control.91 The insights above, however, provide even greater support for such a model, particularly for those who may be opposed to state reforms on their own merits.

As an initial matter, even if we were to put the limitations of federal power in this area aside, the results of the last four decades weigh strongly in favor of encouraging states to innovate and try new approaches. With more teens reporting that it is easier for them to buy marijuana than alcohol92 and nearly three times as many American teens having tried the drug than in the Netherlands where it is openly bought and sold, there is every reason to believe that we could be achieving the same, and likely better, results than we are now, at a lower human and financial cost. While this much seems clear, opinions vary widely as to exactly what the best alternative might be.93 Accordingly, allowing for the maximum possible amount of local and state innovation and diversity in the field of drug laws would better enable us to explore various policy alternatives in the service of achieving a more rational and cost-effective set of drug policies.94 After all, with seventy-five percent of Americans in agreement

91 O’Hear supra note 20, at 873–81 (proposing a “competitive alternative” model of federal and state interaction in the area of drug enforcement).

92 NAT’L CTR. ON ADDICTION AND SUBSTANCE ABUSE, NATIONAL SURVEY OF AMERICAN ATTITUDES ON SUBSTANCE ABUSE XIII: TEENS AND PARENTS 17 Fig.3.P, available at http://www.casacolumbia.org/ articlefiles/380-2008%20Teen%20Survey% 20Report.pdf (showing that twenty-three percent of teens say marijuana is the easiest drug for them to buy, while only fifteen percent say beer is the easiest).

93 See, e.g., O’Hear, supra note 20, at 873 (“Given this diversity of options and the localized nature of the harms flowing from drug use, there seems to be little reason to deny different communities the opportunity to select their own policy responses.”).

94 Id. (“Decentralized policymaking . . . carries the ancillary benefit of promoting the sort of policy innovation and real-world testing that may contribute to resolving some of the longstanding theoretical and empirical disputes in the field.”).
that the war on drugs strategy has failed, and a wide range of policy options for reform, drug policy would appear to be a particularly appropriate area for maximizing the benefits of our federal system.

Even for those who would prefer not to allow states to enact reforms such as legalizing medical marijuana, however, there is much to be said in favor of a decentralized approach. This is because the experience of state medical marijuana laws reveals that the federal government simply may not be able to prevent states from implementing drug laws that are at odds with federal policy. By coming to terms with the limits of its authority, the federal government could actually achieve greater influence over state reforms than it has now. For example, instead of preventing states from directly cultivating and distributing medical marijuana as federal law does now, federal elected officials might consider providing an incentive for states that implement medical marijuana laws to make them state-run. This change could be easily achieved by expanding a provision of the Controlled Substances Act that grants immunity to state and local officials who are "lawfully engaged in the enforcement of any law or municipal ordinance relating to controlled substances." Courts have interpreted the provision to grant immunity from federal prosecution to officers who violate the drug laws while working undercover, but not to officials who are engaged in the implementation of state and local medical marijuana laws. If the provision were extended, however, to explicitly include state and local government officials implementing their own laws, even where they otherwise conflict with federal law, then states and localities that enact reforms would have a strong incentive to adopt a government-run model. This would likely result in reforms that are more limited and strictly controlled than those arising in a private system. As a result, state reforms would be better controlled and less likely to

95 See supra note 19 and accompanying text.
96 For a discussion of the potential for state reforms to result in spillover effects in neighboring states, see O'Hear, supra note 20, at 868–72.
97 See Mikos, supra note 34, at 1458 (discussing this aspect of federal law).
98 For a discussion of the current interpretation of this provision, see id. at 1457–59.
99 See, e.g., id.; United States v. Rosenthal, 454 F.3d 943, 948 (9th Cir. 2006) (holding that an Oakland immunity statute could not shield a defendant from prosecution for ensuring legal distribution of marijuana). For an argument that the plain language of the provision as written should provide immunity to individuals engaged in implementing medical marijuana laws, see, for example, Reply Brief of Appellant at 2–6, United States v. Oakland Cannabis Buyers’ Coop., 259 Fed. App’x 936 (9th Cir. 2007) (No. 05-16466) (arguing that the plain meaning of “enforce” extends beyond compelling compliance with a law and includes giving effect to a law).
result in spillover effects in neighboring states. Similarly, the federal government might consider adopting a policy permitting state and local governments to implement laws that are at odds with the federal prohibitionist preference if they pay a fee from their revenues to a fund that would help defray such spillover costs. One can easily imagine a range of other possible changes to federal law along these lines, and my aim here is not to advocate for any one proposal specifically. Instead, my claim is that by abandoning a futile effort to stop states from implementing their own reforms entirely, the federal government could enact policies that might result in more constrained and limited state reforms.

To be sure, this approach would not fully satisfy those who think that the federal government should dictate state policy or who believe the federal government has a moral imperative to maintain a strict prohibitionist approach regardless of its actual impact. But I would urge those who find these ideas hard to stomach to give serious consideration to whether it would be wise, or even feasible, for the federal government to devote the amount of resources that would be necessary to have even a realistic chance of actually blocking state reforms. The experience to date with state medical marijuana laws indicates that the federal government would need to expend significant amounts of money and law enforcement energy to have even a remote chance of preventing the implementation of state reforms. If a state sought to legalize, say, methamphetamine, then perhaps the argument for marshalling the necessary resources would be compelling. But, when it comes to medical marijuana, or even state proposals to legalize marijuana outright, it seems much more difficult to justify the costs that would be required for the federal government to have even a remote chance of blocking the state reform.

To state the issue somewhat differently, once a state has enacted a law legalizing medical marijuana, the law's opponents have nothing but second-best options. Short of repealing the state's law, the only recourse for the law's opponents is federal law. But at this stage, the calculus is much more complex than whether or not one agrees with the state's law on its own terms. If the federal government is capable of blocking implementation of the state's law, then opponents of the law should naturally and logically see that as the best strategy. But what if the federal government is simply unable to block or even to significantly interfere with the state's law? Would opponents of the law be better served by a haphazard series of federal prosecutions, or by
changing federal law to explicitly permit the state reform but strictly control it?

These are the sorts of questions that federal drug policy will need to address in era of state reform. To date, however, this nuanced view of federal drug law has been almost completely overlooked in favor of a stale and increasingly irrelevant debate. On a related note, the dynamics of state reform also weigh in favor of a broader re-examination of the federal role in drug enforcement, with an eye toward targeting specialized federal resources in areas where they can have the greatest impact. Arguably, many federal trafficking prosecutions today do not fall into the category of offenses that truly require federal attention. A 2007 U.S. Sentencing Commission report, for example, found that 61.5 percent of crack offenders and 53.1 percent of powder cocaine offenders could be classified as low or mid-level offenders—such as couriers, street dealers, or lookouts. These numbers raise serious questions about the current allocation of federal resources in drug enforcement. Even assuming that going after lookouts and other street level offenders is an efficient use of federal dollars, however, it is very difficult to formulate a good justification for the federal government to concern itself with the simple possession of personal-use amounts of a controlled substance. Indeed, the Office of National Drug Control Policy has made it a point to emphasize that the federal government rarely targets drug users, especially marijuana users. Statistics that indicate only about 1,000 drug possession cases were disposed of at the federal level in 2008 confirm that the federal government is simply not well positioned to directly respond to such a localized problem. Since that is the case, there is a strong argument for doing away with federal laws against simple possession of small quantities for all drugs, not because drug decriminalization is necessarily a better policy than prohibition, but because there is little upside and much potential downside to having a federal law that is so rarely enforced and duplicative of state and local efforts. Doing so would have the added benefit of allowing states to implement reforms in areas that might involve simple possession—such as state medical marijuana laws—outside of the shadow of conflicting federal law.

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100 U.S. SENTENCING COMM’N, COCAINE AND FEDERAL SENTENCING POLICY 19 Fig. 2-4 (2007). Similarly, a 1994 Department of Justice report found that 36.1 percent of all federal drug offenders were “low-level” offenders under the Department’s own criteria and that these offenders received an average prison sentence of 25.1 months. The 1994 report did not include mid-level offenders. U.S. DEP’T OF JUSTICE, AN ANALYSIS OF NON-VIOLENT DRUG OFFENDERS WITH MINIMAL CRIMINAL HISTORIES 2–3 (1994).
101 See OFFICE OF NAT’L DRUG CONTROL POLICY, supra note 36 and accompanying text.
This brief discussion is intended only as an overview of the types of reforms that the federal government might examine in an environment where states are adopting laws that are at-odds with federal preferences. These are, of course, only a few of the many possible options that the federal government might consider implementing. My purpose here is not to endorse one specific proposal or another, but to argue that, as states adopt new drug policies, and as support for alternatives to the drug war strategy increases at the federal level, the federal government should carefully consider the merits of policies that respect state policy choices but also provide incentives for states to closely regulate and control any reforms they might enact.

**CONCLUSION**

This essay considers the question of how to think about federal drug laws in a post-drug war era—one in which states are enacting reforms that are at odds with stated federal policy. My approach here has been, by design, limited and focused. I have, for example, omitted some of the most important proposals for reforming federal drug laws, such as reforms that would reduce the severity of federal sentences for low-level drug offenders. Instead, this essay seeks to examine possible reforms that relate to the role of federal law in shaping and enforcing our drug policies.

The discussion reveals the importance of cutting through the debate about prohibition and legalization when thinking about federal drug laws. By looking at a proposal in Congress to "decriminalize" marijuana, we find that the federal government could not unilaterally legalize or decriminalize a drug even if it wanted to. As a practical matter, if the federal government were to remove federal penalties for possession of small amounts of marijuana, the result would not be nationwide decriminalization but a shift in at most 600-odd defendants from federal to state courts. This is in large part because, even in an age of unprecedented federal involvement in criminal law enforcement, states still arrest and prosecute far more offenders than the federal government. For this same reason, the federal government may be unable to stop states from enacting reforms like the legalization of medical marijuana, even though they are inconsistent with federal policy.

102 For some additional proposals along these lines, see O'Hear, *supra* note 20, at 873–81.
The federal government cannot legalize marijuana on its own, but it also cannot stop a state from doing so.103 As a result, if we approach proposals to reform federal drug laws from the prohibition/legalization framework, we will be asking the wrong questions. Instead, we would be much better served by thinking about these issues in terms of the role of federal government in light of state laws. This is not only a more accurate way to look at issues like how the federal government should respond to state medical marijuana laws, but it also has the potential to help begin to bridge the divide in what is often a polarizing debate.

103 See O'Hear, supra note 34, at 788 ("Rather than acting as a dictator of state policy, the federal government exercises, at most, a loose control over the general direction taken by lower levels of government.").
Defining the Opioid Epidemic: Congress, Pressure Groups, and Problem Definition

TALEED EL-SABAWI*

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I. Introduction

The United States has a drug problem—a drug problem that is characterized by high rates of opiate overdose deaths\(^1\) and a drug problem to which people commonly refer as the “Opioid Epidemic.” The Opioid Epidemic has resulted in an increase in popular, political, and scholarly focus on the ineffectiveness of the U.S.’s criminal justice, or punitive legislative approach,\(^2\) to problem drug use.\(^3\) The Opioid Epidemic has also led to an increased focus on the need for Congress to embrace a health approach\(^4\) in addressing problem drug use,\(^5\) an approach that emphasizes the prevention and treatment of addiction. U.S. legislators have responded by distancing themselves from blatant punitive policies of the past and adopting health-oriented definitions of problem drug use that support health-oriented legislative proposals.\(^6\)

\(^1\) Opioid overdose deaths have been rising for at least 16 years, with the number of deaths each year equaling a new historic high. See Opioid Overdose, CTRS. FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/drugoverdose/data/index.html (last updated Jul. 18, 2017).

\(^2\) Although at times the criminal justice and punitive approach may seem interchangeable, the criminal justice approach, by my definition, also includes proposals to administer drug treatment through the criminal justice system. Some may consider such mandatory treatment punitive, while others may argue that it is still a health solution. I would categorize it as a criminal-justice approach, as it uses the criminal justice system to administer it.

\(^3\) Throughout this paper, I use the term “problem drug use” to refer to any drug use that interferes with the ability of the user to meet his or her societal, educational, and occupational obligations. I adopt a similar conceptualization of problem drug use as Anderson, et al., in that I believe problem drug use is “habitual, heavy consumption of something pleasurable”. See Peter Anderson, Jürgen Rehm & Robin Room, The Impact of Addictive Substances and Behaviours on Individual and Societal Well-Being, 38, (2015) [hereinafter ANDERSON ET AL.].

\(^4\) Through the use of cluster analysis of components of European drug policy systems, Ysa and colleagues were able to identify three main approaches to drug policies: a punitive approach, an assistance approach, and a public health approach. Tamiko YSA ET AL., GOVERNANCE OF ADDICTIONS: EUROPEAN PUBLIC POLICIES, 3 (2014). The assistance approach is an approach that treats problem drug use as a disease that necessitates treatment. This is differentiated from a public health approach that emphasizes harm reduction. YSA ET AL., supra note 3, at 4. Throughout this Article, I use the term “health approach” to characterize the U.S. drug policy system, which blends Ysa et al.’s assistance approach with some conservative public health solutions, including education, expanding access to medication-assisted treatment (“MAT”), overdose-reversal medications, and needle-exchange programs. Unfortunately, the support for public health solutions in the U.S. is half-hearted. For example, the U.S. has alternated between federal support for and banning of needle-exchange programs. Syringe Services Programs, CTRS. FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/hiv/risk/ssps.html (last updated Feb. 28, 2018). Even when support for federal funding for needle-exchange programs has existed, federal law only permits use of funds to staff the program and not to purchase the clean needles. Id.

\(^5\) The reasons that advocacy for a health approach has increased for this drug epidemic, while it was absent from previous epidemics, is beyond the scope of this manuscript.

\(^6\) Admittedly the Trump administration’s recent decision to rescind Obama-era policy and once again mobilize federal law enforcement agents to prosecute possessors of marijuana, even in states that have chosen to decriminalize or legalize certain recreational drug use, Memorandum from Jefferson B. Sessions, III., Office of the
Congress has also demonstrated a willingness to use the health approach to address the current Opioid Epidemic by passing the Comprehensive Addiction and Recovery Act of 2016 (“CARA”), health-oriented legislation that Congress drafted and enacted with nearly unanimous bipartisan support and later funded with equal legislative enthusiasm. In doing so, some members of Congress explicitly supported the definition of addiction as a brain disease, as opposed to a moral failing. And defining addiction as a disease, instead of a moral failing, begs a health solution, as opposed to a criminal justice solution.

The increased public and political attention on the issue of drug use and the supportive political climate for a health approach to the Opioid Epidemic have created a political window of opportunity for legal scholars, professionals, researchers, and other concerned citizens to

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7 There are provisions in CARA, however, that do not fit squarely within the criminal justice vs. health dichotomy. For example, CARA emphasizes the need for states to develop prescription monitoring programs to identify prescribers that may be responsible for prescription drug diversion. Comprehensive Addiction and Recovery Act of 2016, Public Law No: 114-198 S. 524 § 601(b). Law enforcement would then have access to these prescription monitoring systems and use the intelligence it provides to criminally prosecute prescribers. Such a supply-side solution runs counter to the demand-side focus typically accompanying a health approach.


11 I use the term “solutions” throughout this manuscript to refer to legislative or administrative policy alternatives or proposals. Although such proposals rarely solve a policy problem in its entirety, lawmakers propose them with the hopes that they are at least partial solutions to the problem. DEBORAH A. STONE, POLICY PARADOX AND POLITICAL REASON (2011). Punitive solutions are those that apply a penalty to a behavior in order to punish and deter the behavior. Id. In the arena of drug policy, supply-side solutions are those focused on decreasing the drug supply and typically involve controlling domestic sale of the drug as well as disrupting the supply from the country of origin. YSA, supra note 4, at 17. Demand-side solutions, on the other hand, decrease the demand for the drug typically through treatment and prevention efforts. Id. at 17.

12 Dr. Kingdon argues that, for an issue to make it to the political agenda, there must be a window of opportunity that occurs when three streams align: the problem stream, the policy stream, and the politics stream. JOHN W. KINGDON, AGENDAS, ALTERNATIVES, AND PUBLIC POLICIES (1984). The problem stream includes social issues that may or may not currently be on the public’s agenda. Id. The policy stream includes legislative proposals, or as I
pressure legislatures and administrative agencies to shift their focus from criminal justice legislative proposals to evidence-based public health proposals. Such public health proposals emphasize harm reduction, access to quality treatment, and the amelioration of the socio-economic risk factors that increase the likelihood of problem drug use.

To effectuate such a policy change, however, concerned citizens must understand the problem definition process and the role that groups play in redefining a problem. Problem definition is the part of the lawmaking process during which actors within the political sphere describe the causes of a problem and the solutions lawmakers should use to address the problem. A rhetorical tool that policy actors commonly use to persuade others in the problem definition process is the causal narrative, a story that identifies the cause of the policy problem, assigns benefits and blame, and limits the alternative legislative solutions. Because policy actors may use different causal stories to define the same social problem, narratives battle to be accepted as the dominant causal story. It is this precise battle between narratives that is at the heart of the lawmaking process. Narrators, including pressure groups, organized interest

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13 Harm reduction approaches focus on reducing the social, economic, and health harms of drug use, as opposed to focusing on user abstinence. YSA, supra note 4, at 5-6. Analysts measure success by the reduction of these harms, as opposed to abstinence of drug use. Id. at 5-6. For examples of harm reduction policies used by European nations, see id. at 34-35, 42-43.

14 The public health approach to improving access to treatment includes not only ensuring that there are enough treatment providers to provide the care, but also that the individual has transportation to get to appointments, the appointments are available during non-work hours, and the individual has the ability to pay for care. Access to Health Services, OFFICE OF DISEASE PREVENTION & HEALTH PROMOTION, https://www.healthypeople.gov/2020/topics-objectives/topic/Access-to-Health-Services.


16 STONE, supra note 13.

17 Id.
groups, and administrative agencies (collectively, “pressure groups”) compete for the opportunity to contribute a problem definition to the discourse. Each narrator hopes that their problem definition will become the dominant problem definition, because the group that dominates the problem definition discourse has the power to limit the alternative solutions available to a policy problem.

Although some scholars and researchers may view the involvement of organized interest groups in the legislative process as a threat to the development of evidence-based policy, our Founding Fathers chose to design a government that permits and even encourages majoritarian pluralism. Majoritarian pluralism encourages governments to consider the preferences of groups that represent the interests of factions of its citizenry. Lawmaking in such a system does not exclude experts from the legislative process. Scholars, researchers and professionals can affect policy change even when lawmakers do not call on them individually for expert testimony. They can push for reform by mobilizing into groups and contributing to the problem definition discourse—by insisting that group leaders advocate for the adoption of new causal narratives; swaying the public to adopt their desired causal stories; calling upon group members

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18 Organized interest groups include citizen groups, trade and business associations, business corporations, professional associations, coalitions on specific issues, unions, foundations and think tanks, governmental associations, and institutions and associations of institutions.
19 ROCHEFORT & COBB, supra note 17. STONE, supra note 13.
20 Id.
22 See THE FEDERALIST No. 10. (James Madison).
23 Majoritarian pluralism can be traced back to James Madison’s Federalist Paper No. 10, in which he referred to diverse “factions” representing the interests of groups of citizens. Although some scholars believe that “factions” could have referenced both parties and organized interest groups, I would argue that Madison’s use of the word “parties” just a few paragraphs before his definition of factions implies that he intended for factions to refer to interest groups. See e.g., Martin Gilens & Benjamin I. Page, Testing Theories of American Politics: Elites, Interest Groups, and Average Citizens, 12 PERSPECTIVES ON POL., 564–81 (2014) (arguing factions could have referenced both parties and interest groups). “By a faction,” Madison writes, “I understand a number of citizens whether amounting to a majority or a minority of the whole, who are united and actuated by some common impulse of passion, or of interest, adverse to the rights of other citizens, or to the permanent and aggregate interests of the community.” THE FEDERALIST No. 10, at 1 (James Madison).
to pressure legislators to adopt their narrative through the use of strategically crafted emails, letters, and phone calls; and promoting their narratives at town halls or Congressional field hearings.

This Article purports to equip legal scholars, researchers, and all concerned citizens with a greater understanding of the legislative problem definition process and the role that pressure groups play in such a process. By referencing examples from drug policy history, this Article demonstrates how pressure groups strategically used problem definitions to shape legislative discourse and pressured Congress into supporting legislative solutions that aligned with their problem definitions—attributing addiction to disease at times and to deviancy at other times. Through the analysis of such examples, this manuscript outlines strategies that legal scholars, researchers, and concerned citizens can use to define problem drug use as a public health issue caused by multiple sociological, psychological, economical and biological factors.

Part II of this Article provides readers with an introduction to the problem definition and policy narrative literature, starting with a general background on its philosophical roots and then explaining how pressure groups use narratives to influence the problem definition process. Part III, then, provides evidence to support the claim that pressure groups affect the legislative decision-making process, primarily through the subject-matter expertise that they provide to legislators. Part IV explains, by use of both hypothetical and historical examples, how groups construct narratives. This part is by no means a complete historic account of all instances in which lobbying groups effectively utilized narratives to further their objectives, nor is it a complete history of drug policy in the U.S. I chose to focus my analysis on time periods during which the health vs. criminal justice narrative battle dominated policy discourse. Part V highlights pivotal times in early U.S. drug policy during which pressure groups defined or
redefined problem drug use as either a health problem or a criminal justice problem. Finally, Part VI concludes with lessons learned from the analysis of narrative use by pressure groups and outlines recommendations for problem definition strategies that legal scholars and professionals can use to further their policy objectives in drug policy debates and beyond.

II. PROBLEM DEFINITION & POLICY NARRATIVES

Problem definition theory is rooted in the epistemological belief of social constructivism, which theorizes that society makes sense of the world around it through shared interpretation and meaning.24 The “Truth,” or absolute reality, may or may not exist; but rather than focusing on compiling evidence or facts that attempt to represent this absolute reality,25 the constructivist focuses on uncovering how society interprets reality. Such an interpretation and assignment of meaning is what influences societal values, beliefs, actions and inaction.26 Policymaking then becomes “[the] struggle over alternative realities.”27

Problem definition²⁸ scholars apply this knowledge-seeking theory to studying how the political process defines social problems.²⁹ Problem definition theorists believe that people

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²⁴ Epistemology generally refers to theories of knowledge gathering or philosophy of knowledge. FRANK FISCHER, REFRAMING PUBLIC POLICY: DISCURSIVE POLITICS AND DELIBERATIVE PRACTICES (2012).
²⁵ Such a knowledge-seeking expedition runs counter to the mainstream scientific philosophy referred to as positivism, or its more modern counterpart post-positivism, which posits that there is an objective reality that we are trying to measure. FISCHER, supra note 26. Within this model, the observer stands at an arm’s length, with a validated measuring stick, and a statistical arsenal with the objective of proving or disproving a hypothetical truth in the form of a hypothesis. Id.
²⁶ Id.
²⁷ Rocheft and Cobb, supra note 17, at 9.
²⁸ Problem definition has different names, depending on the discipline: “problem framing” or “frames” in sociology, communication, and political science, or “policy narratives” in the narrative literature of policy studies. See, e.g., Rocheft and Cobb, supra note 17. David A. Snow & Robert D. Benford, Ideology, Frame Resonance and Participant Mobilization, 1 INT’L SOC. MOVEMENT RES. 197, 197–218 (1988). Because “framing” refers to a variety of constructs, I will use “problem definition” throughout this Article to refer to act of defining a social problem, with the caveat that different disciplines refer to the same construct by different names.
²⁹ Social problems are a “shared understanding of some problematic condition or situation they define as in need of change, make attributions regarding who or what is to blame, articulate an alternative set of arrangements, and urge others to act in concert to affect change.” Snow & Benford, supra note 30, at 615. A social problem differs from a policy problem because a social problem does not become a policy problem until it “gains attention and legitimacy” and lends itself to an “official programmatic response.” Rocheft and Cobb, supra note 17, at 8.
contest and debate social problems in the political sphere based on their perceptions of what the problem is, but one can always contest these perceptions.\textsuperscript{30} I will demonstrate this to be true in the arena of drug policy through examples of competing problem definitions at different junctures in history.

Accepting that problem definitions are contestable is not to say that they are not at all grounded in evidence. Rather, it is an acknowledgement that other factors, aside from empirical evidence, contribute to the manner in which society defines problems. These other factors include “[c]ultural values, interest group advocacy, scientific information, and professional advice.”\textsuperscript{31} People use evidence, facts, and scientific studies to justify or support a narrative. Often, however, problem definition narrators choose the evidence selectively, giving preference to evidence that supports their preferred causal narrative, while discounting, omitting, or ignoring conflicting evidence.\textsuperscript{32} Therefore, evidence is used as one of the many tools of narrative persuasion.

Although different tools are used in the problem definition process, I will focus on the use of policy narratives or stories, as well as the use of synecdoche in these narratives.\textsuperscript{33} Policy narratives “are a way of structuring and communicating our understanding of the world.”\textsuperscript{34} They resemble fictional narratives in that they have characters, a plotline, an ending, and a relatively consistent structure.\textsuperscript{35} Unlike fictional narratives, however, policy narratives require a higher standard of believability, and society judges them as real depending on how believable or

\textsuperscript{30} Id. at 8.
\textsuperscript{31} Id. at 4.
\textsuperscript{32} Id. at 15–24; STONE, supra note 13, at 311-330
\textsuperscript{33} There is disagreement in the policy narrative literature on whether policy narratives and policy stories are the same construct. See SHAUL R. SHENHAV, ANALYZING SOCIAL NARRATIVES (2015). For the purposes of this Article, I will use the terms interchangeably.
\textsuperscript{35} STONE, supra note 13, at 158; SHENHAV, supra note 35, at 35.
credible they appear to be. Narrators can gain credibility through the use of experts or with scientific evidence. Believability, however, depends on the degree to which the narrative resonates with cultural and societal norms, the familiarity of the plotline, and the degree to which the character descriptions coincide with the audiences’ perceptions of that character from their life experiences and encounters. Many of these recycled plotlines apply to different social problems over time, especially because familiar policy narratives tend to be more convincing to legislatures, administrative officials, and the public. These policy narratives are important in that they affect perceptions of the trade-offs between legislative alternatives.

The causal story is type of policy narrative used in legislative discourse. Causal stories describe the cause of the problem, assign blame, and suggest burden and benefit allocations depending in part on the blame assignment and the social construction of the target population that the legislative solution affects.

These stories often identify the actors of the story as either heroes or villains, innocent or guilty, or strong or weak, and they describe the cause of the phenomenon as action or inaction by these characters. Narrators in the legislative discourse use these causal as tools of persuasion to further their legislative objectives.

36 FISCHER, supra note 26, at 177-178.
37 FISCHER, supra note 26, at 177-178; ANNE LARSON SCHNEIDER & HELEN INGRAM, POLICY DESIGN FOR DEMOCRACY (1997).
39 For examples of common plotlines, see STONE, supra note 13, at 168-175
40 FISCHER, supra note 26.
41 STONE, supra note 13.
42 Martin, supra note 41, at 6.
43 In general, the social construction of target populations refers to “the cultural characterizations or popular images of the persons or groups whose behavior and well-being are affected by public policy.” Anne Schneider & Helen Ingram, Social Construction of Target Populations: Implications for Politics and Policy, 87 Am. Pol. Sci. Rev. 334, 334 (1993).
44 STONE, supra note 13, 157-182. SCHNEIDER & INGRAM, supra note 39, at 334.
45 Helen Ingram, Anne L. Schneider, & Peter Deleon, Social Construction and Policy Design in Theories of the Policy Process, (Sabatier, 2007); STONE, supra note 13, at 158.
The narrators, or storytellers, in the legislative discourse can include, but are not limited to, administrative officials, legislators, and organized interest groups. Administrative agency officials use causal stories to convince the legislature that a social issue within their subject-matter expertise is a policy problem that Congress should prioritize. Administrative officials also use causal stories to justify rules and regulations that they promulgate in carrying out their duties of enforcement and implementation of legislation. Legislators use causal stories to persuade colleagues to adopt certain legislative solutions and garner constituent support on issues and proposals. Organized interest groups use causal stories to persuade legislators and administrative officials to adopt legislative and regulatory proposals that benefit their members. Even the judiciary uses causal stories to justify their interpretation of legislative intent. Although multiple actors are involved in the narrative discourse, in this Article I focus on how pressure groups participate in the legislative narrative discourse and influence the types of solutions available to legislators. In order to do so, I begin by presenting evidence that supports the contention that pressure groups influence legislative decision-making and then I explain how they use narratives to do so.

III. PRESSURE GROUPS & LEGISLATIVE INFLUENCE

46 See Part III.B, for examples of narrative use by the Narcotics Bureau to justify the war on drugs and the need to continue their efforts in addressing the drug problem using a law enforcement approach.
47 For example, from the 1970s to the 1990s, the Social Security Administration supported the causal narrative that addiction was a disorder that resulted in a disability. See Max Selver, Disability Benefits and Addiction: Resolving an Uncertain Burden, 91 N.Y.U. L. Rev. 954, 988 (2016). This interpretation allowed individuals with addiction to qualify for Social Security Income benefits. Id.
48 For example, in advocating for the passage of CARA, Senator Robert Portman defined addiction as a chronic disease of the brain. Portman, supra note 12.
49 See e.g., Part IV.D. (discussing how the Parents Group’s use of causal narratives to shift government focus and resources to protecting their children from the temptations of marijuana).
50 See e.g., Daniel Polisar & Aaron Wildavsky, From Individuals to System Blame: A Cultural Analysis of Historical Change in the Law of Torts, 1 J. of POL’Y HIST. 2 (1989) (chronicling how judges defined the problems presented in tort litigation differently over time to accommodating changing public and cultural views on who should be blamed and benefited by tort litigation).
Organized interest groups battle for legislator time and attention so that they can have the opportunity to define problems that affect their members. Administrative agencies also engage in the legislative problem definition process by issuing government reports that outline the cause and scope of public problems and by testifying in front of Congress. By defining the problem, pressure groups can influence legislative outcomes. Although throughout this paper I often refer to both organized interests and administrative agencies collectively as pressure groups, I will review the evidence for organized interest group and administrative agency influence on legislative decision-making separately, because the legislative behavior literature often treats these two groups separately in their analysis.

A. Organized Interests’ Influence on Legislators

Researchers have long hypothesized that organized interests influence legislative decision-making by providing legislators with financial contributions. Politicians need such

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53 In the arena of drug policy, government reports have been very influential in focusing the public’s attention on the nation’s drug problem and in enumerating the magnitude of the problem, usually through reports of increases in the number of persons using illicit substances, persons addicted to illicit substances, or persons overdosing from illicit substances. In Gonzenbach’s analysis of 15 years of U.S. drug policy, the attention cycle for each episode of nationwide problem drug-use began with a federal agency releasing a report publicizing an increase in drug use, after which the media began covering the nation’s drug problem, and then public concern over the nation’s drug problem increased. William J. Gonzenbach, The Media, the President, and Public Opinion: A Longitudinal Analysis of the Drug Issue, 1984-1991 (1996). Public attention would fade, however, even if the problem drug use remained at the same rate. Id. It was not until a government agency released another report that the media, and then the public, would once again pay attention to problem drug use. Id. The order in which this occurred suggests that government reports shape the media’s perception of drug problems.

54 Harry Anslinger was famous for his fiery testimony in front of Congress on drug issues while he was director of the Narcotics Bureau. He preached fire and brimstone for the deviants who used and sold drugs and members of Congress deferred to his judgment. David T. Courtwright, Dark Paradise: A History of Opiate Addiction in America 1–100 (2001); David F. Musto, The American Disease: Origins of Narcotic Control 1–100 (Oxford Univ. Press 3rd ed. 1999) (1973).


campaign funds to pay for advertisements, among other costs, that increase the likelihood that voters will elect the candidate. It reasonably follows that legislators may pay special attention to interest groups that donate to their campaign. As logical as such a deduction may be, the empirical literature, to date, has not been able to find a consistent relationship between campaign contributions and legislative outcomes. Researchers, however, have found that legislators are more likely to meet with groups that donate to their campaign. This indicates that what groups might be buying with their campaign contributions is not necessarily a legislative outcome, but rather, a legislator’s time. Getting some focused time and attention from a legislator allows the group to use that time to define policy problems and try to narrow legislative solutions. In sum, the body of research suggests that, although campaign finance may influence legislative outcomes, it does not provide a reliable predictor of how or why interest groups influence legislators’ decision-making processes.


58 Scholars have also hypothesized that legislators pay special attention to campaign contributors that donate to other legislators’ campaigns in the hopes that these donors will donate funds to their campaign in the future. Kalla & Broockman, supra note 54, at 545–46.

59 Beth L. Leech, Lobbying and Influence, in THE OXFORD HANDBOOK OF AMERICAN POLITICAL PARTIES AND INTEREST GROUPS 534-51 (L. Sandy Maisel & Jeffrey M. Berry eds., 2010). Political scientists also hypothesize that organized interests are influential because they have information on the preferences of their members and can mobilize their members to vote for a legislator. Id. However, the empirical evidence justifying such a claim is weak. See, e.g., id. at 546 (which found only interest groups used arguments that were “electoral in nature” only 3% of the time).

60 Kalla & Broockman, supra note 54, at 546.

61 See id. at 547.

62 Id. Leech also notes that interest groups may use their influence to affect which issues get on the political agenda. Leech, supra note 62. For a legislative outcome to be possible, an issue must first get on the political agenda and be deemed worthy of attention by legislators. Id. By preventing issues from ever getting on the political agenda in the first place, groups can block legislation from being introduced on the issue. Id. It is difficult to measure how many issues do not make it on the agenda and why they do not make it on the agenda, so most research on interest group influence has focused on counting yes or no votes on legislation that has made it through the many hurdles necessary to reach a floor vote. Id.
Interests groups, however, have other resources that they can provide to legislators, aside from dollars and votes—resources that may allow them to otherwise influence legislative decision-making. Interest groups offer subject-matter expertise and specialized information that allow legislators to make informed decisions on issues without incurring the costs for compiling such information. Additionally, advocacy or citizens groups can publish reports on an issue that the public and media find trustworthy and convincing. If such a report aligns with a legislator’s narrative on an issue, the report provides external validity to his or her claims. It is when groups offer this “legislative subsidy” that they are in a prime position to use their research and subject matter expertise to justify a particular problem definition.

B. Administrative Agency Influence on Legislators

Federal, state, and local administrative agencies are another source of specialized information for legislators. These agencies are often privy to data and statistics that measure the type, scope, and cause of a problem. Since legislatures charge administrative agencies with the implementation and enforcement of legislation, the agencies’ technical expertise on the logistics of implementation can be valuable in ensuring that legislators minimize the unintended

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65 Hall & Deardorff, supra note 66.
66 Hall & Deardorff coined the term “legislative subsidy” to refer to the specialized information that organized interest groups can provide to legislators, so that legislators do not have to expend costs in acquiring this information themselves. Id.
67 Cf. United States v. Nova Scotia Food Prods. Corp., 568 F.2d 240 (2d Cir. 1977) (holding that agencies must disclose scientific research they use in rulemaking so interested parties have an opportunity to comment on it or provide their own to address specific policy concerns).
consequences of legislative proposals. Further, administrative agency officials are powerful allies for organized interest groups in successfully redefining a policy issue.

Historically, federal administrative agencies have been especially influential in defining problem drug use and focusing the national attention on America’s drug problem via agency reports on problem drug use. Federal administrative agencies, like the Substance Abuse and Mental Health Services Agency (“SAMHSA”) and the Center for Disease Control and Prevention (“CDC”), collect yearly data on variables that government researchers consider to be measures of problem drug use. These data allow federal agencies to monitor any changes in the variables from year to year and to alert Congress of any increases in rates of use, addiction, or overdose deaths.

Although the inclination is to treat such reports as objective research, it is important to acknowledge that agencies have a stake in results that they publish. On the one hand, highlighting the severity of a problem through numbers and statistics increases focus on the agency’s problem of interest and supports requests for additional funding allocations to that agency. On the other hand, continually having increasing rates of death or addiction can demonstrate that the agency is ineffectively handling the problem. For example, the Narcotics Bureau, the federal predecessor to the Drug Enforcement Agency (“DEA”), knowingly

68 While it is true that traditionally only federal agencies were the sole enforcers of federal law, with the expansion of Congressional delegation of authority and duties to the federal bureaucracy has come the subsequent delegation of enforcement to state and local governments. Mark K. McBeth et al., The Intersection of Narrative Policy Analysis and Policy Change Theory, 35 POL’Y STUD. J., 87–108 (2007). Typically, this occurs through the use of conditional federal funding for state programs. Id.
69 BAUMGARTNER, supra note 55 (which found that support for a narrative by high ranking governmental officials in either the legislature or the administration best predicted whether or not a problem was successfully redefined). See also Part IV where I demonstrate how parents’ groups partnered with NIDA to affect the definition of problem drug use in the late 1970’s and 1980’s.
70 See supra notes 4–7.
overestimated the number of persons addicted to illicit drugs to justify continued budget allocations and ensure the Bureau’s survival.\textsuperscript{73} To demonstrate that it was effective and producing results, however, the Narcotics Bureau balanced its reports of escalating problems with reports of decreases in addiction or, more often, increases in the number of arrests of drug traffickers and users.\textsuperscript{74}

This is not to say that doctoring statistics is the only way agencies have influenced narratives in drug policy. Agencies can steer the narrative discourse simply by making decisions on what to count and how to define the categories that they are counting.\textsuperscript{75} For example, agencies must decide questions of categorical inclusion like, when counting the number of persons abusing prescription opioids, should the law consider doubling the prescribed dose of one’s own prescription to eliminate pain a form of problem drug use?\textsuperscript{76} What criteria should policymakers use to determine whether an accidental overdose caused death relative to an intentional suicide by overdose? Decisions on each of these measurement questions can not only result in the over- or undercounting of a problem but can change the meaning of the results and how lawmakers define the problem.\textsuperscript{77} Further, since the rational decision-making model of policy prefers measurable legislative outcomes, policy actors may prefer legislative solutions that produce outcomes that can be easily measured using pre-existing measurement tools\textsuperscript{78} over

\textsuperscript{73} COURTWRIGHT, supra note 57, at xii.
\textsuperscript{75} STONE, supra note 13, at 183-205.
\textsuperscript{76} See, e.g., NSDUH Data Review National Survey on Drug Use and Health, SAMSHA, https://www.samhsa.gov/data/sites/default/files/NSDUH-FFR2-2015/NSDUH-FFR2-2015.htm (last visited Jan 17, 2018) (which demonstrates that measuring a phenomenon involves decisions how to define and categorize and that these decisions affect the results).
\textsuperscript{77} Id.
\textsuperscript{78} For example, since the CDC monitors overdose deaths, increasing the availability of Naloxone, an overdose reversal medication, is a legislative solution whose outcome can be easily measured by counting the number of overdoses before implementing the legislation and then determining if there is a decrease is the number of overdose deaths after legislative enactment. See CDC WONDER Database, CENTERS FOR DISEASE CONTROL AND PREVENTION, https://wonder.cdc.gov/ (providing the CDC’s database for monitoring overdose deaths); Opioid
legislative solutions that produce outcomes that cannot be as easily measured due to the outcomes’ complexity or the lack of a widely implemented measurement tool. 79 In deciding what to measure, what to report, or how to report it to legislators, administrative agencies influence the narrative discourse. Additionally, they influence the discourse by explicitly supporting some narratives over others.

In conclusion, evidence exists in the empirical literature that justifies the claim that both organized interest groups and administrative agencies can influence how lawmakers define a problem and in doing so limit the legislative alternatives. The next section outlines how groups go about constructing narratives and how that may differ based on their motivations for doing so.

IV. HOW GROUPS CONSTRUCT NARRATIVES

The narrative-generation process is not always a conscious endeavor. Why a group constructs a narrative in the first place, however, influences how a group constructs its narrative. Is the group constructing a narrative to achieve or avoid a legislative solution? Are they constructing a narrative to garner widespread acceptance of a particular causal theory? Or are they developing a narrative to ensure that a specific population benefits from or carries the burden of the legislative solution? Since a group can begin the narrative-construction process by choosing its characters, cause, or desired solution, the group’s objective may determine which story component the group prioritizes. The order in which groups select these components varies, and choices at each juncture affect the alternatives that are available for the remaining

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79 For example, if a lack of hope for a better future is what causes overdose epidemics, it is much more difficult to measure hope. Further no annual administrative agency survey even attempts to measure hope.

story elements. If the group chooses purposefully, they can narrow the available alternatives to those that align with the narrators’ interests.

A. Designing a Narrative to Further a Solution

A narrator may begin the narrative-crafting process by first choosing a desired solution. For example, the National Organization for the Reform of Marijuana Laws (“NORML”), a group that advocates for the legalization of marijuana, could hypothetically see the Opioid Epidemic and the shift in public support for decriminalization as a political window of opportunity through which it can try to further its agenda. As such, if NORML constructed a policy narrative to define the Opioid Epidemic, it could start the narrative-formation process by choosing its preferred solution (marijuana legalization) and then choosing a cause of the Opioid Epidemic that at least makes medical marijuana legalization a likely solution. Perhaps NORML might argue that the Opioid Epidemic resulted from physicians relying on opioid prescription pain pills as the primary treatment for chronic pain because opioids were the only treatment option available in their medical arsenal. The lack of alternative treatment options resulted in

82 See supra note 20.
the over prescription of “highly addictive” opioid prescription pain pills. Legalizing marijuana for medicinal use offers a solution to the problem, as NORML would define it, because patients can use marijuana as an alternative pain treatment to “overly addictive” and overdose-causing prescription pain pills. Evidence indeed supports these hypothetical claims, evidence that would lend credibility to NORML’s narrative. For instance, physicians have cited the lack of alternative pain treatment options for chronic pain patients as an issue in care. Additionally, empirical research has shown that cannabis can effectively treat pain for some patients.

However, NORML’s hypothetical causal theory is not the only causal theory that has empirical support. For example, despair, unemployment, or self-medication could also serve as causes of the Opioid Epidemic in an effective narrative. If NORML focused on these other causes in its causal story, however, marijuana legalization no longer neatly addresses the

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84 I use quotation marks here to indicate that I am quoting pervasive opinion that opioid prescription pain pills are highly addictive and am in no way indicating that such a claim is supported by the weight of the evidence.
85 There is empirical support for these claims. See, e.g., Lauren S. Penney et al., Provider and patient perspectives on opioids and alternative treatments for managing chronic pain: a qualitative study, 17 BMC FAM. PRAC. 164 (2016).
86 Although some have called opioid prescription pain pills “extremely” addictive, the rate of iatrogenic addiction, or addiction caused by medical mistake, is often overestimated because addiction, abuse, misuse, and dependence are all treated as if they are the same construct when they are indeed very different. See, e.g., Nora D. Volkow & A. Thomas McLellan, Opioid Abuse in Chronic Pain — Misconceptions and Mitigation Strategies, 374 NEW ENG. J. OF MED. 1253, 1253–1263 (2016).
89 In 2015, researchers Case & Deaton noticed that the areas that had the highest rates of overdose rates also had high rates of deaths due to alcohol and suicide. Anne Case & Sir Angus Deaton, Mortality and Morbidity in the 21st Century, BROOKINGS (Mar. 23, 2017), https://www.brookings.edu/bpea-articles/mortality-and-morbidity-in-the-21st-century/. These three deaths of despair were highly correlated with “an accumulation of pain, distress, and social dysfunction in the lives of working class whites that took hold as the blue-collar economic heyday of the early 1970s ended, and continued through the 2008 financial crisis and the subsequent slow recovery.” Id.
90 Economically deprived areas with high unemployment rates often have high addiction rates. See generally Katherine McLean, “There’s Nothing Here”: Deindustrialization As Risk Environment for Overdose, INT’L J. OF DRUG POL’Y, Mar. 2016, at 19.
91 Recent studies have shown that opioid misuse is higher for individuals who report untreated pain as well as untreated chronic mental illness, including depression. See, e.g., McLean, supra note 93, at 19.
policy problem. By starting with its desired solution, NORML can limit the list of causes to those that call for legalization of at least some forms of marijuana use. Similarly, it would limit the characters or target population of its narrative to persons with chronic pain, thus excluding persons with problem drug use who do not have a chronic pain diagnosis.\textsuperscript{92} The consequences of such a limitation on the target population is that the legislative solutions enacted would benefit chronic pain patients, but would not offer benefits for members of the target population that are not chronic pain patients. NORML, however, would have come closer to accomplishing its objective by pushing for the legalization of marijuana incrementally, a political feat much easier to accomplish than marijuana legalization wholesale.\textsuperscript{93}

In sum, for pressure groups that are invested in the legislative adoption of a pet legislative solution, beginning by identifying where they want their narrative to end allows them to reverse-engineer a story that guides the discourse to their desired solution.

\textit{B. Devising a Narrative to Avoid a Solution}

Rather than starting the narrative-crafting process with a desired solution, narrators can also choose the elements of their narrative based on a motivation to eliminate undesirable solutions. For example, prescription opioid drug manufacturers, whom some actors have blamed for causing the Opioid Epidemic,\textsuperscript{94} could hypothetically support a causal narrative that Chinese

\textsuperscript{92} Although popular discourse makes it appear as if persons who overdose from opioid addiction are most likely persons who received an opioid prescription from a doctor for long-term treatment of chronic pain, the empirical evidence to date does not support this contention. See, e.g., Michael A. Yokell et al., \textit{Presentation of Prescription and Nonprescription Opioid Overdoses to US Emergency Departments}, JAMA INTERNAL MED., Dec. 2014, at 2034, 2036 (finding that less than 13\% of patients admitted to U.S. emergency rooms for opioid overdoses had a pain diagnosis).

\textsuperscript{93} For an example of attempts to incrementally legalize marijuana, see, e.g., Joel Ebert, \textit{With Assist from House Speaker Beth Harwell, Medical Cannabis Bill Advances in House Subcommittee}, TENNESSEAN (Feb. 27, 2018), https://www.tennessean.com/story/news/politics/2018/02/27/medical-marijuana-law-tennessee-politics-tn-house/378069002/.

\textsuperscript{94} Prescription opioid manufacturers have been blamed for intentionally downplaying the addictiveness of their products, insisting that their medications last for 12 hours while possessing evidence that it only lasts for 8 hours. See Alana Semuels, \textit{Are Pharmaceutical Companies to Blame for the Opioid Epidemic?}, THE ATLANTIC (June 2, 2017), https://www.theatlantic.com/business/archive/2017/06/lawsuit-pharmaceutical-companies-opioids/529020/.
manufacturers have flooded the streets with counterfeit OxyContin and fentanyl, which then caused a spike in overdoses. Here, there is indeed evidence that counterfeit opioids from China have increased the illicit drug supply in the U.S., but other factors that this narrative ignores have also played a role in the increased supply and demand of illicit opioids. However by maintaining that illicit Chinese opioids are the cause of the Opioid Epidemic, U.S. drug manufacturers could shift the blame to China, making it more likely that any proposed regulations will punish China instead of American pharmaceutical companies.

C. Devising a Narrative to Support a Causal Theory

Although the first two strategies that this Article outlines emphasize devising a narrative around a solution, some narrators devise their story with a cause as the focal point. For example, narrators, like advocacy groups that represent persons in recovery from addiction, may devise their narratives by starting with the causal story that addiction is chronic brain disease. These advocacy groups may be invested in popularizing the causal story that addiction is a disease. They have also been blamed for failing to intervene even though they knew or should have known that their medication was likely being diverted. See, e.g., News Releases: Attorney General DeWine Files Lawsuit Against Opioid Distributors for Practices Fueling Opioid Diversion, OHIO ATTORNEY GEN. (Feb. 26, 2018), http://www.ohioattorneygeneral.gov/Media/News-Releases/February-2018/Attorney-General-DeWine-Files-Lawsuit-Against-Opio.


97 Such a problem definition has consequences beyond those desired by the narrators because it encourages punitive solutions. It could, for example, shift the focus to international interdiction strategies that involve agencies in charge of foreign affairs. In the past, some Presidents have supported the definition of problem drug use in a manner that blames other countries, particularly other countries that are less powerful than the U.S. See ANDREW B. WHITFORD & JEFF YATES, PRESIDENTIAL RHETORIC AND THE PUBLIC AGENDA: CONSTRUCTING THE WAR ON DRUGS (2009). As Commander in Chief, the President could then take actions against these countries, simultaneously showing his electorate that he is involved in foreign affairs and is punishing the “bad guys.” And one could foresee President Trump supporting such a narrative, as it adds credibility to his desires to punish China and supports his preferred policy solution of building a wall at the American–Mexican border to further prevent the smuggling of drugs from international sources. See, e.g., Matthew Hall, US Turns to Trump Targets—UN, China and Mexico—for Help in Opioid Crisis, THE GUARDIAN (Jan. 7, 2018), https://www.theguardian.com/us-news/2018/jan/07/us-. American pharmaceutical companies, however, may or may not have intended each of these consequences when they devised their hypothetical narrative. These consequences could be a result of such a narrative all the same.
because it refutes the stigmatizing causal story that addiction is caused by weak character.

Further, the chronic-disease analogy communicates that addiction can recur due to the nature of the disease itself. The disease is then the cause rather than the person’s moral character. Groups that focus their narrative building around a cause may support such a causal story even if they are aware of evidence that socio-economic factors also contribute to problem drug use, because they believe that the “addiction is a disease” causal story is most powerful in combatting stigma. Even if the “addiction is a disease” causal story does not align with the best legislative outcomes, it has utility in and of itself.98

\[ D. \quad \textit{Devising a Narrative to Benefit or Burden a Target Population} \]

Rather than focusing the narrative-design process around achieving or avoiding a legislative solution or promoting a cause, narrators can also begin crafting a narrative by choosing the target population, or characters, they would like to see receive benefit or blame. Problem drug use affects many populations.99 Listing all members of a target population can be not only an exhaustive and seemingly impossible endeavor, but it may also confuse the narrative’s intended audience, which have limited attention and resources. Therefore, in choosing the characters for their narratives, narrators often choose the segment or segments of a heterogeneous population that they are most interested in benefiting or burdening.100

For example, pressure groups can focus on the rural populations of overdose victims,101 downplaying or ignoring the inner-city victims, or they could describe opioid-overdose victims

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100 \textit{Stone}, \textit{supra} note 13; \textit{Schneider & Ingram}, \textit{supra} note 39.
101 Moreover, by limiting the focus to overdose victims, narrators include only recreational drug users and hard core chronic users who overdose, not those who do not overdose.
as White, not Black, or as middle and upper class, not poor. These portrayals only partially represent the target population of overdose victims, as there are many Black and Hispanic, poor city-dwellers that suffer overdoses. Yet, in describing the target population, narrators can choose to focus only on one subpopulation as if it represents the entire target population. Doing so often communicates that this subpopulation is the only part of the population that “should” benefit from the legislative solution. This is an example of employing a literary technique called synecdoche.

102 By focusing on a sub-population, narrators can better control the images and associations that are triggered by the narrative. STONE, supra note 13. Similarly, when pressure groups use anecdotes that describe problem drug use by focusing on an individual who uses, pressure groups can choose to focus on that individual’s membership in one group, while ignoring their membership in other groups. Society categorizes persons into populations, or groups of actors. Any one actor can be a member of multiple populations at a time. For example, an overdose victim can be a physician, a father, and a substance user. As such, each population of actors is comprised of subpopulations of actors (e.g. fathers who are substance users; doctors who are substance users). And each of these subpopulations are socially constructed to represent different images in the listeners’ mind. The image of a father is quite different than that of a doctor. Pressure groups can choose to focus on actors’ membership in one population over others, as if that population membership defines the actor. SCHNEIDER & INGRAM, POLICY DESIGN, supra note 39; STONE, supra note 13.


104 STONE, supra note 13, at 168-171. Such a technique is useful because populations have already been socially constructed as having certain attributes and characteristics, including whether that group is deserving of public assistance, as I discussed later.
Choosing a sub-population of the target population has consequences for the lawmaking process. Legislative solutions tailored for one sub-population may not be effective for other sub-populations because the causes of problem drug use in each sub-population may be different. For example, the causes of marijuana use among teenagers may be different than the causes of opioid prescription pain pill abuse by middle-aged White men. The legislative solutions that address problem drug use in these sub-populations would likely be different as well. A holistic problem definition would acknowledge the various categories of persons whom problem drug use affects, recognize the multiple causes, and devise an array of solutions that would address each. Given that drug policy resources in the U.S. are both finite and rarely enough to address problem drug use even in a single sub-population, lawmakers make choices as to how to define who benefits or who bears the burden.

Pressure groups can use causal stories to persuade legislators to blame or benefit some sub-populations over others. In the late 1970’s and 1980’s, addiction treatment providers warned Congress that persons addicted to cocaine and crack were flooding their clinics. Yet parents’ advocacy groups (“Parents Groups”) insisted that the federal government should stop focusing

105 See, e.g., Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-198, § 3797s-6(d)(1)(B), 130 Stat. 695, 715, which provides research grants, in part, to researchers identifying “unique circumstances” facing teenagers and young adults struggling with drug use. 106 STONE, supra note 13. 107 MICHAEL MASSING, THE FIX (2000). 108 The Parents Movement arose in the late 1970s out of a greater counter-revolution to what parents viewed was the corruption of societal values by the popular media that glorified sex and recreational drug use. Id. at 141-154. Parents pointed to parental defiance, recreational drug use and increased sexual proclivity as indicators that they were losing control of their children. Id. at 141-154. The increase in marijuana use by middle class youth and suburban college students added to their concern, as well as legislative proposals in Congress to decriminalize marijuana. Marsha Manatt, PARENTS, PEERS, AND POT II: PARENTS IN ACTION (1986).
on the “black crack problem”\textsuperscript{109} or reducing the number of “heroin users,”\textsuperscript{110} but should focus instead on teenagers who were experimenting with marijuana.\textsuperscript{111} In defining the drug problem, these Parents Groups focused on youth as the target population because they wanted youth to benefit from the legislative solutions. However, these groups only wanted to benefit non-drug user youth. Parents Groups identified drug users, or “druggies” as they referred to them, as part of the problem. Parents Groups blamed these druggies for using peer pressure to convince “good” teenagers to use drugs and, in some cases, for supplying the “good” teens with drugs.\textsuperscript{112}

However to the dismay of the Parents Groups, there was little to no scientific or medical evidence at the time to support their claims that marijuana was a gateway drug that would lead to a host of evils.\textsuperscript{113} In attempting to locate such evidence, Marsha Schuchard, an English teacher and co-founder of the Parents’ Resource Institute for Drug Education (“PRIDE”), contacted Director Robert DuPont of the National Institute on Drug Abuse (“NIDA”).\textsuperscript{114} In DuPont, Schuchard found an ally and supporter of her narrative. DuPont told Schuchard that he did not realize how marijuana was affecting youth, and DuPont even inquired whether she would be willing to author a NIDA publication that explained to parents how to prevent teenage drug use.\textsuperscript{115} Schuchard agreed and published two papers with NIDA.\textsuperscript{116} Although NIDA asked her to refrain from drawing medical or scientific conclusions about marijuana due to her lack of

\textsuperscript{109} MASSING, \textit{supra} note 110, at 185 (quoting Keith Schuchard, co-founder of Parents’ Resource Institute for Drug Education (PRIDE), a prominent parents group).

\textsuperscript{110} Id. at 146 (quoting Marsha Schuchard, co-founder of PRIDE). The argument used by PRIDE to convince lawmakers to focus on marijuana use was that intensive drug use accounted for 1\% of the population, while teenage use affected all of the nation’s children. MASSING, \textit{supra} note 110, at 146.

\textsuperscript{111} MASSING, \textit{supra} note 100, at 146.

\textsuperscript{112} MASSING, \textit{supra} note 111, at 141-146.

\textsuperscript{113} MASSING, \textit{supra} note 110, at 152-153. The United States President’s Advisory Commission on Narcotics and Drug Abuse had explicitly stated that there was no scientific evidence that marijuana was a gateway drug in the 1960s. \textit{Id.}

\textsuperscript{114} Id. at 141-154.

\textsuperscript{115} \textit{Id.} at 141-154.

\textsuperscript{116} \textit{Id.} at 141-154.
medical or scientific training, Schuchard ignored these requests.\textsuperscript{117} Despite her lack of credentials and the lack of evidence supporting her statements, her publications were the most requested NIDA publications.\textsuperscript{118}

NIDA’s stamp of approval gave the Parents Groups’ narrative credibility, and the Parents Groups’ narrative benefited from the believability that came with focusing on a target population that was already socially constructed as needing protection and deserving of policy benefits.\textsuperscript{119}

Even before Schuchard’s NIDA publications became available to use as evidence in support of their narratives, the members of the Parents Groups argued that they were experts because they were parents. For example, in 1980, when testifying in front of Congress on the potential health issues that might arise from decriminalizing marijuana, a Parent Group member explained:

The most important credential I can give you to substantiate my testimony is that I am a mother, not a doctor, not a scientist. I am here to protect my children. I am also here to protect my neighbor’s children and the children of this nation.\textsuperscript{120}

According to policy scholar Michael Massing, by the end of the Congressional hearing, the possibility of marijuana decriminalization was dead.\textsuperscript{121} Massing credits the Parents Groups with more than just the defeat of marijuana decriminalization. In his view, the Anti-Drug Abuse Act

\begin{itemize}
\item[\textsuperscript{117}] \textit{Id.} at 141-154.
\item[\textsuperscript{118}] \textit{Id.} at 141-154.
\item[\textsuperscript{119}] \textsc{Schneider \\ \\ & Ingram, supra note 39}. Schneider and Ingram theorize that target populations are categorized by society into two groups: those deserving of public assistance and those who are undeserving. \textit{Id.} A group’s deservingness is then moderated by the groups political power to create four types of target populations: Advantaged, Contenders, Dependents and Deviants. \textit{Id.} Advantaged groups are groups that society has determined are most deserving and are groups with the great deal of political power. \textit{Id.} They include businesses, the middle class, senior citizens, military, scientists and family farmers. \textit{Id.} The Contenders also wield political power but are viewed as undeserving. \textit{Id.} They include gun owners, the rich, CEO’s, and savings and loans companies. \textit{Id.} Politically, it would be unwise to punish these groups because of their political power, but it would be equally unpopular with citizens if legislative solutions benefited these groups. Dependents are politically weak but are constructed as deserving and include mothers, children, persons with disabilities, and the ill. \textit{Id.} Because of their social construction, it is not difficult to construct narratives that call for these groups to benefit. For such a narrative to be successful, it requires the mobilization of large amounts of constituents or the endorsement of politically stronger groups. \textit{Id.} Lastly, the Deviants are constructed as undeserving and lack political power. \textit{Id.} They include criminals and most often hard core drug users. \textit{Id.} The construction of individuals who use drugs may be changing, however, as they become constructed as persons with a disease of the brain.
\item[\textsuperscript{120}] \textsc{Massing, supra} note 110, at 153.
\item[\textsuperscript{121}] \textit{Id.} at 153.
\end{itemize}
of 1986, which re-established mandatory minimum sentences for drug possession, was a direct result of the support for this “parent model of drug abuse.” 122

PRIDE and other Parents Groups demonstrate how pressure groups can design a policy narrative based on the desire to benefit a target population. They first centered the narrative composition on youth as the target population, and they secondarily sought facts to establish that there was a problem and that the cause of the problem was marijuana. They utilized their narrative to form coalitions with school boards, school principals, the Parents Teachers Association (“PTA”), and local churches. 123 Maybe most importantly, they found a high-ranking administrative agency official to support their narrative. 124

It is important to note, however, that the Parents Groups’ success in focusing the nation’s attention on the subpopulation of youth was costly to the remaining population addicted to illicit substances, as the latter were more likely to end up in the emergency room than in treatment. 125 And the government’s refusal to pay attention to the growing number of crack-cocaine users contributed to the magnitude of the crack-cocaine epidemic that would hit hard in the late 1980’s to early 1990’s. 126

In conclusion, this section demonstrates theoretically how narrators can use narratives to limit the alternative legislative solutions available in the legislative discourse and assign benefits and burdens to target populations. In structuring their causal stories, narrators can achieve their desired legislative solutions by strategically choosing a solution, cause, or target population on
which to focus. The order in which they choose these elements depends on their goals.

Narrators then use these narratives in the problem definition discourse to persuade lawmakers.

Although there are often multiple problem definitions vying to be the most dominant, only a few become accepted as the “true” definitions of the problem. The longer that people accept a problem definition as true, the more likely the definition becomes permanently institutionalized. 127 Lawmakers create institutions that implement and enforce policy around the legislative solutions that accompany the problem definition. The next part of this Article demonstrates that, once lawmakers create such institutions, it becomes even more difficult to redefine a problem because these institutions are invested in maintaining the status quo definition. 128 As drug policy history demonstrates, however, it is not impossible to redefine policy problems, especially as cultural and societal norms evolve and as the composition and power of interest groups change. 129 The Opioid Epidemic arguably created a juncture at which the cultural and political environment offer a political window for pressure groups to redefine problem drug use as a public health issue. Therefore, exploring historic examples of pressure-group problem definitions during windows of opportunity for change may provide us with a better understanding of how to successfully redefine problem drug use at the current juncture.

127 In my use of the term “institutionalized” here, I am referring to both the behavioral constraints placed on governmental and societal actions, see DOUGLASS C. NORTH, INSTITUTIONS, INSTITUTIONAL CHANGE AND ECONOMIC PERFORMANCE (1990), as well as the governmental structure that makes, implements and enforces the rules and regulations based on these behavioral patterns and societal constraints.

128 BAUMGARTNER supra note 55. For example, as I will demonstrate in Part IV, the adoption of a deviance narrative, and implementation of punitive legislation to address the deviance, has resulted in the allocation of money and resources to federal, state and local law enforcement who are charged with enforcement of the legislation. If activists were successful in redefining problem drug use as a health issue, the need for such an enforcement would decrease, as would the number of law enforcement officials needed and the funding allocated to these institutions. With the allocation of federal funds to the private prison system in the 1980s, private prisons as well as law enforcement unions are heavily incentivized to lobby to maintain the status quo. KENNETH J. MEIER, THE POLITICS OF SIN: DRUGS, ALCOHOL, AND PUBLIC POLICY (1994).

129 See, e.g., BAUMGARTNER, supra note 55 (noting that out of 98 policy issues studied, researchers found four policy issues that had been redefined—three of which were partial redefinitions while one was a complete redefinition).
As renowned drug policy historian David Musto wrote in reference to the crack-cocaine epidemic in the late 1980s:

How can we understand this epidemic? It is important for us to know the history of drug abuse in America if we are to make wise decisions concerning drug abuse now and in the future. . . . When we are in the middle of a drug crisis, however, we tend to forget this history and assume that we must face our drug onslaught with no guideposts. Unaware of how we have overcome past drug problems, we are liable to panic.\(^{130}\)

V. THE USE OF HEALTH VS. DEVIANCY NARRATIVES IN DRUG POLICY HISTORY

Comparing the legislative process for different pieces of legislation over time is a difficult endeavor. The factors that affect the legislative process, including cultural norms, political institutions, ideologies, and political circumstances, especially vary when comparing legislative events that occur decades apart. These evolving factors not only influence the likelihood of the enactment of legislation, but also impact the types of causal narratives that groups use and the way in which they define a problem.\(^{131}\)

Conceding such differences, there is still value in analyzing the types of narratives that groups have used over time to define a policy problem, even if it is not for the purpose of proving that pressure groups’ narratives per se caused a legislative outcome. First, political institutions prefer the status quo, making it more difficult to redefine a problem the more engrained it becomes.\(^{132}\) Studying the past use of narratives to define a problem helps shed light on how such a past may have influenced how we define a problem today. Second, groups often recycle causal narratives, as familiar narratives can be more believable than unfamiliar narratives and may elicit less scrutiny.\(^{133}\) Studying the use of narratives at different junctures of drug

\(^{130}\) MUSTO, supra note 57, at ix.

\(^{131}\) See STONE, supra note 13.

\(^{132}\) See BAUMGARTNER, supra note 55, at 29–45.

\(^{133}\) STONE, supra note 13.
policy history helps us identify the most recycled stories in drug policy. Third, examining how groups strategically crafted narratives to align with their interests illuminates how future groups wishing to influence the problem definition process can use problem definition strategies to further their policy goals. It also demonstrates how such groups can form alliances around their narratives. Finally, the following section illustrates the powerful role that administrative agency officials can play in defining problem drug use in the legislative discourse.

A. The Opiate Epidemic & The Opioid Epidemic

At times, society has attributed problem drug use to a disease or disorder. At other times, narratives blame deviancy or a character flaw for causing problem drug use. Although the policy idea that addiction is a disease or a health issue may seem new to the legislative discourse, because of its recent resurgence, it emerged in political discourse as early as the 1800’s. Since this is the time period during which the “addiction is a disease” narrative developed, it is where this analysis begins.

Examining narrative use to describe an opiate crisis in the mid- to late 19th century to help shed light on causal stories that could define an Opioid Epidemic in the 21st century may seem futile, or even downright silly. Not only was daily life vastly different in the 1800’s, but so were the federal government’s structure and powers. Although the federal government’s powers have grown significantly since the 19th century, the political parties have evolved, the internal structures of Congress have changed, and the number of pressure groups involved in the political process has greatly increased, some definite similarities exist between the Opiate Crisis of the late 19th and early 20th centuries and the current Opioid Epidemic. The target population of both epidemics included a sub-population of iatrogenic addicts, persons who became addicted to a habit-forming drug due to a medical error. This subpopulation of iatrogenic addicts includes
middle to upper class Whites—members of the public that, during both time periods, people viewed as the mainstream and not associated with the deviant underworld.\textsuperscript{134}

Aside from the composition of the target populations, during both epidemics, physicians, and pharmacists, risked blame for causing the epidemic—a causal story that calls for the punishment and regulation of physicians and pharmacists. The Harrison Tax Act of 1914, discussed \textit{infra}, is arguably the prescription drug monitoring program of the early 20\textsuperscript{th} century.\textsuperscript{135} Both require reporting, recordkeeping, and the monitoring of physician and pharmacist prescribing practices.\textsuperscript{136} Both legislative solutions imply that these professionals need oversight, as law enforcement agencies used records from both monitoring systems to punish physicians and pharmacists that appeared to be overprescribing habit-forming medications.\textsuperscript{137} During both epidemics, representatives in Congress made statements supporting the causal narrative that iatrogenic addiction was a disease that necessitated treatment.\textsuperscript{138} Lastly, in both cases, drug manufacturers, pharmacists, and physicians were active in the problem definition process despite these groups’ lobbying not being a constant feature of American drug policy.\textsuperscript{139}

\textsuperscript{134} C\textsc{ourtwright}, supra note 57, at 72. \textit{See} S\textsc{chneider} \& I\textsc{gram}, supra note 39 (which generally discusses the social construction of white and middle class persons).

\textsuperscript{138} Prescription monitoring programs are legislative solutions that involve the state-wide monitoring of the dispensing of habit-forming drugs. \textit{See} S\textsc{tate Prescription Drug Monitoring Programs, Drug Enf’T Admin.: Diversion Control Div.}, https://www.deadiversion.usdoj.gov/faq/rx_monitor.htm (last visited Mar. 31, 2018). Although at times the prescription monitoring programs are sometimes framed as tools to help medical professional identify patients that may be drug-seeking, the data from the electronic system is shared with law enforcement to aid them in identifying and prosecuting physicians and pharmacists that are diverting prescription medication. \textit{Id.}

\textsuperscript{139} \textit{Compare} Harrison Narcotic Act of 1914, 38 Stat. 785 (1914) (repealed 1970), \textit{with} S\textsc{tate Prescription Drug Monitoring Programs, supra note 138.}

\textsuperscript{140} \textit{See} M\textsc{usto}, supra note 57, at 54–68, for a historic account persecution of physicians and pharmacists under the Harrison Tax Act. \textit{See also supra} note 138 for its reference to the use of prescription drug monitoring programs by law enforcement.

\textsuperscript{141} \textit{See} P\textsc{ortman} supra note 12.

\textsuperscript{142} For example, from 1998-2017, the pharmaceutical industry and medical professionals have not consistently lobbied on alcohol and drug abuse issues. \textit{See} A\textsc{lcohol and D\textsc{rug Abuse}, The C\textsc{tr. For Responsive Politics}, https://www.opensecrets.org/lobby/issuesum.php?id=ALC (last visited Mar. 31, 2018).
Due to these similarities, analyzing the types of narratives that defined the problem of addiction during this early epidemic may prove more useful than one would have initially predicted.

B. Defining the Nation’s First Opiate Epidemic

1. Sub-populations of the Target Population

By the late 1800s, an opiate epidemic plagued the nation.\textsuperscript{140} By the end of the 19th century, an estimated 150,000 to 250,000 persons had become addicted to drugs.\textsuperscript{141} The public began to vocalize their fear of habit-forming drugs, especially when it came to drug use by Chinese immigrants and Southern Blacks.\textsuperscript{142} The majority viewed these marginalized populations’ drug use as a direct threat to White safety.\textsuperscript{143} Further, “opium dens,” public places where smokers met to smoke socially, encouraged undesirable social mixing.\textsuperscript{144} As the narrative went, these sub-populations became addicted to opiates and cocaine because their weak moral characters predisposed them to using drugs for their euphoric effect.\textsuperscript{145} Once they became drug users, they posed even more of a threat to society because the drugs increased their sexual proclivity, criminal behavior, and, in the case of Blacks, their physical strength.\textsuperscript{146} The public viewed such a deviant sub-population of drug users as deserving of punishment,\textsuperscript{147} and as a

\textsuperscript{140} Estimates of the number of opiate addicts was between 150,000 to 200,000. \textsc{Stephen Kandall, Substance and Shadow: Women and Addiction in the United States} 15 (1999). For reference, the U.S. population count was 62,979,766. \textit{1890 Fast Facts History}, U.S. \textsc{Census Bureau}, https://www.census.gov/history/www/through_the_decades/fast_facts/1890_fast_facts.html (last visited Mar. 30, 2018).

\textsuperscript{141} \textsc{Courtwright, supra} note 57.

\textsuperscript{142} \textsc{Courtwright, supra} note 57, at 62-81.

\textsuperscript{143} \textsc{Courtwright, supra} note 57, at pg. 94-98.

\textsuperscript{144} \textsc{Courtwright, supra} note 57, at 62-81.

\textsuperscript{145} \textsc{Courtwright, supra} note 57, at 7-8.

\textsuperscript{146} \textsc{Courtwright, supra} note 57, at 61-109, for a summary of the discourse.

\textsuperscript{147} \textsc{Courtwright, supra} note 57, at pg. 94-98.

\textsuperscript{148} \textsc{Courtwright, supra} note 57, at 62-81.
result, these marginalized populations that were politically weak became most likely to bear the burden of punitive legislation aimed at decreasing drug use.\footnote{See generally SCHNEIDER & INGRAM, supra note 39, at 108-111 (outlining legislative solutions often used for politically weak deviant target populations).}

On the other hand, society “tolerated” iatrogenic addicts,\footnote{Even though society tolerated iatrogenic addiction, individuals who became addicted to opiates were often ashamed by their habit and tried to hide it from their loved ones, indicating that there was still societal disapproval of use even for this class of users. KANDALL, supra note 144, at 3.} due in part to their membership in the “‘acceptable’ segment of the mainstream population.”\footnote{Id. at 41.} Most iatrogenic addicts were wives and mothers, two categories of persons that may be politically weak, but are often socially constructed as deserving of policy benefits.\footnote{SCHNEIDER & INGRAM, supra note 39, at 109.} Another factor that made iatrogenic addicts more socially tolerable was the way in which physicians groups, pharmacists associations, and drug manufacturers, which included both patent medicine manufacturers\footnote{Patent-medicine manufacturers produced over-the-counter medicines and tonics, many of which contained morphine, alcohol, and cocaine. ERLEN & SPILLANE, supra note 77, at 4. They were unregulated until the Pure Food and Drug Act of 1906, which required patent medicine companies to list out potentially harmful ingredients on its labels. Id. Prior to the Act, patent-medicine manufactures lobbied long and hard to remain unregulated. Id. Patent medicines did not require a doctor’s prescription and could even be purchased via mail order catalogue for rural Americans who did not have easy access to a pharmacy. Id. The companies that manufactured patent medicines advertised heavily in the common periodicals of the time with remedies for a litany of ailments. KANDALL, supra note 144, at 41; see also generally Martin, supra note 40. They marketed directly to consumers, highlighting the benefits for self-medication and downplaying the need for physicians to play the intermediary between the drug manufacturer and the consumer. ERLEN & SPILLANE, supra note 156, at 4. Ethical drug companies distinguished themselves from patent-medicine manufacturers by refusing to market directly to consumers. ERLEN & SPILLANE, supra note 156, at 4. Instead, they marketed to physicians and pharmacies. Id. They also published studies of the benefits of their medications in their own scholarly journals. Id.} and self-proclaimed “ethical drug companies”\footnote{ERLEN & SPILLANE, supra note 156, at 5-10.} (collectively, the “medical industry”), legitimized these iatrogenic addicts’ use.\footnote{Id.}

As the next section demonstrates, the medical industry’s financial stake in maintaining a customer base within this sub-population incentivized the industry to support policy narratives that benefited this subgroup; at the same time, the medical industry had no financial incentives to protect the marginalized sub-population of users. The social construction of these distinct
subgroups of drug addicts, and the association of the subgroup of iatrogenic addicts with the financial interest of the medical industry, ensured that these subpopulations would be the center of two different causal stories.

2. The Medical Industry’s Desired Legislative Solution

The medical industry had significant financial interest in ensuring that opiates and cocaine remained licit for medicinal purposes, because, throughout the 1800s, physicians and pharmacists prescribed opiates more often than any other medication. Cocaine’s medicinal benefits were not widely publicized until the 1880s, but once people learned about them, they also soon hailed cocaine as a wonder drug that doctors even used to treat opiate addiction. At a time when medicine was not very sophisticated, opiates, and then cocaine, offered physicians a treatment that worked and increased the physicians’ effectiveness in the eyes of their patients. Pharmacists also utilized opiates and cocaine in a variety of ways. Some pharmacists filled physician prescriptions, some prescribed opiates and cocaine, some used opiates and cocaine in creating their own elixirs, and some sold over-the-counter patent medicine. Both opiates and cocaine were common ingredients in patent medicine. While ethical drug companies also

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158 The types of opiates used included opium, morphine and heroin. KANDALL, supra note 144, at 10-42. Morphine is a derivative of the opium poppy that was isolated in 1817 and made much more accessible with the invention of the hypodermic needle in 1856. Id. Heroin was invented in 1874 but was not widely marketed until 1898. Id. 159 More specifically, morphine was commonly prescribed for a variety of ailments. COURTWRIGHT, supra note 27, at 35-60. At the time morphine was invented it was one of the few tools that physicians had at their disposal that was actually effective. Id. After heroin was invented and popularized by the German pharmaceutical company Beyer, it was also prescribed, especially when it was marketed as less addictive than morphine. Id. The list of ailments that heroin was used to treat, however, was less than that of morphine, so the number of persons that became iatrogenically addicted to heroin were much less than those who became addicted to morphine. KANDALL, supra note 144, at 32-36; COURTWRIGHT, supra note 57; MUSTO, supra note 57. 159 As a profession, pharmacists’ political strength was weakened by the competing interest among sub-specialties. There were disagreements within the profession as to whether or not they should fight for the ability to prescribe medication, dispense refills to medications, develop their own medications and sell patent medications. ERLEN & SPILLANE, supra note 77, at 4-5. KANDALL, supra note 144, at 19-23; Musto, supra note 57, at 14-15. 160 ERLEN & SPILLANE, supra note 77, at 4.
wanted to continue producing these drugs, banning these substances would arguably affect patent-medicine manufacturers more than ethical drug companies. This was due to patent-medicine manufacturers relying heavily on these drugs as active ingredients in most of their medications—active ingredients that they did not disclose to their customers until the law forced them to do so.  

Because of the medicinal use of opium, morphine, heroin and cocaine, drug manufacturers, pharmacists, and physicians actively lobbied on early U.S. drug policy issues. Aside from their immediate interest in protecting their access to these “habit forming drugs,” these groups were likely lobbying to secure their position within the medical industry. Although Congress largely did not regulate the medical industry, physicians, drug manufacturers, and pharmacists knew it would only be a matter of time before the federal government would begin regulating it, and each group wanted to make sure that they influenced the legislation that defined which group would have the authority to make, distribute, and sell medication to consumers.


162 See COURTWRIGHT, supra note 57, at 135.

163 Physicians and pharmacists were concerned with which group would be given exclusive control over prescribing and dispensing of medication. ERLEN & SPILLANE, supra note 77, at 5-17. MUSTO, supra note 57, at 13-21. Both physicians and pharmacists’ groups were in the process of establishing training standards, licensure requirements, and scope of practice for their respective professions. Id. They were also vying for the right to be the exclusive prescribers or dispensers of medication. Id. At the time, physicians and pharmacists’ scope of practice overlapped. Some pharmacists wrote prescriptions or at least refills for patients without a doctor’s prescriptions. Id. Some physicians were dispensing physicians and dispensed drugs directly to patients, without physician oversight. Id. Further, pharmacists were trying to internally determine their own scope of practice as it related to drug manufacturing and sales, overlapping at times with patent medicine manufacturers. Some pharmacists sold patent medicines in their drug stores, while some denounced patent medicine as snake oils. Id. And still other pharmacists created their own elixirs, competing in a sense with the patent medicine companies. Id. Pharmacists were not the only competition or threat to the patent medicine manufacturers. Physicians by and large opposed patent medicine, especially because patent-medicine manufacturers marketed directly to patients and advocated self-medication over consulting with a physician. Id. Ethical drug manufacturers saw patent-medicine manufacturers not only as competition, but as a threat to the credibility of the drug manufacturing industry. Id. Ethical drug companies
3. Building a Coalition and Designing a Shared Narrative

Although each of these groups was interested in establishing exclusivity over at least one part of the manufacturing or distribution process, their immediate collective need to keep opiates and cocaine accessible for medicinal use led them to develop a coalition to lobby Congress on anti-narcotic legislation. There was growing professional and public awareness that opiates and cocaine were addictive. By the end of the 19th century, for example, it was difficult for physicians and pharmacists to deny that opiates and cocaine caused addiction. To succeed at convincing Congress to adopt their proposed solution, the medical industry needed to devise a causal story that resonated with public sentiment and accounted for the population of iatrogenic addicts. The American Medical Association (“AMA”) and the American Pharmacists Association (“APhA”) had already acknowledged that the drugs at issue caused addiction. However, they defined addiction as a disease that developed as an unfortunate side effect to an effective medical treatment. Physicians had discretion to decide whether the risk of addiction was worth the benefit of the treatment. Since addiction was a disease, it logically followed that physicians should have license to use methods such as medication-assisted therapies to treat it. This problem definition gave both professions the added benefit of establishing themselves as the decision-maker of its legitimacy.

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Historian Musto describes physicians’ acceptance of the addictiveness of morphine as prolonged and gradual. Id. Although one would imagine that physicians would be allied with ethical drug companies as a result, physicians viewed ethical drug companies with suspicion, as their business model was evolving to one dominated by the corporate structure and one that abandoned the traditional model of developing drugs based on physician demand. Id. Physicians feared becoming slaves to ethical drug companies. Id. In sum, although the medical industry allied on some issues, each group within it was simultaneously struggling to establish its exclusivity in the medical market.

164 Historian Musto describes physicians’ acceptance of the addictiveness of morphine as prolonged and gradual. MUSTO, supra note 57, at 5.
165 MUSTO, supra note 57, at 14-23.
166 MUSTO, supra note 57, at 13-23.
167 MUSTO, supra note 57, at 14-23.
168 MUSTO, supra note 57, at 14-23.
Such a narrative explained iatrogenic addiction and provided a solution that allowed for the continued medicinal use of opiates and cocaine. It did not offer a solution that addressed non-iatrogenic addiction, however, which affected primarily lower-class Whites, opium smokers, Chinese immigrants, and Blacks.\textsuperscript{169} To address non-iatrogenic addiction, physicians and pharmacists created classifications for legitimate and illegitimate drug use.\textsuperscript{170} Illegitimate drug use, or use of drugs obtained without physician approval, purportedly had no therapeutic benefit, and drug users used these drugs to produce euphoric effects.\textsuperscript{171} Under the prevailing view, any addiction that illegitimate drug use caused resulted from the users’ flawed character and desires to over-indulge in hedonistic behavior.\textsuperscript{172}

The medical profession continued to make this distinction between the causes of addiction despite the fact that their leading biological theory of addiction did not support such a differentiation. The leading medical theory explaining the biological cause of addiction, at this time, was the antibody theory, which theorized that addiction was caused by antibodies forming in the blood that prevented the user from refraining from drug use.\textsuperscript{173} Such a causal theory does not distinguish between whether or not the user was exposed to the drug iatrogenically or “illegitimately.” Therefore, theoretically, this medical theory of addiction that the medical community used to justify a medical approach to treating addiction could have just as easily been applied to non-iatrogenic addicts as well as iatrogenic addicts. Despite this logic, physicians and pharmacists continued to offer differing causal theories for legitimate and illegitimate drug use.

\textsuperscript{169} C\textsc{ourtwright}, \textit{supra} note 57, at 85-109.
\textsuperscript{170} E\textsc{rlen} \& S\textsc{pillane}, \textit{supra} note 77, at 5-10.
\textsuperscript{171} E\textsc{rlen} \& S\textsc{pillane}, \textit{supra} note 77, at 5-10.
\textsuperscript{172} M\textsc{usto}, \textit{supra} note 57, at 14-23.
\textsuperscript{173} M\textsc{usto}, \textit{supra} note 57, at 147.
Just as there was no evidentiary support for applying the scientific theory of addiction discriminately, there was no empirical support for the contention that marginalized populations’ drug use made them social deviants.\textsuperscript{174} Since non-iatrogenic, habitual drug users were from socio-economic classes that were commonly employed in jobs requiring strenuous physical labor, marginalized drug users may have been self-medicating for the pain and discomforts of life, just like their White counterparts.\textsuperscript{175} Despite lack of evidence, lawmakers’ still found the medical professions’ differentiating causal stories believable. This may have been because the stories represented the subcategories of drug users in ways that resonated with widely held stereotypes. Further, the APhA and the AMA drew on their credentials as experts, which added to their narrative’s credibility.\textsuperscript{176} In sum, distinguishing between legitimate and illegitimate use allowed the medical industry to develop different causal stories for iatrogenic and non-iatrogenic addiction that accounted for public sentiment and the differing societal construction of the various subpopulations of drug users.

4. From Storytelling to Legislating

State and local governments had already begun to pass laws that regulated the sale or distribution of habit forming drugs, focusing on controlling marginalized populations’ drug use.\textsuperscript{177} As a response, the APhA proposed a model state law that regulated the dispensing of

\textsuperscript{174} If anything, the evidence showed that individuals who committed crimes prior to their drug use just continued committing crime after their drug use. MUSTO, \textit{supra} note 57, at 7.

\textsuperscript{175} Iatrogenic addicts, on the other hand, were mostly Southern White women who had been prescribed morphine by their doctors to alleviate pain and discomfort of daily life as a housewife. COURTWRIGHT, \textit{supra} note 57, at 36. KANDALL, \textit{supra} note 144. Some scholars believe that morphine use in the Civil War created a great many iatrogenic addicts. \textit{See, e.g.,} KANDALL, \textit{supra} note 144. Historian David Courtwright disputes this claim and argues quite convincingly that although Civil War soldiers may have been introduced to morphine and gotten a “taste” for it while fighting in the war, their dosages were quite controlled and it was unlikely that doctor prescribing practices to soldiers during the war resulted in the creation of many iatrogenic addicts. COURTWRIGHT, \textit{supra} note 57, at 54-55. Middle and upper class White women, however, were most likely to seek the care of a physician for ailments and were therefore the most likely to be prescribed opiates. COURTWRIGHT, \textit{Dark Paradise}, \textit{supra} note 57, at 35-53.

\textsuperscript{176} \textit{See generally} FISCHER, \textit{supra} note 26, at 177-178 (discussing the utilization of professional expertise to add to the credibility of the claims made in a narrative, generally).

\textsuperscript{177} MUSTO, \textit{supra} note 57, at 8-13; ERLEN \& SPILLANE, \textit{supra} note 77, at 10-14.
opiates and cocaine but allowed for physicians and licensed pharmacists to prescribe the substance for medicinal use.\textsuperscript{178} The APhA also advocated for the medical maintenance of individuals who had become addicted.\textsuperscript{179} Effectively, the APhA argued that addiction was a health issue for iatrogenic addicts. The APhA’s model state law also addressed the problem of “illegitimate drug use”—namely the use of smoking opium, which both the APhA and AMA agreed had no medicinal value.\textsuperscript{180} The APhA argued that the states should prohibit smoking opium and that the federal government should prohibit importation of smoking opium.\textsuperscript{181} Further, the APhA argued that the entire underclass of non-iatrogenic addicts, “drug fiends” or “the demi-monde, known criminals, or those whose occupations are shady should be totally prohibited” from accessing habit-forming drugs.\textsuperscript{182}

The banning of smoking opium would not affect retail pharmacists’ bottom lines because they sold very little of the substance.\textsuperscript{183} The prohibition also would not affect physicians’ current or future clientele, as non-iatrogenic addicts generally came from socio-economic classes that made them undesirable patients.\textsuperscript{184} Additionally, since Chinese immigrants primarily used smoking opium, society would view prohibiting it as a moral victory.\textsuperscript{185} With no organized interest group lobbying for the protection of smoking opium, the drug’s association with the criminal underclass, and the calls from administrative agency officials to regulate the drug, it was

\textsuperscript{178} MUSTO, supra note 57, at 14-23 (citing the APhA’s Committee on the Acquirement of the Drug Habit, which made recommendations for model laws to be passed by the states to decrease the likelihood of addiction).

\textsuperscript{179} MUSTO, supra note 57, at 18 (citing the APhA’s Committee on the Acquirement of the Drug Habit).

\textsuperscript{180} MUSTO, supra note 57, at 17; ERELEN & SPILLANE, supra note 77, at 5-10.

\textsuperscript{181} MUSTO, supra note 57, at 14-23.

\textsuperscript{182} MUSTO, supra note 57, at 20 (citing the APhA’s Committee on the Acquirement of the Drug Habit).

\textsuperscript{183} See MUSTO, supra note 57, at 17.

\textsuperscript{184} COURTWRIGHT, supra note 57 at 39-40.

\textsuperscript{185} MUSTO, supra note 57, at 4.
of no surprise that smoking opium was the first drug that Congress prohibited. Criminalization is a common solution for a policy problem that is caused by deviant behavior.

The medical industry continued its lobbying, with its sights on Washington. The APhA, with representatives from the AMA and drug manufacturers, formed a coalition, the National Drug Trade Conference (“NDTC”), to lobby on antinarcotic legislation at the federal level. Formalizing their coalition allowed prescribers and manufacturers to present a united front in defining problem drug use. In 1914, members of Congress proposed legislation, the Harrison Tax Act, to tax the sales of certain habit forming drugs. By the time the NDTC finished negotiating with Congress, the bill preserved the AMA and APhA’s ability to prescribe and dispense medication containing habit-forming drugs, as long as it was for a legitimate medical purpose. The legislation also required the registration of sellers, recordkeeping, and reporting of sales to the Bureau of Internal Revenue (BIR).

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186 Municipalities with large concentrations of Chinese immigrants were the first to pass laws outlawing the smoking of opium, demonstrating the racialization of certain drug use. See COURTWRIGHT, supra note 57, at 53. In 1909, the federal government followed suit by passing the Smoking Opium Exclusion Act, which banned the smoking, sale and possession of smoking opium. See MUSTO, supra note 57, at 3. It did not, however, regulate medications containing opium. Members of the Executive had been pressing Congress to pass some legislation regulating opium use to support the U.S.’s condemnation of China for their role in exporting opium. Id. The U.S.’s leadership involvement in the 1909 Shanghai Opium Conference, which was convened to address Chinese exportation of opium, and the 1912 International Opium Convention at which the U.S. became a signatory of a treaty pledging to assist in controlling sale of opiates, necessitated the need for the U.S. to pass legislation addressing opiate sales or risk appearing hypocritical. Id. at 33.


188 MUSTO, supra note 57, at 54–55.


190 MUSTO, supra note 57, at 53.

191 See MUSTO, supra note 57, at 27, 42. The National Association of Retail Druggists (“NARD”), the National Association of Medicinal Products, and The American Association of Pharmaceutical Chemists, the latter two of the three which were drug manufacturers, also lobbied on anti-narcotic legislation. Id. at 55. Each of these groups also used narratives that stressed the medicinal value of habit forming drugs and argued that addiction could be controlled by decreasing illegitimate, or non-medical use. See generally id. (containing examples of arguments used by these drug manufacturers in promoting their objectives).
Due in part to the participation of physicians, drug manufacturers, and pharmacists in the problem definition discourse, the use and possession of morphine, heroin, and cocaine remained licit for medicinal purposes throughout the early 1900s. The medical community benefited from strategically crafting a narrative that defined iatrogenic addiction as a disease that they were best equipped to treat, especially since, at the time, this subpopulation of drug addicts were desirable consumers. In sum, the medical industry lobbied Congress to keep these substances licit for medicinal purposes, while advocating for the punishment of marginalized populations’ illicit or recreational use.

In conclusion, examination of the types of causal narratives that the medical industry used to describe problem drug use, while drug use was licit at the federal level, demonstrates how organized interests shaped the early drug policy problem definition discourse. In doing so, the medical industry advocated for a health definition for at least some target populations, while advocating for a criminal justice approach for others. The previous analysis also demonstrates how groups, aided by political and societal factors, used causal narratives to pressure Congress into action or inaction. The next section demonstrates how administrative agencies took advantage of a political opportunity to capitalize on changes in the public mood to redefine problem drug use in a way that has dominated for almost a century.

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192 Of course, it was not only interest group lobbying that prevented the regulation of opiates during this era. The acceptance of opiate use by the public as well as the lack of federal regulation of domestic issue in general also played a role. See generally COURTWRIGHT, supra note 57. MUSTO, supra note 57.
193 See COURTWRIGHT, supra note 57, at 2.
194 They were desirable mainly because of their class and their ability to pay for treatment and medications. See COURTWRIGHT, supra note 57, at 2.
195 It is important to note that, during this era, the federal bureaucracy was small and Congress had left much of the regulation of social problems to the local governments. THEDA SKOCPOL, SOCIAL POLICY IN THE UNITED STATES: FUTURE POSSIBILITIES IN HISTORICAL PERSPECTIVE (1995). The federal government had not yet established its power to police under the interstate commerce clause. See Wickard v. Filburn, 317 U.S. 111, 128–29 (1942). Thus, the general political atmosphere would have favored less federal interference and regulation and greater inertia would have been needed to propel Congress to outlaw drug use in its entirety.
5. The Role of Administrative Agencies in the Retreat from the Health Frame

Aside from the State Department’s interest in regulating opium as a way to participate in worldwide initiatives to prevent the exportation and trafficking of China’s opium, federal administrative agencies did not concern themselves with early efforts to define problem drug use. After the passage of the Harrison Tax Act in 1914, however, the stakes changed.

Congress directed the BIR to enforce the Harrison Tax Act, under Cornell Levis Nutt’s direction. Nutt and his colleagues masterfully capitalized on the nation’s fear of deviants to ensure that Congress generously funded their department. Americans had just fought a World War and were fearful of the “others” that threatened to disrupt the semblance of American life that they had left. Americans did not tolerate drug users whose inability to contribute to the war effort made them appear un-American. Further, a growing group of reformers during the Prohibition Era viewed both alcohol and drugs as vices that the law should prohibit. Nutt and his colleagues, whom the president appointed to the Treasury Department’s Special Narcotic Committee, capitalized on the public mood by publishing a report that estimated that there were 1 million addicts in the U.S. by 1919, a figure that they actively disseminated to the press. This figure added to public fear of this target population and justified the need for the creation of the Narcotic Division of the Treasury Department’s Prohibition Unit, a division of the BIR that

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196 ERLEN & SPILLANE, supra note 77, at 25. Although there were early efforts by the commissioner of BIR, Daniel C. Roper, to define addiction as a medical issue, including his assistance in drafting the France Bill, the window of opportunity had ended, as the Republicans gained control of Congress. Id. at 26. Further, the lack of support by his own bureau quelled any hope for BIR support of a public health solution to addiction. Id. Once Roper retired, Cornell Levis Nutt stepped up the rhetoric in defining addiction as a criminal justice issue, ensuring a law enforcement approach. Id.
197 Id. at 30-31.
198 MUSTO, supra note 57, at 133-134.
199 Id.
200 See generally U.S. CONST. amend. XVIII, repealed by U.S. CONST. amend XXI.
201 ERLEN & SPILLANE, supra note 77, at 30-31.
Congress created at the end of 1919. Of course, even the BIR later admitted that the figure of 1 million was an overestimation.

However, such a figure justified the creation of the Narcotics Division, a division that the BIR needed to coordinate their massive efforts to not only collect taxes and maintain a record of drug sales, but also to control the use of these medicinal substances by physicians—an interpretation of the Harrison Tax Act that many physicians and pharmacists thought conflicted with legislative intent. The BIR believed that the Act prohibited the prescription of narcotics to any addict, even for medication maintenance treatment. The BIR arrested thousands of physicians and heckled pharmacists over claims that they were prescribing and dispensing habit-forming drugs in quantities that exceeded legitimate medical treatment. It issued regulations giving itself authority beyond that which the Harrison Tax Act expressly outlined, most of which the Supreme Court upheld as constitutional.

Facing the full force of the BIR, the AMA repudiated their initial support for medication-maintenance treatment in 1920. Physicians were targeted for arrest and administrative agencies blamed physicians in congressional hearing testimony for causing the addiction epidemic. The political costs for continuing to advocate for narcotic prescriptions was high, and the payoff was rather low. By the early 1900s, the population of iatrogenic users that consisted of middle- and upper-class Whites, had dwindled. Physician education and self-regulation amongst the physician community led to a change in physician prescribing practices

202 Id. at 30-31.
203 Id. at 30-31.
204 Id. at 30-31; MUSTO, supra note 57, at 117.
205 MUSTO, supra note 57, at 121-150.
206 MUSTO, supra note 57, at 121-134. The Supreme Court responded by first curtailing the BIR’s authority and then adding its stamp of approval. See MUSTO, supra note 57, at 121-134.
207 MUSTO, supra note 57, at 200.
208 Id. at 134-139; 194-195.
209 COURTWRIGHT, supra note 57, at 110-123.
of opiates and cocaine.\textsuperscript{210} Further, medical treatment had evolved with new treatments replacing opiates and cocaine.\textsuperscript{211} The growing acceptance of the germ theory of disease, as well as vast improvements in sanitation, decreased the need for drug use.\textsuperscript{212} Non-iatrogenic heroin users, comprised of mostly young urban men who were associated with the criminal underworld—addicts that neither society nor the medical industry viewed with the same compassion as model iatrogenic patients—began to replace iatrogenic addicts.\textsuperscript{213} They were a target population that the AMA had no incentive to protect.

So the AMA, which had grown in size and strength, abandoned the claims that addiction was a disease and distanced itself from treatment of addiction.\textsuperscript{214} Many of its new members were general practitioners who were more conservative than their predecessors and most concerned with federal government intrusion into the practice of medicine and the threat of socialized medicine.\textsuperscript{215} Further, disagreement grew within the medical community over whether addiction was indeed a disease. In 1919, researchers falsified the antibody theory, the leading justification for the addiction as a disease argument, further convincing many physicians to abandon their claim that addiction was a disease.\textsuperscript{216} Additionally, physicians were becoming disenchanted by claims that addiction was curable after studies debunked a series of treatments that purportedly cured addiction.\textsuperscript{217} A growing number of physicians began advocating for incarceration of the addict to protect both society and the addict from himself.\textsuperscript{218}

\textsuperscript{210} Id. at 110-137.
\textsuperscript{211} Id. at 110-137.
\textsuperscript{212} Id. at 110-137.
\textsuperscript{213} Id. at 110-137.
\textsuperscript{214} MUSTO, supra note 57, at 200-201
\textsuperscript{215} ERLEN & SPILLANE, supra note 156, at 27; MUSTO, supra note 57, at 144-146.
\textsuperscript{216} MUSTO, supra note 57, at 76, 83. Although the anti-body theory was falsified in 1919, even at the height of its support, the theory never had any substantial evidence or proof supporting it. ERLEN & SPILLANE, supra note 156, at 28.
\textsuperscript{217} MUSTO, supra note 57.
\textsuperscript{218} COURTWRIGHT, supra note 57, at 123-137.
When Senator Joseph I. France introduced a bill in the summer of 1919 that defined addiction as a health issue, called for the use of the Public Health Service (“PHS”) hospitals to offer treatment for addiction, and requested a federal matching for all addiction treatment programs, the AMA withdrew their support for maintenance treatment and medical treatment for addiction.219 The AMA was growing increasingly concerned about the possibility of “government medicine” or a nationalized health system, and the idea that federally funded institutions would provide addiction treatment represented to the AMA just another example of the federal government’s increasing involvement in providing healthcare.220 The AMA further distanced itself from conversations of addiction, going so far as to repudiate their previous claims that addiction was a disease.221 Addiction was not a disease but a manifestation of repressed psychological issues, claimed the AMA.222

The PHS had no desire to take responsibility for treating addicts, so they endorsed the AMA narrative and expanded on it, claiming that addiction was actually a personality disorder, a type of psychopathy, one that not only predisposed addicts to drug use but also to criminal and anti-social behavior.223 There was no cure for psychopathy, so the PHS advocated for the use of the criminal justice system to handle this population.224 Such a narrative ensured that PHS hospitals would not be required to act as treatment centers for the nation’s population of drug users, a legislative solution that they were trying to avoid.

219 ERLEN & SPILLANE, supra note 156, at 27.
220 Id.
221 MUSTO, supra note 57, at 83.
222 ERLEN & SPILLANE, supra note 156, at 28; MUSTO, supra note 57, at 83.
223 ERLEN & SPILLANE, supra note 156, at 28.
224 ERLEN & SPILLANE, supra note 156, at 28.
With physicians and pharmacists under the watchful eye of the BIR, and the drug manufacturing industry undergoing a fundamental transformation, the coalition of interest groups that supported the narrative that addiction was a disease was no longer interested in continuing to support such a narrative. The strength with which the BIR entered the problem definition discourse and the shift in public sentiment required these groups to adjust their narrative and their involvement in drug policy legislative discourse. This era marked the end of the dominance of the “addiction as a disease” narrative and the beginning of the era in which the “addiction as deviance” narrative became most dominant in the discourse. Various narrators would use the deviance narrative over the next thirty years to justify the creation of additional federal law enforcement agencies invested in the portrayal of the addict as a criminal.

6. Attempts to Battle Narratives with Numbers

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225 Ethical drug companies evolved as they took on the corporate structure and began to invest more in the research and development of new medications that they could then market to physicians using their own research journals. ERLEN & SPILLANE, supra note 156, at 3. They no longer relied on physicians’ demand to dictate what drugs to make and instead focused on creating new drugs and then inducing demand by marketing the drug to physicians. Id. Moreover, as physicians changed their prescribing practices and the demand for opiates and cocaine decreased, it is likely that the profit stream for drug manufacturers from these medications was already decreasing drug manufacturers. Further, with the public’s growing awareness of the risks of morphine, heroin and cocaine, reformer’s calls for prohibition of alcohol and drugs, and physician’s vocal criticism of drug manufacturers taking the callous corporate form, which concerned itself with profits rather than patient well-being, continuing to adopt the narrative that addiction was a mere side effect of a medical treatment would have been politically risky. Congress signaled its disapproval of drug manufacturers role in the opiate epidemic by refraining from holding hearings on the amendments to the Harrison Act to prevent the drug manufacturers, amongst other organized interests, from watering down the amendments proposed. MUSTO, supra note 57, at 136. Further, although losing out on the revenue from opiate and cocaine sales would not be pleasant, if the country were to outlaw the use of opiates and cocaine, then they would also be eliminating the greatest source of revenue for their largest competitor: the patent-medicine manufacturer. Patent-medicine manufacturers were already experiencing political and financial turmoil. Id. They were busy staving off attacks from ethical drug companies and physicians. Id. Physicians lobbied for the regulation of patent-medicine manufacturers, which they accused of undermining physician authority by marketing directly to consumers and claiming that public had the tools necessary to treat their own illnesses by purchasing medication directly from the patent medicine manufacturers. Id. The passage of the Pure Food and Drug Act of 1906 marked the beginning of the end of the reign of the patent-drug companies, as they now had to label their medication with any potentially harmful ingredients, including cocaine, alcohol and morphine. Id. The requirement that manufacturers disclose the use of opium, morphine, heroin, alcohol or cocaine caused their sales to drop by 1/3. Id.
The most politically active federal law enforcement agency in the legislative problem definition discourse on substance abuse issues was the Federal Bureau of Narcotics ("FBN"), founded in 1930 with Harry J. Anslinger as its first commissioner. 226 Anslinger came from the Prohibition Bureau prior to its dismantling, and he was determined to not let his bureau fall prey to the same fate of the Prohibition Bureau.227 Luckily for Anslinger, he was a master story-teller who specialized in creating believable narratives that resonated with public sentiment. He supported his policy narratives with half-truths, questionable statistics, and harrowing tales of the perils of drugs use.228 He was also very adept at using the media to garner support for his narratives and legislative proposals.229 As faulty as his evidence may have been, he was convincing, and, throughout his thirty-two year tenure, Congress often deferred to his judgment when considering legislative proposals to address problem drug use.230 For much of his career, Anslinger argued that drug use was a sign of deviance and that the only suitable solution for such deviancy was stricter and harsher penalties for drug users and drug traffickers. 231 “The addict,“ he claimed, “is like a typhoid carrier; he will spread crime and disease wherever he goes. He will spread addiction.”232 The legislative solutions that aligned with such a narrative included incarceration of the addict to protect society. Such a causal story eliminated the possibility of medical-maintenance or medical-assisted therapies as a legislative solution, which Anslinger was also clear to explicitly denounce.233 “The idea of the government poisoning its citizens with

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226 ERLEN & SPILLANE, supra note 156, at 61.
227 ERLEN & SPILLANE, supra note 156, at 64.
228 ERLEN & SPILLANE, supra note 77, at 66.
229 ERLEN & SPILLANE, supra note 77, at 70-73.
230 ERLEN & SPILLANE, supra note 77, at 61, 66.
231 ERLEN & SPILLANE, supra note 77, at 61.
232 ERLEN & SPILLANE, supra note 77, at 129 (citing Anslinger’s 1959 television interview on the Monitor talk show).
233 ERLEN & SPILLANE, supra note 77, at 127.
narcotics is nonsense. Why don’t they set up bar rooms for alcoholic . . . ? Why not furnish everybody with what they want, bullets, or department stores for kleptomaniacs, and so on…”

Anslinger presented anecdotes and “fabricated horror stories connecting drug use with violent crime” as testimony in several congressional hearings, and they “weighed heavily” in Congress’s decision to enact major narcotics legislation, including the Boggs Act of 1951 and the Narcotic Control Act of 1956 (“NCA”). By 1956, Anslinger had accomplished his goals of persuading Congress to pass legislation requiring stiff mandatory minimum sentencing for possession and drug sale. The NCA even allowed for the jury to recommend the death penalty for a conviction of drug sales to a minor. As rhetoric expert Dr. Rebecca Carroll put it, “After twenty-six years, Anslinger was the recognized authority on narcotics. By controlling the discussion on narcotics, Anslinger controlled the policy on narcotics.”

Not until mandatory minimums became a reality did organized interest groups make a concentrated effort to publicly challenge the legitimacy of the United States’ criminal justice approach to the nation’s drug problems or attempt to redefine the problem of addiction as a medical disease. During the late 1950’s, the American Bar Association (“ABA”) and the AMA led the way in the attempt to redefine addiction as a health issue by testifying at congressional hearings and forming a formal, joint committee to study narcotic drugs. The ABA-AMA Committee hoped that their research would add credence to their criticisms of the United States’ criminal justice approach to addiction and would open up a dialogue between the Committee, the

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234 Id. at 127 (citing Anslinger’s 1959 television interview on the Monitor talk show).
235 Id. at 66.
237 Id. at § 107(i).
238 ERLEN & SPILLANE, supra note 77, at 112.
239 ERLEN & SPILLANE, supra note 77.
Narcotics Bureau, and Congress regarding alternative legislative solutions for the drug problem.\textsuperscript{240}

Instead, it enraged Anslinger, who wrote them letters dismissing the evidence in their 1958 Interim Report\textsuperscript{241} as inconsistent and lacking in factual accuracy.\textsuperscript{242} Anslinger had devoted his career to ensuring that the FBN was the federal agency responsible for addressing problem drug use and a problem definition that attributed the cause of drug use to psychological or medical causes would shift power to health agencies as fixers of the problem. Not only would the FBN’s appearance as the fixers of drug use be impacted, but so would the funding allocations that accompanied the delegated powers to fix the problem. If drug abuse is a health problem, then funding would flow away from law enforcement agencies, like the FBN, and towards health agencies. As such, Anslinger was invested in maintaining the “addiction as deviance” narrative.

As such, Anslinger refused the Committee’s multiple requests to meet and used the media to communicate his disgust for the Interim Report.\textsuperscript{243} Later that year the FBN released official Comments on the Narcotic Drug Interim Report of the ABA-AMA, a compilation of previously published texts that supported the FBN’s narratives—none of which directly addressed the claims made in the Interim Report.\textsuperscript{244} The FBN, under Anslinger’s direction, did what it did best: battle the evidence with stories. The ABA-AMA released their final report in 1961, which

\textsuperscript{240} The Committee was especially interested in exploring the expansion of Medication Assisted Treatments (MAT). \textit{ERLEN \& SPILLANE}, \textit{supra} note 77.
\textsuperscript{241} The report summarized the two approaches to addressing problem drug use: the punitive approach and the health approach. \textit{See generally THE JOINT COMM. OF THE AM. BAR ASS’N \& AM. MED. ASS’N ON NARCOTIC DRUGS, NARCOTIC DRUGS: INTERIM REPORT (1958) [hereinafter ABA-AMA].} It advocated that the federal government fund an experimental pilot program that prescribed opioids on an outpatient basis as treatment for addiction. \textit{Id.} at 11. The report included a detailed appendix outlining Britain’s approach to treating addiction, a harm reduction approach that favored MAT. \textit{Id.}

\textsuperscript{242} \textit{ERLEN \& SPILLANE}, \textit{supra} note 77.

\textsuperscript{243} \textit{Id.}

\textsuperscript{244} \textit{ADVISORY COMM. TO THE FED. BUREAU OF NARCOTICS, COMMENTS ON NARCOTIC DRUGS: INTERIM REPORT OF THE JOINT COMMITTEE OF THE AMERICAN BAR ASSOCIATION AND THE AMERICAN MEDICAL ASSOCIATION ON NARCOTIC DRUGS, (1959).} \textit{See also ERLLEN \& SPILLANE, supra} note 77.
they titled “Drug Addiction, Crime or Disease?” However, as Rufus King, one of the authors of the report, later wrote in his book entitled The Drug Hang-Up: the “ABA-AMA, [was] No Match for HJA.”

Although the ABA-AMA tried to redefine addiction as a disease, they did not have a high-ranking government official supporting their narrative. Rather, a high ranking administrative officer who had established himself as a narcotics expert directly opposed their narrative. Aside from not having the necessary support from an official, support that Baumgartner, et al., argue is an important predictor of successful problem redefinition, the ABA-AMA made an erroneous assumption: that gathering scientific or empirical evidence to support claims and arguments was the key to refuting the dominant causal story that problem drug use was a character flaw. Essentially, they brought facts to a battle of stories.

After all, Anslinger’s dominance in the drug policy discourse did not result from his use of “facts” or scientific evidence to support his arguments. Anslinger invested his energy in telling a compelling narrative that resonated with his audience and with legislators who were interested in assuaging their constituents’ fears. His narratives were consistent, his description of the target population elicited images that made his solutions more persuasive, and he artfully utilized the media to communicate his stories. The ABA-AMA Committee, on the other hand, did not even produce enough copies of the Interim Report for mass circulation, and they ran out of copies soon after it was published. Initially, they made enough prints to provide copies to the FBN and some ABA and AMA members for review, but the Committee wanted to make sure

---

245 ABA-AMA, supra note 244.
246 ERLEN & SPILLANE, supra note 77.
247 See generally ERLEN & SPILLANE, supra note 77.
248 BAUMGARTNER, supra note 55, at 78.
249 ERLEN & SPILLANE, supra note 77.
that the Interim Report was factually accurate and approved by the Board before copies got into
the hands of the media, libraries, schools, and even all of the members of the ABA and AMA.\textsuperscript{250} This decision allowed Anslinger to control the discourse by criticizing the Interim Report in the
media, when few had the opportunity to read the Interim Report for themselves.\textsuperscript{251} Further,
Anslinger insisted that the FBN widely circulate its Comments to the Interim Report as soon as it
was published in 1958, making sure to send copies to the media,\textsuperscript{252} while the ABA-AMA
Interim Report did not become widely distributed until 1961 as an attachment to the Final
Report.\textsuperscript{253} By the time the report was available, legislators had already made their judgments.
Anslinger understood that the key to success was to ensure that the FBN narrative dominated,
while the ABA-AMA was more concerned with ensuring that they had their facts straight—even
if it meant delaying its reports’ entrances into the discourse. As well-researched as the Interim
and Final Reports may have been, lawmakers dismissed them even before they became widely
available to the public, and with their dismissal, the efforts to redefine addiction as a disease
died. In the legislative process, evidence is only one input into the decision-making process and,
in this case, it was no substitute for a well-crafted story.

VI. LESSONS LEARNED: CONCLUDING REMARKS

As legal scholars, we devote many of our printed words to analyzing legislation that has
been enacted or proposed. We propose “better” legislative proposals or argue that current
proposals or enacted legislation are inadequate. Little legal scholarship analyzes or suggests how
to convince legislators to enact model legislative solutions. Even when making such

\textsuperscript{250} Id.
\textsuperscript{251} \textsc{Erlen & Spillane}, supra note 74, at 120-129.
\textsuperscript{252} Id. King argued that the FBN purposely made their publication appear similar to the Interim Report by printing it
on the same colored paper and formatting the cover similarly in an effort to confuse readers into thinking that they
were reading the Interim Report and not the comments to it. \textit{Id}.
\textsuperscript{253} Id.
suggestions, they often ignore the politics of the legislative process, the institutions that are involved, and the problem definition process that comes before, and drastically influences, the types of legislative proposals that lawmakers consider. In the academy, we place so much emphasis on the numbers, the facts, and the evidence, as if the side with the best evidence and the most publications in the highest-ranked journals wins. If the endgame is to contribute to the legislative process, however — if the goal is to help lawmakers reform our ineffective and costly criminal justice approach to problem drug use and replace it with any one of the model public health-oriented drug policies that many developed nations have effectively implemented, then continuing to focus on compiling more evidence will not help us reach our objective, because the existence of evidence alone does not change policy. The AMA and ABA had sufficient evidence to support their policy position, yet Harry Anslinger silenced them with his story. Arguably, the AMA was more successful in achieving their objectives in the late 1800s and early 1900s, when they had little evidence to support their narrative that addiction was a disease, than they were when they had a well-researched and documented report in the late 1950s. As groups like the Parents Groups of the 1970s and 1980s have shown us, the power lies within the narrative.

Although narratives may trump evidence, there is still strength in numbers in the sense that more voices in unison are stronger than a single voice. The coalitions that have formed around common narratives throughout drug policy history have shown us that the more narrators that tell the same story, the more likely that the narrative will dominate the legislative discourse. In each instance, groups had choices or alternatives as to how they wanted to craft their narrative, yet each compelling narrative had some commonalities. They each drew from cultural norms and beliefs in order to make their narratives believable. Their descriptions of their characters coincided with that population’s social construction. And, their causal theory framed the
solution they supported. Not only did these groups have commonalities in their narrative structure, they also shared an understanding of the power of narratives in the legislative process. They used their narratives to persuade other groups, legislators, and even high-ranking administrative officials to support their causal explanations and their legislative proposals.

Concerned citizens, including legal scholars, have at their disposal several strategies that they can use to take advantage of the current political window of opportunity that bi-partisan and public support for the addiction-as-a-disease narrative has created. Since a plethora of evidence supporting the efficacy of a public health-oriented approach already exists, proponents of the public health approach can focus their efforts on affecting the legislative process by using some of the strategies that this Article outlines. Namely, proponents can begin by (1) identifying preferred public health solutions, (2) strategically crafting a compelling causal story that aligns with the desired public health solutions and accounts for cultural norms and beliefs, (3) forming coalitions with other proponents that support the narrative and its aligning solutions, and (4) using the narrative to persuade high-ranking government officials in both the executive and the legislature to support public health solutions.

Moreover, advocates for the public health approach will need to broaden the problem definition of the Opioid Epidemic specifically, and problem drug use in general, to sufficiently address current and future problem drug use. For example, as with other health outcomes, the social determinants of health influence addiction and overdose death rates. If advocates supported a policy narrative that attributes problem drug use, at least in part, to social, economic and environmental factors, a multi-modal public health-oriented solution would have a greater likelihood for political success. Such a narrative does not negate the “addiction-is-a-disease
narrative,” but rather builds on it to focus on both treatment and establishing a system of supports that ensures the greatest likelihood for lifelong treatment success. Advocates can add to the credibility of such a narrative by pointing to the evidence that demonstrates that such multi-modal approaches are not only more effective, but are also more cost-effective in the long term.256

Since legal professionals and legal scholars are already predisposed to seeking policy change through the judicial system, this Article has focused on another avenue by which legal scholars and professionals can contribute to the problem definition discourse and influence policy outcomes—the legislative process. Although this manuscript focuses on affecting the legislative process, narrators can apply the problem definition strategies it presents to the implementation and interpretation phases of lawmaking. Moreover, although this discussion focuses on the issue of problem drug use, pressure groups can apply these strategies to other issues, like gun violence, for which groups desire to redefine the problem and effect policy change.

For a multi-modal public health approach to become a legislative staple in American policy, advocates of such an approach must learn from the failures and successes of past organized interest groups and focus on building a dominant and compelling narrative to supplement existing scientific evidence and seek support for such a narrative from coalitions and high-ranking government officials. After all, it is not the evidence, but the problem redefinition and its accompanying narratives that drive policy change.257

256 YSA ET AL., supra note 4.
The opioid epidemic has claimed more than 300,000 lives in the United States since 2000 and could claim another half million over the next decade. Although heroin and illicitly manufactured fentanyl account for an increasing proportion of opioid-involved overdoses, the majority of persons with opioid addiction started with prescribed painkillers. The search for solutions has spread in many directions, and one tentacle is probing the legal accountability of companies that supply opioids to the prescription market. Even as the federal government, among others, pursues civil and criminal actions against physicians and pharmacies to address inappropriate prescribing and dispensing of opioids, a variety of lawsuits have been filed and continue to be filed against opioid manufacturers and distributors.

These lawsuits commenced in the early 2000s but have increased in frequency and profile in recent years (see table). The earliest suits against opioid manufacturers — typically Purdue Pharma, the maker of OxyContin (oxycodeone) — were personal injury claims brought on behalf of persons with addiction who overdosed. Opioid products, they alleged, were defectively designed because companies failed to include safety mechanisms, such as an antagonist agent or tamper-resistant formulation. Manufacturers also purportedly failed to adequately warn about addiction risks on drug packaging and in promotional activities. Some claims alleged that opioid manufacturers deliberately withheld information about their products’ dangers, misrepresenting them as safer than alternatives.

These suits faced formidable barriers that persist today. As with other prescription drugs, persuading a jury that an opioid is defectively designed if the Food and Drug Administration approved it is challenging. Furthermore, in most states, a drug manufacturer’s duty to warn about risks is limited to issuing an adequate warning to prescribers, who are responsible for communicating with patients. Finally, juries may resist laying legal responsibility at the manufacturer's feet when the prescriber’s decisions and the patient’s behavior contributed to the harm. Some individuals do not take opioids as prescribed or purchase them illegally. Companies...

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<td><strong>State and local suits</strong></td>
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<td>West Virginia ex rel. McGraw v. Purdue Pharma L.P.</td>
<td>Nov. 5, 2004 (settled)</td>
<td>Aggressively marketing OxyContin to state residents, many of whom became addicted. Concealing from prescribers the extent to which OxyContin’s qualities could lead to addiction.</td>
<td>$10 million paid over 4 yr to support drug abuse and education programs, law-enforcement initiatives, and medical programs on drug abuse. No fault admitted.</td>
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<td>State of Oregon ex rel. Hardy Myers v. Purdue Pharma L.P. et al.</td>
<td>May 8, 2007 (settled)</td>
<td>Unlawfully marketing OxyContin for off-label uses. Misbranding OxyContin as “less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications.”</td>
<td>$19.5 million. Purdue pledged not to promote OxyContin for off-label uses. Requires Purdue to maintain abuse- and diversion-detection program, report problem prescribing, and have field sales personnel undergo special training before selling OxyContin. No fault admitted.</td>
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<tr>
<td>The People of the State of California v. Purdue Pharma L.P. et al.</td>
<td>May 21, 2014 (filed) May 24, 2017 (settled with Teva)</td>
<td>Engaging in false advertising by deceptively marketing opioid drugs meant for short-term use as appropriate for chronic pain. Engaging in unfair competition, in violation of the California Unfair Competition Law. Creating a public nuisance under California law by engaging in deceptive marketing that led to an epidemic of opioid abuse.</td>
<td>$1.6 million paid by Teva Pharmaceuticals, to be spent on combating the ongoing opioid epidemic impacts in Santa Clara and Orange Counties. Bars Teva from deceptive marketing. No fault admitted by Teva. Charges against Purdue, Endo Health Solutions, Janssen, and Actavis remain unresolved, although litigation stayed by state court judge pending outcome of FDA studies related to risks of long-term opioid treatment.</td>
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<tr>
<td>The People of the State of Illinois v. Insys Therapeutics, Inc.</td>
<td>Aug. 25, 2016 (filed) Aug. 18, 2017 (settled)</td>
<td>Violating the Illinois Consumer Fraud Act by engaging in the unfair and deceptive practices of deliberately marketing Subsys, the synthetic opioid approved for breakthrough cancer pain, for off-label purposes to high-volume opioid prescribers and paying prescribers to prescribe Subsys under a sham speaker program</td>
<td>$4.45 million. No fault admitted. Prohibits Insys from engaging in any false, misleading, or deceptive marketing and from promoting off-label use of its opioid drugs in Illinois. Requires Insys to promote its opioid Subsys only to prescribers who are oncologists or who are enrolled in an applicable FDA Risk Evaluation and Mitigation Strategy.</td>
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### Allegations

#### Commonwealth of Massachusetts v. Insys Therapeutics, Inc.

**Oct. 5, 2017 (filed and settled)**

- Violating the Massachusetts Consumer Protection Act by engaging in unfair and deceptive acts of misleading health care professionals about the appropriate use of Subsys, including by promoting the drug for off-label uses and paying kickbacks to health care professionals to induce them to prescribe Subsys

- **Settlement Details**
  - **Settlement Amount:** $500,000
  - **No fault admitted**
  - Prohibits Insys from engaging in any unfair or deceptive marketing practices of Subsys in Massachusetts, including for off-label purposes or by paying kickbacks to prescribers.
  - Prohibits Insys from promoting Subsys to any health care professional unless he or she provides cancer care or is enrolled in an applicable FDA Risk Evaluation and Mitigation Strategy.

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### Federal Suits

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<td><strong>United States of America v. The Purdue Frederick Company, Inc., et al.</strong></td>
<td>May 10, 2007 (filed) June 25, 2007 (settled)</td>
<td>Violating FDCA by misbranding OxyContin with the intent to defraud or mislead</td>
<td>$600 million paid by Purdue $34 million paid by three of Purdue's top executives Parties admitted to misleading physicians and patients about product's addictiveness and misbranding it as abuse-resistant</td>
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<td><strong>United States of America v. Cardinal Health, Inc.; United States of America v. Kinray, LLC</strong></td>
<td>Dec. 23, 2016 (settled)</td>
<td>Violating CSA by failing to report suspicious orders of controlled substances to pharmacies in Maryland, Florida, and New York Violating Washington record-keeping laws</td>
<td>$44 million, consisting of $34 million pursuant to Cardinal settlement and $10 million pursuant to Kinlay (acquired by Cardinal in 2010) settlement Cardinal admitted failure to report suspicious orders to the DEA</td>
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<td><strong>United States of America v. McKesson Corporation</strong></td>
<td>Jan. 5, 2017 (settled)</td>
<td>Violating CSA by failing to maintain effective controls against diversion of controlled substances, including opioids, and to report suspicious orders to the DEA Violating 2008 administrative agreement with federal government to monitor sales and report suspicious orders to the DEA</td>
<td>$150 million Requires McKesson to suspend sales of controlled substances from distribution centers in Colorado, Ohio, Michigan, and Florida for 1–3 yr. Because McKesson admitted failure to report suspicious pharmacy orders, it agreed to enhanced compliance with earlier 2008 agreement (which had also included a $13.25 million settlement)</td>
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<td><strong>United States of America v. Mallinckrodt, Inc.</strong></td>
<td>July 11, 2017 (settled)</td>
<td>Violating CSA by failing to notify DEA of suspicious orders, as well as failing to implement an effective system to detect such orders</td>
<td>$35 million Allows DEA to analyze data Mallinckrodt collects on orders from customers No fault admitted</td>
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### Foreign Suits

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<td><strong>Canada-wide class proceedings v. Purdue Pharma et al.</strong></td>
<td>June 8, 2007 (commenced) Aug. 24, 2017 (settlement approved)</td>
<td>Failing to disclose the known risk of addiction and withdrawal associated with OxyContin and OxyNEO to a class of persons who were prescribed and ingested these products from Jan. 1, 1996, through Feb. 28, 2017</td>
<td>$20 million (Canadian) settlement proposed and accepted by three of four jurisdictions overseeing the cases, consisting of $2 million to provincial health providers, $4.5 million in legal fees, and ~ $13,000–$17,000 per class member</td>
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* CSA denotes Controlled Substances Act; DEA Drug Enforcement Agency; FDA Food and Drug Administration; and FDCA Food, Drug, and Cosmetic Act.
may argue that such conduct precludes holding manufacturers liable, or at least should reduce damages awards.³

One procedural strategy adopted in opioid litigation that can help overcome defenses based on users’ conduct is the class action suit, brought by a large group of similarly situated individuals. In such suits, the causal relationship between the companies’ business practices and the harm is assessed at the group level, with the focus on statistical associations between product use and injury. The use of class actions was instrumental in overcoming tobacco companies’ defenses based on smokers’ conduct. But early attempts to bring class actions against opioid manufacturers encountered procedural barriers. Because of different factual circumstances surrounding individuals’ opioid use and clinical conditions, judges often deemed proposed class members to lack sufficiently common claims.³

The tide may turn for such lawsuits, however. As the population harmed by opioids grows and more information about the populations is documented, it becomes easier to identify subgroups with similar factual circumstances and legal claims — for example, newborns with neonatal abstinence syndrome. A class action brought against Purdue Pharma in Canadian court by persons who were prescribed and ingested OxyContin and OxyNEO (controlled-release oxycodone), which alleged claims similar to those in many U.S. cases, is on the verge of being settled for $20 million, if all involved provinces agree (see table).

Perhaps the most promising development in opioid litigation has been the advent of suits brought against drug makers and distributors by the federal government and dozens of states, counties, cities, and Native American tribes. Because the government itself is claiming injury and seeking restitution so that it can repair social systems debilitated by opioid addiction, these suits avoid defenses that blame opioid consumers or prescribers. They also garner substantial publicity.

Government strategies include traditional types of enforcement actions based on the federal Food, Drug, and Cosmetic Act, which prohibits introducing “misbranded” drugs into interstate commerce. However, governments have recently embraced several more creative strategies, borrowing from playbooks used for suing tobacco and firearm companies.

The first strategy focuses on the public scourge created by the opioid epidemic. Governments allege that opioid companies unreasonably interfered with the public’s health by oversaturating the market with drugs and failing to implement controls against misuse and diversion, thereby creating a public nuisance. State attorneys general made similar arguments about firearm manufacturers, which allegedly knew that the high volume of guns they were supplying could find buyers only on the black market.

The second strategy paints opioid companies’ business practices as deceptive. In these fraud claims, sometimes brought in connection with Medicaid claims or consumer protection laws, governments charge that companies made false representations about their products’ addictiveness and effectiveness, all calculated to mislead the state, prescribers, and the public. This argument proved powerful in suits against tobacco companies.

A third strategy calls out companies’ lax monitoring of suspicious opioid orders. The federal Controlled Substances Act requires drug suppliers to maintain effective controls against, and to notify the Drug Enforcement Agency of, potentially illegitimate orders.

Whereas tobacco lawsuits benefited from leaked evidence that tobacco companies were aware of nicotine’s addictiveness and sought to understate it and to manipulate nicotine levels in tobacco products, no comparable whistleblower evidence has emerged with regard to opioids. Without such evidence, it is harder to establish an intent to deceive. Nevertheless, other information may help prove that companies knew that what
they were doing was harmful: admissions of liability in some settlements; documents obtained in government investigations, investigatory reporting, and litigation; and marketing practices that persisted despite mounting evidence linking opioids to adverse health outcomes.\textsuperscript{3,4,5}

A final strategy highlights the profits that opioid companies have reaped at the government’s expense through allegedly unfair business practices. In these “unjust enrichment” claims, governments argue that opioid companies should have to disgorge such profits. This argument has intuitive appeal, as it did in litigation over tobacco, firearms, and lead paint, because attorneys can point to huge pecuniary gains enjoyed while the government was saddled with vast medical and law-enforcement costs. Such claims have struggled to find legal footing in cases involving other products because courts typically require evidence that the government conferred a benefit on the company. For opioids, though, government payment for excessive prescriptions under public insurance programs directly contributed to companies’ profits. Already, two large settlements have occurred in cases that included unjust enrichment claims, although pharmaceutical companies avoided admitting fault (see table).

Notwithstanding the $600 million federal settlement with Purdue in 2007 — one of the largest in history with a drug company — opioid litigation has yet to financially dent the $13-billion-a-year opioid industry. Moreover, opioid litigation victories have all taken the form of settlements, in which companies usually have not admitted any fault. Even when litigation costs have no prospect of exceeding the economic benefits of continuing to produce a dangerous product, though, litigation can have value as a public health strategy and may mitigate some harms of the opioid epidemic.

The funds obtained in several government suits have provided desperately needed resources for opioid addiction treatment and law enforcement. Future payouts, reasonably likely to increase in frequency and magnitude, could also be earmarked for other support services for persons with addiction — such as housing and employment assistance — and for distributing the overdose-reversal drug naloxone. Experience suggests that the challenge will be ensuring that the windfalls to state governments are not diverted to unrelated purposes.

Ligation could also help alleviate the opioid epidemic by changing industry practices and building public awareness. Settlement agreements may include commitments to modify particular marketing and distribution practices, as in the case of McKesson (see table). Lawsuits may bring to light harmful, unethical, and even illegal business practices that sour public opinion of opioid companies and prompt patients to ask more questions about what their doctor prescribes. Finally, snowballing litigation helps build the case for greater regulation. Win or lose, lawsuits that very publicly paint the opioid industry as contributing to the worst drug crisis in American history put wind in the sails of agencies and legislatures seeking stronger oversight.\textsuperscript{5} Together, litigation and its spillover effects hold real hope for arresting the opioid epidemic.

Disclosure forms provided by the authors are available at NEJM.org.

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Defining the Opioid Epidemic: Congress, Pressure Groups, and Problem Definition

TALEED EL-SABAWI*

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* Doctoral Candidate, Graduate Teaching Associate, Graduate Research Associate, The Ohio State University, College of Public Health, Division of Health Services Management and Policy. Special thanks to Sandra Tanenbaum for unplugging me from the “Matrix” that is positivism and teaching me the value of a well-crafted policy narrative. If it wasn’t for Sandy, I would still be sitting in a room somewhere counting numbers, with no real understanding of what and why I was even counting in the first place.
I. Introduction

The United States has a drug problem—a drug problem that is characterized by high rates of opiate overdose deaths and a drug problem to which people commonly refer as the “Opioid Epidemic.” The Opioid Epidemic has resulted in an increase in popular, political, and scholarly focus on the ineffectiveness of the U.S.’s criminal justice, or punitive legislative approach, to problem drug use. The Opioid Epidemic has also led to an increased focus on the need for Congress to embrace a health approach in addressing problem drug use, an approach that emphasizes the prevention and treatment of addiction. U.S. legislators have responded by distancing themselves from blatant punitive policies of the past and adopting health-oriented definitions of problem drug use that support health-oriented legislative proposals.

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1 Opioid overdose deaths have been rising for at least 16 years, with the number of deaths each year equaling a new historic high. See Opioid Overdose, CTRS. FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/drugoverdose/data/index.html (last updated Jul. 18, 2017).

2 Although at times the criminal justice and punitive approach may seem interchangeable, the criminal justice approach, by my definition, also includes proposals to administer drug treatment through the criminal justice system. Some may consider such mandatory treatment punitive, while others may argue that it is still a health solution. I would categorize it as a criminal-justice approach, as it uses the criminal justice system to administer it.

3 Throughout this paper, I use the term “problem drug use” to refer to any drug use that interferes with the ability of the user to meet his or her societal, educational, and occupational obligations. I adopt a similar conceptualization of problem drug use as Anderson, et al., in that I believe problem drug use is “habitual, heavy consumption of something pleasurable”. See Peter Anderson, Jürgen Rehm & Robin Room, The Impact of Addictive Substances and Behaviours on Individual and Societal Well-being, 38, (2015) [hereinafter Anderson et al.].

4 Through the use of cluster analysis of components of European drug policy systems, Ysa and colleagues were able to identify three main approaches to drug policies: a punitive approach, an assistantship approach, and a public health approach. Tamiko Ysa et al., Governance of Addictions: European Public Policies, 3 (2014). The assistantship approach is an approach that treats problem drug use as a disease that necessitates treatment. This is differentiated from a public health approach that emphasizes harm reduction. Ysa et al., supra note 3, at 4.

5 The reasons that advocacy for a health approach has increased for this drug epidemic, while it was absent from previous epidemics, is beyond the scope of this manuscript.

6 Admittedly the Trump administration’s recent decision to rescind Obama-era policy and once again mobilize federal law enforcement agents to prosecute possessors of marijuana, even in states that have chosen to decriminalize or legalize certain recreational drug use, Memorandum from Jefferson B. Sessions, III., Office of the

Congress has also demonstrated a willingness to use the health approach to address the current Opioid Epidemic by passing the Comprehensive Addiction and Recovery Act of 2016 ("CARA"), health-oriented legislation\(^7\) that Congress drafted and enacted with nearly unanimous bipartisan support\(^8\) and later funded with equal legislative enthusiasm.\(^9\) In doing so, some members of Congress explicitly supported the definition of addiction as a brain disease, as opposed to a moral failing.\(^10\) And defining addiction as a disease, instead of a moral failing, begs a health solution,\(^11\) as opposed to a criminal justice solution.

The increased public and political attention on the issue of drug use and the supportive political climate for a health approach to the Opioid Epidemic have created a political window of opportunity\(^12\) for legal scholars, professionals, researchers, and other concerned citizens to

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7 There are provisions in CARA, however, that do not fit squarely within the criminal justice vs. health dichotomy. For example, CARA emphasizes the need for states to develop prescription monitoring programs to identify prescribers that may be responsible for prescription drug diversion. Comprehensive Addiction and Recovery Act of 2016, Public Law No: 114-198 S. 524 § 601(b). Law enforcement would then have access to these prescription monitoring systems and use the intelligence it provides to criminally prosecute prescribers. Such a supply-side solution runs counter to the demand-side focus typically accompanying a health approach.


11 I use the term "solutions" throughout this manuscript to refer to legislative or administrative policy alternatives or proposals. Although such proposals rarely solve a policy problem in its entirety, lawmakers propose them with the hopes that they are at least partial solutions to the problem. DEBORAH A. STONE, POLICY PARADOX AND POLITICAL REASON (2011). Punitive solutions are those that apply a penalty to a behavior in order to punish and deter the behavior. Id. In the arena of drug policy, supply-side solutions are those focused on decreasing the drug supply and typically involve controlling domestic sale of the drug as well as disrupting the supply from the country of origin. YSA, supra note 4, at 17. Demand-side solutions, on the other hand, decrease the demand for the drug typically through treatment and prevention efforts. Id. at 17.

12 Dr. Kingdon argues that, for an issue to make it to the political agenda, there must be a window of opportunity that occurs when three streams align: the problem stream, the policy stream, and the politics stream. JOHN W. KINGDON, AGENDAS, ALTERNATIVES, AND PUBLIC POLICIES (1984). The problem stream includes social issues that may or may not currently be on the public’s agenda. Id. The policy stream includes legislative proposals, or as I
pressure legislatures and administrative agencies to shift their focus from criminal justice legislative proposals to evidence-based public health proposals. Such public health proposals emphasize harm reduction,¹³ access to quality treatment, and the amelioration of the socio-economic risk factors that increase the likelihood of problem drug use.¹⁴

To effectuate such a policy change, however, concerned citizens must understand the problem definition process and the role that groups play in redefining a problem. Problem definition is the part of the lawmaking process during which actors within the political sphere describe the causes of a problem and the solutions lawmakers should use to address the problem.¹⁵ A rhetorical tool that policy actors commonly use to persuade others in the problem definition process is the causal narrative, a story that identifies the cause of the policy problem, assigns benefits and blame, and limits the alternative legislative solutions.¹⁶ Because policy actors may use different causal stories to define the same social problem, narratives battle to be accepted as the dominant causal story. It is this precise battle between narratives that is at the heart of the lawmaking process.¹⁷ Narrators, including pressure groups, organized interest refer to them throughout this paper, legislative solutions. Id. The politics stream refers to the political environment. Id. Often there are champions of particular problem definitions in the problem stream, or legislative proposals in the policy stream, who lay in wait for all three streams to align so that they can take advantage of the political window of opportunity to place their issue and/or solution on the political agenda. Id.

¹³Harm reduction approaches focus on reducing the social, economic, and health harms of drug use, as opposed to focusing on user abstinence. YSA, supra note 4, at 5-6. Analysts measure success by the reduction of these harms, as opposed to abstinence of drug use. Id. at 5-6. For examples of harm reduction policies used by European nations, see id. at 34-35, 42-43.

¹⁴The public health approach to improving access to treatment includes not only ensuring that there are enough treatment providers to provide the care, but also that the individual has transportation to get to appointments, the appointments are available during non-work hours, and the individual has the ability to pay for care. Access to Health Services, OFFICE OF DISEASE PREVENTION & HEALTH PROMOTION, https://www.healthypeople.gov/2020/topics-objectives/topic/Access-to-Health-Services.


¹⁶STONE, supra note 13.

¹⁷Id.
groups, and administrative agencies (collectively, “pressure groups”) compete for the opportunity to contribute a problem definition to the discourse. Each narrator hopes that their problem definition will become the dominant problem definition, because the group that dominates the problem definition discourse has the power to limit the alternative solutions available to a policy problem.

Although some scholars and researchers may view the involvement of organized interest groups in the legislative process as a threat to the development of evidence-based policy, our Founding Fathers chose to design a government that permits and even encourages majoritarian pluralism. Majoritarian pluralism encourages governments to consider the preferences of groups that represent the interests of factions of its citizenry. Lawmaking in such a system does not exclude experts from the legislative process. Scholars, researchers and professionals can affect policy change even when lawmakers do not call on them individually for expert testimony. They can push for reform by mobilizing into groups and contributing to the problem definition discourse—by insisting that group leaders advocate for the adoption of new causal narratives; swaying the public to adopt their desired causal stories; calling upon group members

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18 Organized interest groups include citizen groups, trade and business associations, business corporations, professional associations, coalitions on specific issues, unions, foundations and think tanks, governmental associations, and institutions and associations of institutions.

19 ROCHEFORT & COBB, supra note 17. STONE, supra note 13.

20 Id.


22 See THE FEDERALIST No. 10. (James Madison).

23 Majoritarian pluralism can be traced back to James Madison’s Federalist Paper No. 10, in which he referred to diverse “factions” representing the interests of groups of citizens. Although some scholars believe that “factions” could have referenced both parties and organized interest groups, I would argue that Madison’s use of the word “parties” just a few paragraphs before his definition of factions implies that he intended for factions to refer to interest groups. See e.g., Martin Gilens & Benjamin I. Page, Testing Theories of American Politics: Elites, Interest Groups, and Average Citizens, 12 PERSPECTIVES ON POL., 564–81 (2014) (arguing factions could have referenced both parties and interest groups). “By a faction,” Madison writes, “I understand a number of citizens whether amounting to a majority or a minority of the whole, who are united and actuated by some common impulse of passion, or of interest, adverse to the rights of other citizens, or to the permanent and aggregate interests of the community.” THE FEDERALIST No. 10, at 1 (James Madison).
to pressure legislators to adopt their narrative through the use of strategically crafted emails, letters, and phone calls; and promoting their narratives at town halls or Congressional field hearings.

This Article purports to equip legal scholars, researchers, and all concerned citizens with a greater understanding of the legislative problem definition process and the role that pressure groups play in such a process. By referencing examples from drug policy history, this Article demonstrates how pressure groups strategically used problem definitions to shape legislative discourse and pressured Congress into supporting legislative solutions that aligned with their problem definitions—attributing addiction to disease at times and to deviancy at other times. Through the analysis of such examples, this manuscript outlines strategies that legal scholars, researchers, and concerned citizens can use to define problem drug use as a public health issue caused by multiple sociological, psychological, economical and biological factors.

Part II of this Article provides readers with an introduction to the problem definition and policy narrative literature, starting with a general background on its philosophical roots and then explaining how pressure groups use narratives to influence the problem definition process. Part III, then, provides evidence to support the claim that pressure groups affect the legislative decision-making process, primarily through the subject-matter expertise that they provide to legislators. Part IV explains, by use of both hypothetical and historical examples, how groups construct narratives. This part is by no means a complete historic account of all instances in which lobbying groups effectively utilized narratives to further their objectives, nor is it a complete history of drug policy in the U.S. I chose to focus my analysis on time periods during which the health vs. criminal justice narrative battle dominated policy discourse. Part V highlights pivotal times in early U.S. drug policy during which pressure groups defined or
redefined problem drug use as either a health problem or a criminal justice problem. Finally, Part VI concludes with lessons learned from the analysis of narrative use by pressure groups and outlines recommendations for problem definition strategies that legal scholars and professionals can use to further their policy objectives in drug policy debates and beyond.

II. Problem Definition & Policy Narratives

Problem definition theory is rooted in the epistemological belief of social constructivism, which theorizes that society makes sense of the world around it through shared interpretation and meaning.\(^{24}\) The “Truth,” or absolute reality, may or may not exist; but rather than focusing on compiling evidence or facts that attempt to represent this absolute reality,\(^{25}\) the constructivist focuses on uncovering how society interprets reality. Such an interpretation and assignment of meaning is what influences societal values, beliefs, actions and inaction.\(^{26}\) Policymaking then becomes “[the] struggle over alternative realities.”\(^{27}\)

Problem definition\(^ {28}\) scholars apply this knowledge-seeking theory to studying how the political process defines social problems.\(^ {29}\) Problem definition theorists believe that people

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\(^{24}\) Epistemology generally refers to theories of knowledge gathering or philosophy of knowledge. Frank Fischer, Reframing Public Policy: Discursive Politics and Deliberative Practices (2012).

\(^{25}\) Such a knowledge-seeking expedition runs counter to the mainstream scientific philosophy referred to as positivism, or its more modern counterpart post-positivism, which posits that there is an objective reality that we are trying to measure. Fischer, supra note 26. Within this model, the observer stands at an arm’s length, with a validated measuring stick, and a statistical arsenal with the objective of proving or disproving a hypothetical truth in the form of a hypothesis. Id.

\(^{26}\) Id.

\(^{27}\) Id.

\(^{28}\) Id. note 17.

\(^{29}\) Problem definition has different names, depending on the discipline: “problem framing” or “frames” in sociology, communication, and political science, or “policy narratives” in the narrative literature of policy studies. See, e.g., Rochefort and Cobb, supra note 17. David A. Snow & Robert D. Benford, Ideology, Frame Resonance and Participant Mobilization, 1 INT’L SOC. MOVEMENT RES. 197, 197–218 (1988). Because “framing” refers to a variety of constructs, I will use “problem definition” throughout this Article to refer to act of defining a social problem, with the caveat that different disciplines refer to the same construct by different names.

\(^{29}\) Social problems are a “shared understanding of some problematic condition or situation they define as in need of change, make attributions regarding who or what is to blame, articulate an alternative set of arrangements, and urge others to act in concert to affect change.” Snow & Benford, supra note 30, at 615. A social problem differs from a policy problem because a social problem does not become a policy problem until it “gains attention and legitimacy” and lends itself to an “official programmatic response.” Rochefort and Cobb, supra note 17, at 8.
contest and debate social problems in the political sphere based on their perceptions of what the problem is, but one can always contest these perceptions.30 I will demonstrate this to be true in the arena of drug policy through examples of competing problem definitions at different junctures in history.

Accepting that problem definitions are contestable is not to say that they are not at all grounded in evidence. Rather, it is an acknowledgement that other factors, aside from empirical evidence, contribute to the manner in which society defines problems. These other factors include “[c]ultural values, interest group advocacy, scientific information, and professional advice.”31 People use evidence, facts, and scientific studies to justify or support a narrative. Often, however, problem definition narrators choose the evidence selectively, giving preference to evidence that supports their preferred causal narrative, while discounting, omitting, or ignoring conflicting evidence.32 Therefore, evidence is used as one of the many tools of narrative persuasion.

Although different tools are used in the problem definition process, I will focus on the use of policy narratives or stories, as well as the use of synecdoche in these narratives.33 Policy narratives “are a way of structuring and communicating our understanding of the world.”34 They resemble fictional narratives in that they have characters, a plotline, an ending, and a relatively consistent structure.35 Unlike fictional narratives, however, policy narratives require a higher standard of believability, and society judges them as real depending on how believable or

30 Id. at 8.
31 Id. at 4.
32 Id. at 15–24; STONE, supra note 13, at 311-330
33 There is disagreement in the policy narrative literature on whether policy narratives and policy stories are the same construct. See SHAUL R. SHENHAV, ANALYZING SOCIAL NARRATIVES (2015). For the purposes of this Article, I will use the terms interchangeably.
35 STONE, supra note 13, at 158; SHENHAV, supra note 35, at 35.
credible they appear to be. Narrators can gain credibility through the use of experts or with scientific evidence. Believability, however, depends on the degree to which the narrative resonates with cultural and societal norms, the familiarity of the plotline, and the degree to which the character descriptions coincide with the audiences’ perceptions of that character from their life experiences and encounters. Many of these recycled plotlines apply to different social problems over time, especially because familiar policy narratives tend to be more convincing to legislatures, administrative officials, and the public. These policy narratives are important in that they affect perceptions of the trade-offs between legislative alternatives.

The causal story is type of policy narrative used in legislative discourse. Causal stories describe the cause of the problem, assign blame, and suggest burden and benefit allocations depending in part on the blame assignment and the social construction of the target population that the legislative solution affects.

These stories often identify the actors of the story as either heroes or villains, innocent or guilty, or strong or weak, and they describe the cause of the phenomenon as action or inaction by these characters. Narrators in the legislative discourse use these causal as tools of persuasion to further their legislative objectives.

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36 FISCHER, supra note 26, at 177-178.
37 FISCHER, supra note 26, at 177-178; ANNE LARSON SCHNEIDER & HELEN INGRAM, POLICY DESIGN FOR DEMOCRACY (1997).
39 For examples of common plotlines, see STONE, supra note 13, at 168-175
40 FISCHER, supra note 26.
41 STONE, supra note 13.
42 Martin, supra note 41, at 6.
43 In general, the social construction of target populations refers to “the cultural characterizations or popular images of the persons or groups whose behavior and well-being are affected by public policy.” Anne Schneider & Helen Ingram, Social Construction of Target Populations: Implications for Politics and Policy, 87 Am. Pol. Sci. Rev. 334, 334 (1993).
44 STONE, supra note 13, 157-182. SCHNEIDER & INGRAM, supra note 39, at 334.
45 Helen Ingram, Anne L. Schneider, & Peter Deleon, Social Construction and Policy Design in Theories of the Policy Process, (Sabatier, 2007); STONE, supra note 13, at 158.
The narrators, or storytellers, in the legislative discourse can include, but are not limited to, administrative officials, legislators, and organized interest groups. Administrative agency officials use causal stories to convince the legislature that a social issue within their subject-matter expertise is a policy problem that Congress should prioritize. Administratives officials also use causal stories to justify rules and regulations that they promulgate in carrying out their duties of enforcement and implementation of legislation. Legislators use causal stories to persuade colleagues to adopt certain legislative solutions and garner constituent support on issues and proposals. Organized interest groups use causal stories to persuade legislators and administrative officials to adopt legislative and regulatory proposals that benefit their members. Even the judiciary uses causal stories to justify their interpretation of legislative intent.

Although multiple actors are involved in the narrative discourse, in this Article I focus on how pressure groups participate in the legislative narrative discourse and influence the types of solutions available to legislators. In order to do so, I begin by presenting evidence that supports the contention that pressure groups influence legislative decision-making and then I explain how they use narratives to do so.

III. PRESSURE GROUPS & LEGISLATIVE INFLUENCE

46 See Part III.B, for examples of narrative use by the Narcotics Bureau to justify the war on drugs and the need to continue their efforts in addressing the drug problem using a law enforcement approach.
47 For example, from the 1970s to the 1990s, the Social Security Administration supported the causal narrative that addiction was a disorder that resulted in a disability. See Max Selver, Disability Benefits and Addiction: Resolving an Uncertain Burden, 91 N.Y.U. L. Rev. 954, 988 (2016). This interpretation allowed individuals with addiction to qualify for Social Security Income benefits. Id.
48 For example, in advocating for the passage of CARA, Senator Robert Portman defined addiction as a chronic disease of the brain. Portman, supra note 12.
49 See e.g., Part IV.D. (discussing how the Parents Group’s use of causal narratives to shift government focus and resources to protecting their children from the temptations of marijuana).
50 See e.g., Daniel Polisar & Aaron Wildavsky, From Individuals to System Blame: A Cultural Analysis of Historical Change in the Law of Torts, 1 J. OF POL’Y HIST. 2 (1989) (chronicling how judges defined the problems presented in tort litigation differently over time to accommodating changing public and cultural views on who should be blamed and benefited by tort litigation).
Organized interest groups battle for legislator time and attention so that they can have the opportunity to define problems that affect their members. Administrative agencies also engage in the legislative problem definition process by issuing government reports that outline the cause and scope of public problems and by testifying in front of Congress. By defining the problem, pressure groups can influence legislative outcomes. Although throughout this paper I often refer to both organized interests and administrative agencies collectively as pressure groups, I will review the evidence for organized interest group and administrative agency influence on legislative decision-making separately, because the legislative behavior literature often treats these two groups separately in their analysis.

A. Organized Interests’ Influence on Legislators

Researchers have long hypothesized that organized interests influence legislative decision-making by providing legislators with financial contributions. Politicians need such

53 In the arena of drug policy, government reports have been very influential in focusing the public’s attention on the nation’s drug problem and in enumerating the magnitude of the problem, usually through reports of increases in the number of persons using illicit substances, persons addicted to illicit substances, or persons overdosing from illicit substances. In Gonzenbach’s analysis of 15 years of U.S. drug policy, the attention cycle for each episode of nationwide problem drug-use began with a federal agency releasing a report publicizing an increase in drug use, after which the media began covering the nation’s drug problem, and then public concern over the nation’s drug problem increased. WILLIAM J. GONZENBACH, THE MEDIA, THE PRESIDENT, AND PUBLIC OPINION: A LONGITUDINAL ANALYSIS OF THE DRUG ISSUE, 1984-1991 (1996). Public attention would fade, however, even if the problem drug use remained at the same rate. Id. It was not until a government agency released another report that the media, and then the public, would once again pay attention to problem drug use. Id. The order in which this occurred suggests that government reports shape the media’s perception of drug problems.
54 Harry Anslinger was famous for his fiery testimony in front of Congress on drug issues while he was director of the Narcotics Bureau. He preached fire and brimstone for the deviants who used and sold drugs and members of Congress deferred to his judgment. DAVID T. CURTWRIGHT, DARK PARADISE: A HISTORY OF OPIATE ADDICTION IN AMERICA 1–100 (2001); DAVID F. MUSTO, THE AMERICAN DISEASE: ORIGINS OF NARCOTIC CONTROL 1–100 (OXFORD UNIV. PRESS 3rd ed. 1999) (1973).
campaign funds to pay for advertisements, among other costs, that increase the likelihood that voters will elect the candidate.\textsuperscript{57} It reasonably follows that legislators may pay special attention to interest groups that donate to their campaign.\textsuperscript{58} As logical as such a deduction may be, the empirical literature, to date, has not been able to find a consistent relationship between campaign contributions and legislative outcomes.\textsuperscript{59} Researchers, however, have found that legislators are more likely to meet with groups that donate to their campaign.\textsuperscript{60} This indicates that what groups might be buying with their campaign contributions is not necessarily a legislative outcome, but rather, a legislator’s time.\textsuperscript{61} Getting some focused time and attention from a legislator allows the group to use that time to define policy problems and try to narrow legislative solutions.\textsuperscript{62} In sum, the body of research suggests that, although campaign finance may influence legislative outcomes, it does not provide a reliable predictor of how or why interest groups influence legislators’ decision-making processes.


\textsuperscript{58} Scholars have also hypothesized that legislators pay special attention to campaign contributors that donate to other legislators’ campaigns in the hopes that these donors will donate funds to their campaign in the future. Kalla & Broockman, \textit{supra} note 54, at 545–46.

\textsuperscript{59} Beth L. Leech, \textit{Lobbying and Influence}, in \textsc{The Oxford Handbook of American Political Parties and Interest Groups} 534-51 (L. Sandy Maisel & Jeffrey M. Berry eds., 2010). Political scientists also hypothesize that organized interests are influential because they have information on the preferences of their members and can mobilize their members to vote for a legislator. \textit{Id.} However, the empirical evidence justifying such a claim is weak. See, \textit{e.g.}, \textit{id.} at 546 (which found only interest groups used arguments that were “electoral in nature” only 3% of the time).

\textsuperscript{60} Kalla & Broockman, \textit{supra} note 54, at 546.

\textsuperscript{61} \textit{See id.} at 547.

\textsuperscript{62} \textit{Id.} Leech also notes that interest groups may use their influence to affect which issues get on the political agenda. Leech, \textit{supra} note 62. For a legislative outcome to be possible, an issue must first get on the political agenda and be deemed worthy of attention by legislators. \textit{Id.} By preventing issues from ever getting on the political agenda in the first place, groups can block legislation from being introduced on the issue. \textit{Id.} It is difficult to measure how many issues do not make it on the agenda and why they do not make it on the agenda, so most research on interest group influence has focused on counting yes or no votes on legislation that has made it through the many hurdles necessary to reach a floor vote. \textit{Id.}
Interests groups, however, have other resources that they can provide to legislators, aside from dollars and votes—resources that may allow them to otherwise influence legislative decision-making. Interest groups offer subject-matter expertise and specialized information that allow legislators to make informed decisions on issues without incurring the costs for compiling such information. Additional, advocacy or citizens groups can publish reports on an issue that the public and media find trustworthy and convincing. If such a report aligns with a legislator’s narrative on an issue, the report provides external validity to his or her claims. It is when groups offer this “legislative subsidy” that they are in a prime position to use their research and subject matter expertise to justify a particular problem definition.

B. Administrative Agency Influence on Legislators

Federal, state, and local administrative agencies are another source of specialized information for legislators. These agencies are often privy to data and statistics that measure the type, scope, and cause of a problem. Since legislatures charge administrative agencies with the implementation and enforcement of legislation, the agencies’ technical expertise on the logistics of implementation can be valuable in ensuring that legislators minimize the unintended

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65 Hall & Deardorff, supra note 66.
66 Hall & Deardorff coined the term “legislative subsidy” to refer to the specialized information that organized interest groups can provide to legislators, so that legislators do not have to expend costs in acquiring this information themselves. Id.
67 Cf. United States v. Nova Scotia Food Prods. Corp., 568 F.2d 240 (2d Cir. 1977) (holding that agencies must disclose scientific research they use in rulemaking so interested parties have an opportunity to comment on it or provide their own to address specific policy concerns).
consequences of legislative proposals.  Further, administrative agency officials are powerful allies for organized interest groups in successfully redefining a policy issue.  

Historically, federal administrative agencies have been especially influential in defining problem drug use and focusing the national attention on America’s drug problem via agency reports on problem drug use. Federal administrative agencies, like the Substance Abuse and Mental Health Services Agency (“SAMHSA”) and the Center for Disease Control and Prevention (“CDC”), collect yearly data on variables that government researchers consider to be measures of problem drug use. These data allow federal agencies to monitor any changes in the variables from year to year and to alert Congress of any increases in rates of use, addiction, or overdose deaths.  

Although the inclination is to treat such reports as objective research, it is important to acknowledge that agencies have a stake in results that they publish. On the one hand, highlighting the severity of a problem through numbers and statistics increases focus on the agency’s problem of interest and supports requests for additional funding allocations to that agency. On the other hand, continually having increasing rates of death or addiction can demonstrate that the agency is ineffectively handling the problem. For example, the Narcotics Bureau, the federal predecessor to the Drug Enforcement Agency (“DEA”), knowingly

68 While it is true that traditionally only federal agencies were the sole enforcers of federal law, with the expansion of Congressional delegation of authority and duties to the federal bureaucracy has come the subsequent delegation of enforcement to state and local governments. Mark K. McBeth et al., The Intersection of Narrative Policy Analysis and Policy Change Theory, 35 Pol’Y Stud. J., 87–108 (2007). Typically, this occurs through the use of conditional federal funding for state programs. Id.
69 BAUMGARTNER, supra note 55 (which found that support for a narrative by high ranking governmental officials in either the legislature or the administration best predicted whether or not a problem was successfully redefined). See also Part IV where I demonstrate how parents’ groups partnered with NIDA to affect the definition of problem drug use in the late 1970’s and 1980’s.
70 See supra notes 4–7.
overestimated the number of persons addicted to illicit drugs to justify continued budget allocations and ensure the Bureau’s survival.\textsuperscript{73} To demonstrate that it was effective and producing results, however, the Narcotics Bureau balanced its reports of escalating problems with reports of decreases in addiction or, more often, increases in the number of arrests of drug traffickers and users.\textsuperscript{74}

This is not to say that doctoring statistics is the only way agencies have influenced narratives in drug policy. Agencies can steer the narrative discourse simply by making decisions on what to count and how to define the categories that they are counting.\textsuperscript{75} For example, agencies must decide questions of categorical inclusion like, when counting the number of persons abusing prescription opioids, should the law consider doubling the prescribed dose of one’s own prescription to eliminate pain a form of problem drug use?\textsuperscript{76} What criteria should policymakers use to determine whether an accidental overdose caused death relative to an intentional suicide by overdose? Decisions on each of these measurement questions can not only result in the over- or undercounting of a problem but can change the meaning of the results and how lawmakers define the problem.\textsuperscript{77} Further, since the rational decision-making model of policy prefers measurable legislative outcomes, policy actors may prefer legislative solutions that produce outcomes that can be easily measured using pre-existing measurement tools\textsuperscript{78} over

\textsuperscript{73} COURTWRIGHT, supra note 57, at xii.
\textsuperscript{75} STONE, supra note 13, at 183-205.
\textsuperscript{76} See, e.g., NSDUH Data Review National Survey on Drug Use and Health, SAMSHA, https://www.samhsa.gov/data/sites/default/files/NSDUH-FFR2-2015/NSDUH-FFR2-2015.htm (last visited Jan 17, 2018) (which demonstrates that measuring a phenomenon involves decisions how to define and categorize and that these decisions affect the results).
\textsuperscript{77} Id.
\textsuperscript{78} For example, since the CDC monitors overdose deaths, increasing the availability of Naloxone, an overdose reversal medication, is a legislative solution whose outcome can be easily measured by counting the number of overdoses before implementing the legislation and then determining if there is a decrease is the number of overdose deaths after legislative enactment. See CDC WONDER Database, CENTERS FOR DISEASE CONTROL AND PREVENTION, https://wonder.cdc.gov/ (providing the CDC’s database for monitoring overdose deaths); Opioid
legislative solutions that produce outcomes that cannot be as easily measured due to the outcomes’ complexity or the lack of a widely implemented measurement tool. In deciding what to measure, what to report, or how to report it to legislators, administrative agencies influence the narrative discourse. Additionally, they influence the discourse by explicitly supporting some narratives over others.

In conclusion, evidence exists in the empirical literature that justifies the claim that both organized interest groups and administrative agencies can influence how lawmakers define a problem and in doing so limit the legislative alternatives. The next section outlines how groups go about constructing narratives and how that may differ based on their motivations for doing so.

IV. HOW GROUPS CONSTRUCT NARRATIVES

The narrative-generation process is not always a conscious endeavor. Why a group constructs a narrative in the first place, however, influences how a group constructs its narrative. Is the group constructing a narrative to achieve or avoid a legislative solution? Are they constructing a narrative to garner widespread acceptance of a particular causal theory? Or are they developing a narrative to ensure that a specific population benefits from or carries the burden of the legislative solution? Since a group can begin the narrative-construction process by choosing its characters, cause, or desired solution, the group’s objective may determine which story component the group prioritizes. The order in which groups select these components varies, and choices at each juncture affect the alternatives that are available for the remaining

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For example, if a lack of hope for a better future is what causes overdose epidemics, it is much more difficult to measure hope. Further no annual administrative agency survey even attempts to measure hope.
story elements. If the group chooses purposefully, they can narrow the available alternatives to those that align with the narrators’ interests.

A. Designing a Narrative to Further a Solution

A narrator may begin the narrative-crafting process by first choosing a desired solution. For example, the National Organization for the Reform of Marijuana Laws (“NORML”), a group that advocates for the legalization of marijuana, could hypothetically see the Opioid Epidemic and the shift in public support for decriminalization as a political window of opportunity through which it can try to further its agenda. As such, if NORML constructed a policy narrative to define the Opioid Epidemic, it could start the narrative-formation process by choosing its preferred solution (marijuana legalization) and then choosing a cause of the Opioid Epidemic that at least makes medical marijuana legalization a likely solution. Perhaps NORML might argue that the Opioid Epidemic resulted from physicians relying on opioid prescription pain pills as the primary treatment for chronic pain because opioids were the only treatment option available in their medical arsenal. The lack of alternative treatment options resulted in

82 See supra note 20.
the over prescription of “highly addictive” opioid prescription pain pills. Legalizing marijuana for medicinal use offers a solution to the problem, as NORML would define it, because patients can use marijuana as an alternative pain treatment to “overly addictive” and overdose-causing prescription pain pills. Evidence indeed supports these hypothetical claims, evidence that would lend credibility to NORML’s narrative. For instance, physicians have cited the lack of alternative pain treatment options for chronic pain patients as an issue in care. Additionally, empirical research has shown that cannabis can effectively treat pain for some patients.

However, NORML’s hypothetical causal theory is not the only causal theory that has empirical support. For example, despair, unemployment, or self-medication could also serve as causes of the Opioid Epidemic in an effective narrative. If NORML focused on these other causes in its causal story, however, marijuana legalization no longer neatly addresses the

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84 I use quotation marks here to indicate that I am quoting pervasive opinion that opioid prescription pain pills are highly addictive and am in no way indicating that such a claim is supported by the weight of the evidence.
85 There is empirical support for these claims. See, e.g., Lauren S. Penney et al., Provider and patient perspectives on opioids and alternative treatments for managing chronic pain: a qualitative study, 17 BMC FAM. PRAC. 164 (2016).
86 Although some have called opioid prescription pain pills “extremely” addictive, the rate of iatrogenic addiction, or addiction caused by medical mistake, is often overestimated because addiction, abuse, misuse, and dependence are all treated as if they are the same construct when they are indeed very different. See, e.g., Nora D. Volkow & A. Thomas McLellan, Opioid Abuse in Chronic Pain — Misconceptions and Mitigation Strategies, 374 NEW ENGL. J. OF MED. 1253, 1253–1263 (2016).
89 In 2015, researchers Case & Deaton noticed that the areas that had the highest rates of overdose rates also had high rates of deaths due to alcohol and suicide. Anne Case & Sir Angus Deaton, Mortality and Morbidity in the 21st Century, BROOKINGS (Mar. 23, 2017), https://www.brookings.edu/bpea-articles/mortality-and-morbidity-in-the-21st-century/. These three deaths of despair were highly correlated with “an accumulation of pain, distress, and social dysfunction in the lives of working class whites that took hold as the blue-collar economic heyday of the early 1970s ended, and continued through the 2008 financial crisis and the subsequent slow recovery.” Id.
90 Economically deprived areas with high unemployment rates often have high addiction rates. See generally Katherine McLean, “There’s Nothing Here”: Deindustrialization As Risk Environment for Overdose, INT’L J. OF DRUG POL’Y, Mar. 2016, at 19.
91 Recent studies have shown that opioid misuse is higher for individuals who report untreated pain as well as untreated chronic mental illness, including depression. See, e.g., McLean, supra note 93, at 19.
policy problem. By starting with its desired solution, NORML can limit the list of causes to those that call for legalization of at least some forms of marijuana use. Similarly, it would limit the characters or target population of its narrative to persons with chronic pain, thus excluding persons with problem drug use who do not have a chronic pain diagnosis. The consequences of such a limitation on the target population is that the legislative solutions enacted would benefit chronic pain patients, but would not offer benefits for members of the target population that are not chronic pain patients. NORML, however, would have come closer to accomplishing its objective by pushing for the legalization of marijuana incrementally, a political feat much easier to accomplish than marijuana legalization wholesale.

In sum, for pressure groups that are invested in the legislative adoption of a pet legislative solution, beginning by identifying where they want their narrative to end allows them to reverse-engineer a story that guides the discourse to their desired solution.

B. Devising a Narrative to Avoid a Solution

Rather than starting the narrative-crafting process with a desired solution, narrators can also choose the elements of their narrative based on a motivation to eliminate undesirable solutions. For example, prescription opioid drug manufacturers, whom some actors have blamed for causing the Opioid Epidemic, could hypothetically support a causal narrative that Chinese

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92 Although popular discourse makes it appear as if persons who overdose from opioid addiction are most likely persons who received an opioid prescription from a doctor for long-term treatment of chronic pain, the empirical evidence to date does not support this contention. See, e.g., Michael A. Yokell et al., Presentation of Prescription and Nonprescription Opioid Overdoses to US Emergency Departments, JAMA INTERNAL MED., Dec. 2014, at 2034, 2036 (finding that less than 13% of patients admitted to U.S. emergency rooms for opioid overdoses had a pain diagnosis).

93 For an example of attempts to incrementally legalize marijuana, see, e.g., Joel Ebert, With Assist from House Speaker Beth Harwell, Medical Cannabis Bill Advances in House Subcommittee, Tennessean (Feb. 27, 2018), https://www.tennessean.com/story/news/politics/2018/02/27/medical-marijuana-law-tennessee-politics-tn-house/378069002/.

94 Prescription opioid manufacturers have been blamed for intentionally downplaying the addictiveness of their products, insisting that their medications last for 12 hours while possessing evidence that it only lasts for 8 hours. See Alana Semuels, Are Pharmaceutical Companies to Blame for the Opioid Epidemic?, THE ATLANTIC (June 2, 2017), https://www.theatlantic.com/business/archive/2017/06/lawsuit-pharmaceutical-companies-opioids/529020/.
manufacturers have flooded the streets with counterfeit OxyContin and fentanyl, which then caused a spike in overdoses. Here, there is indeed evidence that counterfeit opioids from China have increased the illicit drug supply in the U.S., but other factors that this narrative ignores have also played a role in the increased supply and demand of illicit opioids. However by maintaining that illicit Chinese opioids are the cause of the Opioid Epidemic, U.S. drug manufacturers could shift the blame to China, making it more likely that any proposed regulations will punish China instead of American pharmaceutical companies.

C. Devising a Narrative to Support a Causal Theory

Although the first two strategies that this Article outlines emphasize devising a narrative around a solution, some narrators devise their story with a cause as the focal point. For example, narrators, like advocacy groups that represent persons in recovery from addiction, may devise their narratives by starting with the causal story that addiction is chronic brain disease. These advocacy groups may be invested in popularizing the causal story that addiction is a disease.

They have also been blamed for failing to intervene even though they knew or should have known that their medication was likely being diverted. See, e.g., News Releases: Attorney General DeWine Files Lawsuit Against Opioid Distributors for Practices Fueling Opioid Diversion, OHIO ATTORNEY GEN. (Feb. 26, 2018), http://www.ohioattorneygeneral.gov/Media/News-Releases/February-2018/Attorney-General-DeWine-Files-Lawsuit-Against-Opio.


Such a problem definition has consequences beyond those desired by the narrators because it encourages punitive solutions. It could, for example, shift the focus to international interdiction strategies that involve agencies in charge of foreign affairs. In the past, some Presidents have supported the definition of problem drug use in a manner that blames other countries, particularly other countries that are less powerful than the U.S. See ANDREW B. WHITFORD & JEFF YATES, PRESIDENTIAL RHETORIC AND THE PUBLIC AGENDA: CONSTRUCTING THE WAR ON DRUGS (2009). As Commander in Chief, the President could then take actions against these countries, simultaneously showing his electorate that he is involved in foreign affairs and is punishing the “bad guys.” And one could foresee President Trump supporting such a narrative, as it adds credibility to his desires to punish China and supports his preferred policy solution of building a wall at the American–Mexican border to further prevent the smuggling of drugs from international sources. See, e.g., Matthew Hall, US Turns to Trump Targets—UN, China and Mexico—for Help in Opioid Crisis, THE GUARDIAN (Jan. 7, 2018), https://www.theguardian.com/us-news/2018/jan/07/us-. American pharmaceutical companies, however, may or may not have intended each of these consequences when they devised their hypothetical narrative. These consequences could be a result of such a narrative all the same.
because it refutes the stigmatizing causal story that addiction is caused by weak character. Further, the chronic-disease analogy communicates that addiction can recur due to the nature of the disease itself. The disease is then the cause rather than the person’s moral character. Groups that focus their narrative building around a cause may support such a causal story even if they are aware of evidence that socio-economic factors also contribute to problem drug use, because they believe that the “addiction is a disease” causal story is most powerful in combatting stigma. Even if the “addiction is a disease” causal story does not align with the best legislative outcomes, it has utility in and of itself.98

D. Devising a Narrative to Benefit or Burden a Target Population

Rather than focusing the narrative-design process around achieving or avoiding a legislative solution or promoting a cause, narrators can also begin crafting a narrative by choosing the target population, or characters, they would like to see receive benefit or blame. Problem drug use affects many populations.99 Listing all members of a target population can be not only an exhaustive and seemingly impossible endeavor, but it may also confuse the narrative’s intended audience, which have limited attention and resources. Therefore, in choosing the characters for their narratives, narrators often choose the segment or segments of a heterogeneous population that they are most interested in benefiting or burdening.100

For example, pressure groups can focus on the rural populations of overdose victims,101 downplaying or ignoring the inner-city victims, or they could describe opioid-overdose victims

100 STONE, supra note 13; SCHNEIDER & INGRAM, supra note 39.
101 Moreover, by limiting the focus to overdose victims, narrators include only recreational drug users and hard core chronic users who overdose, not those who do not overdose.
as White, not Black, or as middle and upper class, not poor.102 These portrayals only partially represent the target population of overdose victims, as there are many Black and Hispanic, poor city-dwellers that suffer overdoses.103 Yet, in describing the target population, narrators can choose to focus only on one subpopulation as if it represents the entire target population. Doing so often communicates that this subpopulation is the only part of the population that “should” benefit from the legislative solution. This is an example of employing a literary technique called synecdoche.104

102 By focusing on a sub-population, narrators can better control the images and associations that are triggered by the narrative. STONE, supra note 13. Similarly, when pressure groups use anecdotes that describe problem drug use by focusing on an individual who uses, pressure groups can choose to focus on that individual’s membership in one group, while ignoring their membership in other groups. Society categorizes persons into populations, or groups of actors. Any one actor can be a member of multiple populations at a time. For example, an overdose victim can be a physician, a father, and a substance user. As such, each population of actors is comprised of subpopulations of actors (e.g. fathers who are substance users; doctors who are substance users). And each of these subpopulations are socially constructed to represent different images in the listeners’ mind. The image of a father is quite different than that of a doctor. Pressure groups can choose to focus on actors’ membership in one population over others, as if that population membership defines the actor. SCHNEIDER & INGRAM, POLICY DESIGN, supra note 39; STONE, supra note 13.


104 STONE, supra note 13, at 168-171. Such a technique is useful because populations have already been socially constructed as having certain attributes and characteristics, including whether that group is deserving of public assistance, as I discussed later.
Choosing a sub-population of the target population has consequences for the lawmaking process. Legislative solutions tailored for one sub-population may not be effective for other sub-populations because the causes of problem drug use in each sub-population may be different. For example, the causes of marijuana use among teenagers may be different than the causes of opioid prescription pain pill abuse by middle-aged White men. The legislative solutions that address problem drug use in these sub-populations would likely be different as well. A holistic problem definition would acknowledge the various categories of persons whom problem drug use affects, recognize the multiple causes, and devise an array of solutions that would address each. Given that drug policy resources in the U.S. are both finite and rarely enough to address problem drug use even in a single sub-population, lawmakers make choices as to how to define who benefits or who bears the burden.

Pressure groups can use causal stories to persuade legislators to blame or benefit some sub-populations over others. In the late 1970’s and 1980’s, addiction treatment providers warned Congress that persons addicted to cocaine and crack were flooding their clinics. Yet parents’ advocacy groups (“Parents Groups”) insisted that the federal government should stop focusing

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106 STONE, supra note 13.
108 The Parents Movement arose in the late 1970s out of a greater counter-revolution to what parents viewed was the corruption of societal values by the popular media that glorified sex and recreational drug use. Id. at 141-154. Parents pointed to parental defiance, recreational drug use and increased sexual proclivity as indicators that they were losing control of their children. Id. at 141-154. The increase in marijuana use by middle class youth and suburban college students added to their concern, as well as legislative proposals in Congress to decriminalize marijuana. Marsha Manatt, PARENTS, PEERS, AND POT II: PARENTS IN ACTION (1986).
on the “black crack problem” or reducing the number of “heroin users,” but should focus instead on teenagers who were experimenting with marijuana. In defining the drug problem, these Parents Groups focused on youth as the target population because they wanted youth to benefit from the legislative solutions. However, these groups only wanted to benefit non-drug user youth. Parents Groups identified drug users, or “druggies” as they referred to them, as part of the problem. Parents Groups blamed these druggies for using peer pressure to convince “good” teenagers to use drugs and, in some cases, for supplying the “good” teens with drugs.

However to the dismay of the Parents Groups, there was little to no scientific or medical evidence at the time to support their claims that marijuana was a gateway drug that would lead to a host of evils. In attempting to locate such evidence, Marsha Schuchard, an English teacher and co-founder of the Parents’ Resource Institute for Drug Education (“PRIDE”), contacted Director Robert DuPont of the National Institute on Drug Abuse (“NIDA”). In DuPont, Schuchard found an ally and supporter of her narrative. DuPont told Schuchard that he did not realize how marijuana was affecting youth, and DuPont even inquired whether she would be willing to author a NIDA publication that explained to parents how to prevent teenage drug use. Schuchard agreed and published two papers with NIDA. Although NIDA asked her to refrain from drawing medical or scientific conclusions about marijuana due to her lack of

109 MASSING, supra note 110, at 185 (quoting Keith Schuchard, co-founder of Parents’ Resource Institute for Drug Education (PRIDE), a prominent parents group).
110 Id. at 146 (quoting Marsha Schuchard, co-founder of PRIDE). The argument used by PRIDE to convince lawmakers to focus on marijuana use was that intensive drug use accounted for 1% of the population, while teenage use affected all of the nation’s children. MASSING, supra note 110, at 146.
111 MASSING, supra note 100, at 146.
112 MASSING, supra note 111, at 141-146.
113 MASSING, supra note 110, at 152-153. The United States President’s Advisory Commission on Narcotics and Drug Abuse had explicitly stated that there was no scientific evidence that marijuana was a gateway drug in the 1960s. Id.
114 Id. at 141-154.
115 Id. at 141-154.
116 Id. at 141-154.
medical or scientific training, Schuchard ignored these requests.\textsuperscript{117} Despite her lack of credentials and the lack of evidence supporting her statements, her publications were the most requested NIDA publications.\textsuperscript{118}

NIDA’s stamp of approval gave the Parents Groups’ narrative credibility, and the Parents Groups’ narrative benefited from the believability that came with focusing on a target population that was already socially constructed as needing protection and deserving of policy benefits.\textsuperscript{119} Even before Schuchard’s NIDA publications became available to use as evidence in support of their narratives, the members of the Parents Groups argued that they were experts because they were parents. For example, in 1980, when testifying in front of Congress on the potential health issues that might arise from decriminalizing marijuana, a Parent Group member explained:

\begin{quote}
The most important credential I can give you to substantiate my testimony is that I am a mother, not a doctor, not a scientist. I am here to protect my children. I am also here to protect my neighbor’s children and the children of this nation.\textsuperscript{120}
\end{quote}

According to policy scholar Michael Massing, by the end of the Congressional hearing, the possibility of marijuana decriminalization was dead.\textsuperscript{121} Massing credits the Parents Groups with more than just the defeat of marijuana decriminalization. In his view, the Anti-Drug Abuse Act

\begin{footnotesize}
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\item[117] \textit{Id.} at 141-154.
\item[118] \textit{Id.} at 141-154.
\item[119] \textsc{Schneider} \& \textsc{Ingram}, \textit{supra} note 39. Schneider and Ingram theorize that target populations are categorized by society into two groups: those deserving of public assistance and those who are undeserving. \textit{Id.} A group’s deservingness is then moderated by the groups political power to create four types of target populations: Advantaged, Contenders, Dependents and Deviants. \textit{Id.} Advantaged groups are groups that society has determined are most deserving and are groups with the great deal of political power. \textit{Id.} They include businesses, the middle class, senior citizens, military, scientists and family farmers. \textit{Id.} The Contenders also wield political power but are viewed as undeserving. \textit{Id.} They include gun owners, the rich, CEO’s, and savings and loans companies. \textit{Id.} Politically, it would be unwise to punish these groups because of their political power, but it would be equally unpopular with citizens if legislative solutions benefited these groups. Dependents are politically weak but are constructed as deserving and include mothers, children, persons with disabilities, and the ill. \textit{Id.} Because of their social construction, it is not difficult to construct narratives that call for these groups to benefit. For such a narrative to be successful, it requires the mobilization of large amounts of constituents or the endorsement of politically stronger groups. \textit{Id.} Lastly, the Deviants are constructed as undeserving and lack political power. \textit{Id.} They include criminals and most often hard core drug users. \textit{Id.} The construction of individuals who use drugs may be changing, however, as they become constructed as persons with a disease of the brain.
\item[120] \textsc{Massing}, \textit{supra} note 110, at 153.
\item[121] \textit{Id.} at 153.
\end{enumerate}
\end{footnotesize}
of 1986, which re-established mandatory minimum sentences for drug possession, was a direct result of the support for this “parent model of drug abuse.”

PRIDE and other Parents Groups demonstrate how pressure groups can design a policy narrative based on the desire to benefit a target population. They first centered the narrative composition on youth as the target population, and they secondarily sought facts to establish that there was a problem and that the cause of the problem was marijuana. They utilized their narrative to form coalitions with school boards, school principals, the Parents Teachers Association (“PTA”), and local churches. Maybe most importantly, they found a high-ranking administrative agency official to support their narrative.

It is important to note, however, that the Parents Groups’ success in focusing the nation’s attention on the subpopulation of youth was costly to the remaining population addicted to illicit substances, as the latter were more likely to end up in the emergency room than in treatment. And the government’s refusal to pay attention to the growing number of crack-cocaine users contributed to the magnitude of the crack-cocaine epidemic that would hit hard in the late 1980’s to early 1990’s.

In conclusion, this section demonstrates theoretically how narrators can use narratives to limit the alternative legislative solutions available in the legislative discourse and assign benefits and burdens to target populations. In structuring their causal stories, narrators can achieve their desired legislative solutions by strategically choosing a solution, cause, or target population on

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122 Id. at 184.
123 MASSING, supra note 111, at 151.
124 They later aligned themselves with Nancy Raegan and played a big role in the First Lady’s anti-drug campaign. MASSING, supra note 110, at 187-190.
125 Id. at 153-154, 189-190.
126 Id.
which to focus. The order in which they choose these elements depends on their goals.

Narrators then use these narratives in the problem definition discourse to persuade lawmakers.

Although there are often multiple problem definitions vying to be the most dominant, only a few become accepted as the “true” definitions of the problem. The longer that people accept a problem definition as true, the more likely the definition becomes permanently institutionalized.\textsuperscript{127} Lawmakers create institutions that implement and enforce policy around the legislative solutions that accompany the problem definition. The next part of this Article demonstrates that, once lawmakers create such institutions, it becomes even more difficult to redefine a problem because these institutions are invested in maintaining the status quo definition.\textsuperscript{128} As drug policy history demonstrates, however, it is not impossible to redefine policy problems, especially as cultural and societal norms evolve and as the composition and power of interest groups change.\textsuperscript{129} The Opioid Epidemic arguably created a juncture at which the cultural and political environment offer a political window for pressure groups to redefine problem drug use as a public health issue. Therefore, exploring historic examples of pressure-group problem definitions during windows of opportunity for change may provide us with a better understanding of how to successfully redefine problem drug use at the current juncture.

\textsuperscript{127} In my use of the term “institutionalized” here, I am referring to both the behavioral constraints placed on governmental and societal actions, see DOUGLASS C. NORTH, INSTITUTIONS, INSTITUTIONAL CHANGE AND ECONOMIC PERFORMANCE (1990), as well as the governmental structure that makes, implements and enforces the rules and regulations based on these behavioral patterns and societal constraints.

\textsuperscript{128} BAUMGARTNER supra note 55. For example, as I will demonstrate in Part IV, the adoption of a deviance narrative, and implementation of punitive legislation to address the deviance, has resulted in the allocation of money and resources to federal, state and local law enforcement who are charged with enforcement of the legislation. If activists were successful in redefining problem drug use as a health issue, the need for such an enforcement would decrease, as would the number of law enforcement officials needed and the funding allocated to these institutions. With the allocation of federal funds to the private prison system in the 1980s, private prisons as well as law enforcement unions are heavily incentivized to lobby to maintain the status quo. KENNETH J. MEIER, THE POLITICS OF SIN: DRUGS, ALCOHOL, AND PUBLIC POLICY (1994).

\textsuperscript{129} See, e.g., BAUMGARTNER, supra note 55 (noting that out of 98 policy issues studied, researchers found four policy issues that had been redefined—three of which were partial redefinitions while one was a complete redefinition).
As renowned drug policy historian David Musto wrote in reference to the crack-cocaine epidemic in the late 1980s:

> How can we understand this epidemic? It is important for us to know the history of drug abuse in America if we are to make wise decisions concerning drug abuse now and in the future. . . . When we are in the middle of a drug crisis, however, we tend to forget this history and assume that we must face our drug onslaught with no guideposts. Unaware of how we have overcome past drug problems, we are liable to panic.\(^{130}\)

V. **THE USE OF HEALTH VS. DEVIANCY NARRATIVES IN DRUG POLICY HISTORY**

Comparing the legislative process for different pieces of legislation over time is a difficult endeavor. The factors that affect the legislative process, including cultural norms, political institutions, ideologies, and political circumstances, especially vary when comparing legislative events that occur decades apart. These evolving factors not only influence the likelihood of the enactment of legislation, but also impact the types of causal narratives that groups use and the way in which they define a problem.\(^{131}\)

Conceding such differences, there is still value in analyzing the types of narratives that groups have used over time to define a policy problem, even if it is not for the purpose of proving that pressure groups’ narratives per se *caused* a legislative outcome. First, political institutions prefer the status quo, making it more difficult to redefine a problem the more engrained it becomes.\(^{132}\) Studying the past use of narratives to define a problem helps shed light on how such a past may have influenced how we define a problem today. Second, groups often recycle causal narratives, as familiar narratives can be more believable than unfamiliar narratives and may elicit less scrutiny.\(^{133}\) Studying the use of narratives at different junctures of drug

\(^{130}\) MUSTO, *supra* note 57, at ix.

\(^{131}\) See STONE, *supra* note 13.


\(^{133}\) STONE, *supra* note 13.
policy history helps us identify the most recycled stories in drug policy. Third, examining how groups strategically crafted narratives to align with their interests illuminates how future groups wishing to influence the problem definition process can use problem definition strategies to further their policy goals. It also demonstrates how such groups can form alliances around their narratives. Finally, the following section illustrates the powerful role that administrative agency officials can play in defining problem drug use in the legislative discourse.

A. *The Opiate Epidemic & The Opioid Epidemic*

At times, society has attributed problem drug use to a disease or disorder. At other times, narratives blame deviancy or a character flaw for causing problem drug use. Although the policy idea that addiction is a disease or a health issue may seem new to the legislative discourse, because of its recent resurgence, it emerged in political discourse as early as the 1800’s. Since this is the time period during which the “addiction is a disease” narrative developed, it is where this analysis begins.

Examining narrative use to describe an opiate crisis in the mid- to late 19th century to help shed light on causal stories that could define an Opioid Epidemic in the 21st century may seem futile, or even downright silly. Not only was daily life vastly different in the 1800’s, but so were the federal government’s structure and powers. Although the federal government’s powers have grown significantly since the 19th century, the political parties have evolved, the internal structures of Congress have changed, and the number of pressure groups involved in the political process has greatly increased, some definite similarities exist between the Opiate Crisis of the late 19th and early 20th centuries and the current Opioid Epidemic. The target population of both epidemics included a sub-population of iatrogenic addicts, persons who became addicted to a habit-forming drug due to a medical error. This subpopulation of iatrogenic addicts includes
middle to upper class Whites—members of the public that, during both time periods, people viewed as the mainstream and not associated with the deviant underworld. 134

Aside from the composition of the target populations, during both epidemics, physicians, and pharmacists, risked blame for causing the epidemic—a causal story that calls for the punishment and regulation of physicians and pharmacists. The Harrison Tax Act of 1914, discussed infra, is arguably the prescription drug monitoring program of the early 20th century. 135 Both require reporting, recordkeeping, and the monitoring of physician and pharmacist prescribing practices. 136 Both legislative solutions imply that these professionals need oversight, as law enforcement agencies used records from both monitoring systems to punish physicians and pharmacists that appeared to be overprescribing habit-forming medications. 137 During both epidemics, representatives in Congress made statements supporting the causal narrative that iatrogenic addiction was a disease that necessitated treatment. 138 Lastly, in both cases, drug manufacturers, pharmacists, and physicians were active in the problem definition process despite these groups’ lobbying not being a constant feature of American drug policy. 139

134 COURTWRIGHT, supra note 57, at 72. See SCHNEIDER & INGRAM, supra note 39 (which generally discusses the social construction of white and middle class persons).

135 Prescription monitoring programs are legislative solutions that involve the state-wide monitoring of the dispensing of habit-forming drugs. See State Prescription Drug Monitoring Programs, DRUG ENF’T ADMIN.: DIVERSION CONTROL DIV., https://www.deadiversion.usdoj.gov/faq/rx_monitor.htm (last visited Mar. 31, 2018). Although at times the prescription monitoring programs are sometimes framed as tools to help medical professional identify patients that may be drug-seeking, the data from the electronic system is shared with law enforcement to aid them in identifying and prosecuting physicians and pharmacists that are diverting prescription medication. Id.


137 See MUSTO, supra note 57, at 54–68, for a historic account persecution of physicians and pharmacists under the Harrison Tax Act. See also supra note 138 for its reference to the use of prescription drug monitoring programs by law enforcement.

138 See Portman supra note 12.

139 For example, from 1998-2017, the pharmaceutical industry and medical professionals have not consistently lobbied on alcohol and drug abuse issues. See Alcohol and Drug Abuse, THE CTR. FOR RESPONSIVE POLITICS, https://www.opensecrets.org/lobby/issuesum.php?id=ALC (last visited Mar. 31, 2018).
Due to these similarities, analyzing the types of narratives that defined the problem of addiction during this early epidemic may prove more useful than one would have initially predicted.

**B. Defining the Nation’s First Opiate Epidemic**

1. Sub-populations of the Target Population

By the late 1800s, an opiate epidemic plagued the nation.\(^{140}\) By the end of the 19th century, an estimated 150,000 to 250,000 persons had become addicted to drugs.\(^{141}\) The public began to vocalize their fear of habit-forming drugs, especially when it came to drug use by Chinese immigrants and Southern Blacks.\(^{142}\) The majority viewed these marginalized populations’ drug use as a direct threat to White safety.\(^{143}\) Further, “opium dens,” public places where smokers met to smoke socially, encouraged undesirable social mixing.\(^{144}\) As the narrative went, these sub-populations became addicted to opiates and cocaine because their weak moral characters predisposed them to using drugs for their euphoric effect.\(^{145}\) Once they became drug users, they posed even more of a threat to society because the drugs increased their sexual proclivity, criminal behavior, and, in the case of Blacks, their physical strength.\(^{146}\) The public viewed such a deviant sub-population of drug users as deserving of punishment,\(^{147}\) and as a

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\(^{141}\) **Courtwright, supra note 57.**

\(^{142}\) **Courtwright, supra note 57, at 62-81.**

\(^{143}\) **Id. at 62-81.**

\(^{144}\) **Erlen & Spillane, supra note 77, at 7-8.**

\(^{145}\) **See generally, id. at 61-109, for a summary of the discourse.**

\(^{146}\) **Courtwright, supra note 57, at pg. 94-98.**

\(^{147}\) **Courtwright, supra note 57, at 62-81.**
result, these marginalized populations that were politically weak became most likely to bear the burden of punitive legislation aimed at decreasing drug use.\textsuperscript{148}

On the other hand, society “tolerated” iatrogenic addicts,\textsuperscript{149} due in part to their membership in the “‘acceptable’ segment of the mainstream population.”\textsuperscript{150} Most iatrogenic addicts were wives and mothers, two categories of persons that may be politically weak, but are often socially constructed as deserving of policy benefits.\textsuperscript{151} Another factor that made iatrogenic addicts more socially tolerable was the way in which physicians groups, pharmacists associations, and drug manufacturers, which included both patent medicine manufacturers\textsuperscript{152} and self-proclaimed “ethical drug companies”\textsuperscript{153} (collectively, the “medical industry”), legitimized these iatrogenic addicts’ use.\textsuperscript{154}

As the next section demonstrates, the medical industry’s financial stake in maintaining a customer base within this sub-population incentivized the industry to support policy narratives that benefited this subgroup; at the same time, the medical industry had no financial incentives to protect the marginalized sub-population of users. The social construction of these distinct

\textsuperscript{151} See generally SCHNEIDER & INGRAM, supra note 39, at 108-111 (outlining legislative solutions often used for politically weak deviant target populations).

\textsuperscript{152} Even though society tolerated iatrogenic addiction, individuals who became addicted to opiates were often ashamed by their habit and tried to hide it from their loved ones, indicating that there was still societal disapproval of use even for this class of users. KANDALL, supra note 144, at 3.

\textsuperscript{153} Id. at 41.

\textsuperscript{154} SCHNEIDER & INGRAM, supra note 39, at 109.

\textsuperscript{155} Patent-medicine manufacturers produced over-the-counter medicines and tonics, many of which contained morphine, alcohol, and cocaine. ERLEN & SPILLANE, supra note 77, at 4. They were unregulated until the Pure Food and Drug Act of 1906, which required patent medicine companies to list out potentially harmful ingredients on its labels. Id. Prior to the Act, patent-medicine manufacturers lobbied long and hard to remain unregulated. Id. Patent medicines did not require a doctor’s prescription and could even be purchased via mail order catalogue for rural Americans who did not have easy access to a pharmacy. Id. The companies that manufactured patent medicines advertised heavily in the common periodicals of the time with remedies for a litany of ailments. KANDALL, supra note 144, at 41; see also generally Martin, supra note 40. They marketed directly to consumers, highlighting the benefits for self-medication and downplaying the need for physicians to play the intermediary between the drug manufacturer and the consumer. ERLEN & SPILLANE, supra note 156, at 4.

\textsuperscript{156} Ethical drug companies distinguished themselves from patent-medicine manufacturers by refusing to market directly to consumers. ERLEN & SPILLANE, supra note 156, at 4. Instead, they marketed to physicians and pharmacies. Id. They also published studies of the benefits of their medications in their own scholarly journals. Id.

\textsuperscript{157} ERLEN & SPILLANE, supra note 156, at 5-10.
subgroups of drug addicts, and the association of the subgroup of iatrogenic addicts with the financial interest of the medical industry, ensured that these subpopulations would be the center of two different causal stories.

2. The Medical Industry’s Desired Legislative Solution

The medical industry had significant financial interest in ensuring that opiates and cocaine remained licit for medicinal purposes, because, throughout the 1800s, physicians and pharmacists prescribed opiates more often than any other medication. Cocaine’s medicinal benefits were not widely publicized until the 1880s, but once people learned about them, they also soon hailed cocaine as a wonder drug that doctors even used to treat opiate addiction. At a time when medicine was not very sophisticated, opiates, and then cocaine, offered physicians a treatment that worked and increased the physicians’ effectiveness in the eyes of their patients. Pharmacists also utilized opiates and cocaine in a variety of ways. Some pharmacists filled physician prescriptions, some prescribed opiates and cocaine, some used opiates and cocaine in creating their own elixirs, and some sold over-the-counter patent medicine. Both opiates and cocaine were common ingredients in patent medicine. While ethical drug companies also

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158 The types of opiates used included opium, morphine and heroin. KANDALL, supra note 144, at 10-42. Morphine is a derivative of the opium poppy that was isolated in 1817 and made much more accessible with the invention of the hypodermic needle in 1856. Id. Heroin was invented in 1874 but was not widely marketed until 1898. Id. More specifically, morphine was commonly prescribed for a variety of ailments. COURTWRIGHT, supra note 27, at 35-60. At the time morphine was invented it was one of the few tools that physicians had it their disposal that was actually effective. Id. After heroin was invented and popularized by the German pharmaceutical company Beyer, it was also prescribed, especially when it was marketed as less addictive than morphine. Id. The list of ailments that heroin was used to treat, however, was less than that of morphine, so the number of persons that became iatrogenically addicted to heroin were much less than those who became addicted to morphine. KANDALL, supra note 144, at 32-36; COURTWRIGHT, supra note 57; MUSTO, supra note 57.

159 KANDALL, supra note 144, at 33; MUSTO, supra note 57, at 7.

158 COURTWRIGHT, supra note 57, at 42-60.

159 As a profession, pharmacists’ political strength was weakened by the competing interest among sub-specialties. There were disagreements within the profession as to whether or not they should fight for the ability to prescribe medication, dispense refills to medications, develop their own medications and sell patent medications. ERLEN & SPILLANE, supra note 77, at 4-5. KANDALL, supra note 144, at 19-23; Musto, supra note 57, at 14-15.

160 ERLEN & SPILLANE, supra note 77, at 4.
wanted to continue producing these drugs, banning these substances would arguably affect patent-medicine manufacturers more than ethical drug companies. This was due to patent-medicine manufacturers relying heavily on these drugs as active ingredients in most of their medications—active ingredients that they did not disclose to their customers until the law forced them to do so.161

Because of the medicinal use of opium, morphine, heroin and cocaine, drug manufacturers, pharmacists, and physicians actively lobbied on early U.S. drug policy issues. Aside from their immediate interest in protecting their access to these “habit forming drugs,”162 these groups were likely lobbying to secure their position within the medical industry. Although Congress largely did not regulate the medical industry, physicians, drug manufacturers, and pharmacists knew it would only be a matter of time before the federal government would begin regulating it, and each group wanted to make sure that they influenced the legislation that defined which group would have the authority to make, distribute, and sell medication to consumers.163

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162 “Habit forming drugs” was a phrase used in the 19th and early 20th century to refer to what is now referred to as narcotics. See COURTWRIGHT, supra note 57, at 135.
163 Physicians and pharmacists were concerned with which group would be given exclusive control over prescribing and dispensing of medication. ERLEN & SPILLANE, supra note 77, at 5-17. MUSTO, supra note 57, at 13-21. Both physicians and pharmacists’ groups were in the process of establishing training standards, licensure requirements, and scope of practice for their respective professions. Id. They were also vying for the right to be the exclusive prescribers or dispensers of medication. Id. At the time, physicians and pharmacists’ scope of practice overlapped. Some pharmacists wrote prescriptions or at least refills for patients without a doctor’s prescriptions. Id. Some physicians were dispensing physicians and dispensed drugs directly to patients, without physician oversight. Id. Further, pharmacists were trying to internally determine their own scope of practice as it related to drug manufacturing and sales, overlapping at times with patent medicine manufacturers. Some pharmacists sold patent medicines in their drug stores, while some denounced patent medicine as snake oils. Id. And still other pharmacists created their own elixirs, competing in a sense with the patent medicine companies. Id. Pharmacists were not the only competition or threat to the patent medicine manufacturers. Physicians by and large opposed patent medicine, especially because patent-medicine manufacturers marketed directly to patients and advocated self-medication over consulting with a physician. Id. Ethical drug manufacturers saw patent-medicine manufacturers not only as competition, but as a threat to the credibility of the drug manufacturing industry. Id. Ethical drug companies
3. Building a Coalition and Designing a Shared Narrative

Although each of these groups was interested in establishing exclusivity over at least one part of the manufacturing or distribution process, their immediate collective need to keep opiates and cocaine accessible for medicinal use led them to develop a coalition to lobby Congress on anti-narcotic legislation. There was growing professional and public awareness that opiates and cocaine were addictive. By the end of the 19th century, for example, it was difficult for physicians and pharmacists to deny that opiates and cocaine caused addiction. To succeed at convincing Congress to adopt their proposed solution, the medical industry needed to devise a causal story that resonated with public sentiment and accounted for the population of iatrogenic addicts. The American Medical Association (“AMA”) and the American Pharmacists Association (“APhA”) had already acknowledged that the drugs at issue caused addiction. However, they defined addiction as a disease that developed as an unfortunate side effect to an effective medical treatment. Physicians had discretion to decide whether the risk of addiction was worth the benefit of the treatment. Since addiction was a disease, it logically followed that physicians should have license to use methods such as medication-assisted therapies to treat it. This problem definition gave both professions the added benefit of establishing themselves as the decision-maker of its legitimacy.

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164 Historian Musto describes physicians’ acceptance of the addictiveness of morphine as prolonged and gradual. MUSTO, supra note 57, at 5.
165 MUSTO, supra note 57, at 14-23.
166 MUSTO, supra note 57, at 13-23.
167 MUSTO, supra note 57, at 14-23.
168 MUSTO, supra note 57, at 14-23.
Such a narrative explained iatrogenic addiction and provided a solution that allowed for the continued medicinal use of opiates and cocaine. It did not offer a solution that addressed non-iatrogenic addiction, however, which affected primarily lower-class Whites, opium smokers, Chinese immigrants, and Blacks.\textsuperscript{169} To address non-iatrogenic addiction, physicians and pharmacists created classifications for legitimate and illegitimate drug use.\textsuperscript{170} Illegitimate drug use, or use of drugs obtained without physician approval, purportedly had no therapeutic benefit, and drug users used these drugs to produce euphoric effects.\textsuperscript{171} Under the prevailing view, any addiction that illegitimate drug use caused resulted from the users’ flawed character and desires to over-indulge in hedonistic behavior.\textsuperscript{172}

The medical profession continued to make this distinction between the causes of addiction despite the fact that their leading biological theory of addiction did not support such a differentiation. The leading medical theory explaining the biological cause of addiction, at this time, was the antibody theory, which theorized that addiction was caused by antibodies forming in the blood that prevented the user from refraining from drug use.\textsuperscript{173} Such a causal theory does not distinguish between whether or not the user was exposed to the drug iatrogenically or “illegitimately.” Therefore, theoretically, this medical theory of addiction that the medical community used to justify a medical approach to treating addiction could have just as easily been applied to non-iatrogenic addicts as well as iatrogenic addicts. Despite this logic, physicians and pharmacists continued to offer differing causal theories for legitimate and illegitimate drug use.

\textsuperscript{169} COURTWRIGHT, supra note 57, at 85-109.
\textsuperscript{170} ERLEN & SPILLANE, supra note 77, at 5-10.
\textsuperscript{171} ERLEN & SPILLANE, supra note 77, at 5-10.
\textsuperscript{172} MUSTO, supra note 57, at 14-23.
\textsuperscript{173} MUSTO, supra note 57, at 147.
Just as there was no evidentiary support for applying the scientific theory of addiction
discriminately, there was no empirical support for the contention that marginalized populations’
drug use made them social deviants.\textsuperscript{174} Since non-iatrogenic, habitual drug users were from
socio-economic classes that were commonly employed in jobs requiring strenuous physical
labor, marginalized drug users may have been self-medicating for the pain and discomforts of
life, just like their White counterparts.\textsuperscript{175} Despite lack of evidence, lawmakers’ still found the
medical professions’ differentiating causal stories believable. This may have been because the
stories represented the subcategories of drug users in ways that resonated with widely held
stereotypes. Further, the APhA and the AMA drew on their credentials as experts, which added
to their narrative’s credibility.\textsuperscript{176} In sum, distinguishing between legitimate and illegitimate use
allowed the medical industry to develop different causal stories for iatrogenic and non-iatrogenic
addiction that accounted for public sentiment and the differing societal construction of the
various subpopulations of drug users.

4. From Storytelling to Legislating

State and local governments had already begun to pass laws that regulated the sale or
distribution of habit forming drugs, focusing on controlling marginalized populations’ drug
use.\textsuperscript{177} As a response, the APhA proposed a model state law that regulated the dispensing of

\textsuperscript{174} If anything, the evidence showed that individuals who committed crimes prior to their drug use just continued
committing crime after their drug use. MUSTO, supra note 57, at 7.

\textsuperscript{175} Iatrogenic addicts, on the other hand, were mostly Southern White women who had been prescribed morphine by
their doctors to alleviate pain and discomfort of daily life as a housewife. COURTWRIGHT, supra note 57, at 36.

\textsuperscript{176} See generally FISCHER, supra note 26, at 177-178 (discussing the utilization of professional expertise to add to the
credibility of the claims made in a narrative, generally).

\textsuperscript{177} MUSTO, supra note 57, at 8-13; ERLEN & SPILLANE, supra note 77, at 10-14.
opiates and cocaine but allowed for physicians and licensed pharmacists to prescribe the substance for medicinal use.\textsuperscript{178} The APhA also advocated for the medical maintenance of individuals who had become addicted.\textsuperscript{179} Effectively, the APhA argued that addiction was a health issue for iatrogenic addicts. The APhA’s model state law also addressed the problem of “illegitimate drug use”—namely the use of smoking opium, which both the APhA and AMA agreed had no medicinal value.\textsuperscript{180} The APhA argued that the states should prohibit smoking opium and that the federal government should prohibit importation of smoking opium.\textsuperscript{181} Further, the APhA argued that the entire underclass of non-iatrogenic addicts, “drug fiends” or “the demi-monde, known criminals, or those whose occupations are shady should be totally prohibited” from accessing habit-forming drugs.\textsuperscript{182}

The banning of smoking opium would not affect retail pharmacists’ bottom lines because they sold very little of the substance.\textsuperscript{183} The prohibition also would not affect physicians’ current or future clientele, as non-iatrogenic addicts generally came from socio-economic classes that made them undesirable patients.\textsuperscript{184} Additionally, since Chinese immigrants primarily used smoking opium, society would view prohibiting it as a moral victory.\textsuperscript{185} With no organized interest group lobbying for the protection of smoking opium, the drug’s association with the criminal underclass, and the calls from administrative agency officials to regulate the drug, it was

\textsuperscript{178} MUSTO, supra note 57, at 14-23 (citing the APhA’s Committee on the Acquirement of the Drug Habit, which made recommendations for model laws to be passed by the states to decrease the likelihood of addiction).
\textsuperscript{179} MUSTO, supra note 57, at 18 (citing the APhA’s Committee on the Acquirement of the Drug Habit).
\textsuperscript{180} MUSTO, supra note 57, at 17; ERLEN & SPILLANE, supra note 77, at 5-10.
\textsuperscript{181} MUSTO, supra note 57, at 14-23.
\textsuperscript{182} MUSTO, supra note 57, at 20 (citing the APhA’s Committee on the Acquirement of the Drug Habit).
\textsuperscript{183} See MUSTO, supra note 57, at 17.
\textsuperscript{184} COURTWRIGHT, supra note 57 at 39-40.
\textsuperscript{185} MUSTO, supra note 57, at 4.
of no surprise that smoking opium was the first drug that Congress prohibited.\footnote{Municipalities with large concentrations of Chinese immigrants were the first to pass laws outlawing the smoking of opium, demonstrating the racialization of certain drug use. \textit{See} COURTWRIGHT, \textit{supra} note 57, at 53. In 1909, the federal government followed suit by passing the Smoking Opium Exclusion Act, which banned the smoking, sale and possession of smoking opium. \textit{See} MUSTO, \textit{supra} note 57, at 3. It did not, however, regulate medications containing opium. Members of the Executive had been pressuring Congress to pass some legislation regulating opium use to support the U.S.’s condemnation of China for their role in exporting opium. \textit{Id.} The U.S.’s leadership involvement in the 1909 Shanghai Opium Conference, which was convened to address Chinese exportation of opium, and the 1912 International Opium Convention at which the U.S. became a signatory of a treaty pledging to assist in controlling sale of opiates, necessitated the need for the U.S. to pass legislation addressing opiate sales or risk appearing hypocritical. \textit{Id.} at 33.}

Criminalization is a common solution for a policy problem that is caused by deviant behavior.\footnote{See SCHNEIDER \& INGRAM, \textit{supra} note 39, at 109-110.}

The medical industry continued its lobbying, with its sights on Washington. The APhA, with representatives from the AMA and drug manufacturers, formed a coalition, the National Drug Trade Conference (“NDTC”), to lobby on antinarcotic legislation at the federal level.\footnote{MUSTO, \textit{supra} note 57, at 54–55.}

Formalizing their coalition allowed prescribers and manufacturers to present a united front in defining problem drug use. In 1914, members of Congress proposed legislation, the Harrison Tax Act, to tax the sales of certain habit forming drugs.\footnote{Harrison Narcotics Tax Act, ch. 1, 38 Stat. 785 (1914).} By the time the NDTC finished negotiating with Congress, the bill preserved the AMA and APhA’s ability to prescribe and dispense medication containing habit-forming drugs, as long as it was for a legitimate medical purpose.\footnote{MUSTO, \textit{supra} note 57, at 53.} The legislation also required the registration of sellers, recordkeeping, and reporting of sales to the Bureau of Internal Revenue (BIR).\footnote{See MUSTO, \textit{supra} note 57, at 27, 42. The National Association of Retail Druggists (“NARD”), the National Association of Medicinal Products, and The American Association of Pharmaceutical Chemists, the latter two of the three which were drug manufacturers, also lobbied on anti-narcotic legislation. \textit{Id.} at 55. Each of these groups also used narratives that stressed the medicinal value of habit forming drugs and argued that addiction could be controlled by decreasing illegitimate, or non-medical use. \textit{See generally} id. (containing examples of arguments used by these drug manufacturers in promoting their objectives).
Due in part to the participation of physicians, drug manufacturers, and pharmacists in the problem definition discourse,\(^{192}\) the use and possession of morphine, heroin, and cocaine remained licit for medicinal purposes throughout the early 1900s.\(^{193}\) The medical community benefited from strategically crafting a narrative that defined iatrogenic addiction as a disease that they were best equipped to treat, especially since, at the time, this subpopulation of drug addicts were desirable consumers.\(^{194}\) In sum, the medical industry lobbied Congress to keep these substances licit for medicinal purposes, while advocating for the punishment of marginalized populations’ illicit or recreational use.

In conclusion, examination of the types of causal narratives that the medical industry used to describe problem drug use, while drug use was licit at the federal level, demonstrates how organized interests shaped the early drug policy problem definition discourse. In doing so, the medical industry advocated for a health definition for at least some target populations, while advocating for a criminal justice approach for others. The previous analysis also demonstrates how groups, aided by political and societal factors,\(^{195}\) used causal narratives to pressure Congress into action or inaction. The next section demonstrates how administrative agencies took advantage of a political opportunity to capitalize on changes in the public mood to redefine problem drug use in a way that has dominated for almost a century.

\(^{192}\) Of course, it was not only interest group lobbying that prevented the regulation of opiates during this era. The acceptance of opiate use by the public as well as the lack of federal regulation of domestic issue in general also played a role. See generally COURTWRIGHT, supra note 57. MUSTO, supra note 57.

\(^{193}\) See COURTWRIGHT, supra note 57, at 2.

\(^{194}\) They were desirable mainly because of their class and their ability to pay for treatment and medications. See COURTWRIGHT, supra note 57, at 2.

\(^{195}\) It is important to note that, during this era, the federal bureaucracy was small and Congress had left much of the regulation of social problems to the local governments. THEDA SKOCPOL, SOCIAL POLICY IN THE UNITED STATES: FUTURE POSSIBILITIES IN HISTORICAL PERSPECTIVE (1995). The federal government had not yet established its power to police under the interstate commerce clause. See Wickard v. Filburn, 317 U.S. 111, 128–29 (1942). Thus, the general political atmosphere would have favored less federal interference and regulation and greater inertia would have been needed to propel Congress to outlaw drug use in its entirety.
5. The Role of Administrative Agencies in the Retreat from the Health Frame

Aside from the State Department’s interest in regulating opium as a way to participate in worldwide initiatives to prevent the exportation and trafficking of China’s opium, federal administrative agencies did not concern themselves with early efforts to define problem drug use. After the passage of the Harrison Tax Act in 1914, however, the stakes changed.

Congress directed the BIR to enforce the Harrison Tax Act, under Cornell Levis Nutt’s direction. Nutt and his colleagues masterfully capitalized on the nation’s fear of deviants to ensure that Congress generously funded their department. Americans had just fought a World War and were fearful of the “others” that threatened to disrupt the semblance of American life that they had left. Americans did not tolerate drug users whose inability to contribute to the war effort made them appear un-American. Further, a growing group of reformers during the Prohibition Era viewed both alcohol and drugs as vices that the law should prohibit. Nutt and his colleagues, whom the president appointed to the Treasury Department’s Special Narcotic Committee, capitalized on the public mood by publishing a report that estimated that there were 1 million addicts in the U.S. by 1919, a figure that they actively disseminated to the press. This figure added to public fear of this target population and justified the need for the creation of the Narcotic Division of the Treasury Department’s Prohibition Unit, a division of the BIR that

196 ERLEN & SPILLANE, supra note 77, at 25. Although there were early efforts by the commissioner of BIR, Daniel C. Roper, to define addiction as a medical issue, including his assistance in drafting the France Bill, the window of opportunity had ended, as the Republicans gained control of Congress. Id. at 26. Further, the lack of support by his own bureau quelled any hope for BIR support of a public health solution to addiction. Id. Once Roper retired, Cornell Levis Nutt stepped up the rhetoric in defining addiction as a criminal justice issue, ensuring a law enforcement approach. Id.
197 Id. at 30-31.
198 MUSTO, supra note 57, at 133-134.
199 Id.
200 See generally U.S. CONST. amend. XVIII, repealed by U.S. CONST. amend XXI.
201 ERLEN & SPILLANE, supra note 77, at 30-31.
Congress created at the end of 1919.\textsuperscript{202} Of course, even the BIR later admitted that the figure of 1 million was an overestimation.\textsuperscript{203}

However, such a figure justified the creation of the Narcotics Division, a division that the BIR needed to coordinate their massive efforts to not only collect taxes and maintain a record of drug sales, but also to control the use of these medicinal substances by physicians—an interpretation of the Harrison Tax Act that many physicians and pharmacists thought conflicted with legislative intent.\textsuperscript{204} The BIR believed that the Act prohibited the prescription of narcotics to any addict, even for medication maintenance treatment. The BIR arrested thousands of physicians and heckled pharmacists over claims that they were prescribing and dispensing habit-forming drugs in quantities that exceeded legitimate medical treatment.\textsuperscript{205} It issued regulations giving itself authority beyond that which the Harrison Tax Act expressly outlined, most of which the Supreme Court upheld as constitutional.\textsuperscript{206}

Facing the full force of the BIR, the AMA repudiated their initial support for medication-maintenance treatment in 1920.\textsuperscript{207} Physicians were targeted for arrest and administrative agencies blamed physicians in congressional hearing testimony for causing the addiction epidemic.\textsuperscript{208} The political costs for continuing to advocate for narcotic prescriptions was high, and the payoff was rather low. By the early 1900s, the population of iatrogenic users that consisted of middle- and upper-class Whites, had dwindled.\textsuperscript{209} Physician education and self-regulation amongst the physician community led to a change in physician prescribing practices

\begin{footnotesize}
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\item \textsuperscript{202} \textit{Id.} at 30-31.
\item \textsuperscript{203} \textit{Id.} at 30-31.
\item \textsuperscript{204} \textit{Id.} at 30-31; MUSTO, \textit{supra} note 57, at 117.
\item \textsuperscript{205} MUSTO, \textit{supra} note 57, at 121-150.
\item \textsuperscript{206} MUSTO, \textit{supra} note 57, at 121-134. The Supreme Court responded by first curtailing the BIR’s authority and then adding its stamp of approval. \textit{See} MUSTO, \textit{supra} note 57, at 121-134.
\item \textsuperscript{207} MUSTO, \textit{supra} note 57, at 200.
\item \textsuperscript{208} \textit{Id.} at 134-139; 194-195.
\item \textsuperscript{209} COURTWRIGHT, \textit{supra} note 57, at 110-123.
\end{itemize}
\end{footnotesize}
of opiates and cocaine. Further, medical treatment had evolved with new treatments replacing opiates and cocaine. The growing acceptance of the germ theory of disease, as well as vast improvements in sanitation, decreased the need for drug use. Non-iatrogenic heroin users, comprised of mostly young urban men who were associated with the criminal underworld—addicts that neither society nor the medical industry viewed with the same compassion as model iatrogenic patients—began to replace iatrogenic addicts. They were a target population that the AMA had no incentive to protect.

So the AMA, which had grown in size and strength, abandoned the claims that addiction was a disease and distanced itself from treatment of addiction. Many of its new members were general practitioners who were more conservative than their predecessors and most concerned with federal government intrusion into the practice of medicine and the threat of socialized medicine. Further, disagreement grew within the medical community over whether addiction was indeed a disease. In 1919, researchers falsified the antibody theory, the leading justification for the addiction as a disease argument, further convincing many physicians to abandon their claim that addiction was a disease. Additionally, physicians were becoming disenchanted by claims that addiction was curable after studies debunked a series of treatments that purportedly cured addiction. A growing number of physicians began advocating for incarceration of the addict to protect both society and the addict from himself.

210 Id. at 110-137.
211 Id. at 110-137.
212 Id. at 110-137.
213 Id. at 110-137.
214 MUSTO, supra note 57, at 200-201
215 ERLEN & SPILLANE, supra note 156, at 27; MUSTO, supra note 57, at 144-146.
216 MUSTO, supra note 57, at 76, 83. Although the anti-body theory was falsified in 1919, even at the height of its support, the theory never had any substantial evidence or proof supporting it. ERLEN & SPILLANE, supra note 156, at 28.
217 MUSTO, supra note 57.
218 COURTWRIGHT, supra note 57, at 123-137.
When Senator Joseph I. France introduced a bill in the summer of 1919 that defined addiction as a health issue, called for the use of the Public Health Service ("PHS") hospitals to offer treatment for addiction, and requested a federal matching for all addiction treatment programs, the AMA withdrew their support for maintenance treatment and medical treatment for addiction.\textsuperscript{219} The AMA was growing increasingly concerned about the possibility of "government medicine" or a nationalized health system, and the idea that federally funded institutions would provide addiction treatment represented to the AMA just another example of the federal government’s increasing involvement in providing healthcare.\textsuperscript{220} The AMA further distanced itself from conversations of addiction, going so far as to repudiate their previous claims that addiction was a disease.\textsuperscript{221} Addiction was not a disease but a manifestation of repressed psychological issues, claimed the AMA.\textsuperscript{222}

The PHS had no desire to take responsibility for treating addicts, so they endorsed the AMA narrative and expanded on it, claiming that addiction was actually a personality disorder, a type of psychopathy, one that not only predisposed addicts to drug use but also to criminal and anti-social behavior.\textsuperscript{223} There was no cure for psychopathy, so the PHS advocated for the use of the criminal justice system to handle this population.\textsuperscript{224} Such a narrative ensured that PHS hospitals would not be required to act as treatment centers for the nation’s population of drug users, a legislative solution that they were trying to avoid.

\begin{itemize}
\item \textsuperscript{219} ERLEN & SPILLANE, supra note 156, at 27.
\item \textsuperscript{220} Id.
\item \textsuperscript{221} MUSTO, supra note 57, at 83.
\item \textsuperscript{222} ERLEN & SPILLANE, supra note 156, at 28; MUSTO, supra note 57, at 83.
\item \textsuperscript{223} ERLEN & SPILLANE, supra note 156, at 28.
\item \textsuperscript{224} ERLEN & SPILLANE, supra note 156, at 28.
\end{itemize}
With physicians and pharmacists under the watchful eye of the BIR, and the drug manufacturing industry undergoing a fundamental transformation, the coalition of interest groups that supported the narrative that addiction was a disease was no longer interested in continuing to support such a narrative. The strength with which the BIR entered the problem definition discourse and the shift in public sentiment required these groups to adjust their narrative and their involvement in drug policy legislative discourse. This era marked the end of the dominance of the “addiction as a disease” narrative and the beginning of the era in which the “addiction as deviance” narrative became most dominant in the discourse. Various narrators would use the deviance narrative over the next thirty years to justify the creation of additional federal law enforcement agencies invested in the portrayal of the addict as a criminal.

6. Attempts to Battle Narratives with Numbers

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225 Ethical drug companies evolved as they took on the corporate structure and began to invest more in the research and development of new medications that they could then market to physicians using their own research journals. ERLEN & SPILLANE, supra note 156, at 3. They no longer relied on physicians’ demand to dictate what drugs to make and instead focused on creating new drugs and then inducing demand by marketing the drug to physicians. Id. Moreover, as physicians changed their prescribing practices and the demand for opiates and cocaine decreased, it is likely that the profit stream for drug manufacturers from these medications was already decreasing drug manufacturers. Further, with the public’s growing awareness of the risks of morphine, heroin and cocaine, reformer’s calls for prohibition of alcohol and drugs, and physician’s vocal criticism of drug manufacturers taking the callous corporate form, which concerned itself with profits rather than patient well-being, continuing to adopt the narrative that addiction was a mere side effect of a medical treatment would have been politically risky. Congress signaled its disapproval of drug manufacturers role in the opiate epidemic by refraining from holding hearings on the amendments to the Harrison Act to prevent the drug manufacturers, amongst other organized interests, from watering down the amendments proposed. MUSTO, supra note 57, at 136. Further, although losing out on the revenue from opiate and cocaine sales would not be pleasant, if the country were to outlaw the use of opiates and cocaine, then they would also be eliminating the greatest source of revenue for their largest competitor: the patent-medicine manufacturer. Patent-medicine manufacturers were already experiencing political and financial turmoil. Id. They were busy staving off attacks from ethical drug companies and physicians. Id. Physicians lobbied for the regulation of patent-medicine manufacturers, which they accused of undermining physician authority by marketing directly to consumers and claiming that public had the tools necessary to treat their own illnesses by purchasing medication directly from the patent medicine manufacturers. Id. The passage of the Pure Food and Drug Act of 1906 marked the beginning of the end of the reign of the patent-drug companies, as they now had to label their medication with any potentially harmful ingredients, including cocaine, alcohol and morphine. Id. The requirement that manufacturers disclose the use of opium, morphine, heroin, alcohol or cocaine caused their sales to drop by 1/3. Id.
The most politically active federal law enforcement agency in the legislative problem definition discourse on substance abuse issues was the Federal Bureau of Narcotics ("FBN"), founded in 1930 with Harry J. Anslinger as its first commissioner. Anslinger came from the Prohibition Bureau prior to its dismantling, and he was determined to not let his bureau fall prey to the same fate of the Prohibition Bureau. Luckily for Anslinger, he was a master story-teller who specialized in creating believable narratives that resonated with public sentiment. He supported his policy narratives with half-truths, questionable statistics, and harrowing tales of the perils of drugs use. He was also very adept at using the media to garner support for his narratives and legislative proposals. As faulty as his evidence may have been, he was convincing, and, throughout his thirty-two year tenure, Congress often deferred to his judgment when considering legislative proposals to address problem drug use. For much of his career, Anslinger argued that drug use was a sign of deviance and that the only suitable solution for such deviancy was stricter and harsher penalties for drug users and drug traffickers. "The addict," he claimed, "is like a typhoid carrier; he will spread crime and disease wherever he goes. He will spread addiction." The legislative solutions that aligned with such a narrative included incarceration of the addict to protect society. Such a causal story eliminated the possibility of medical-maintenance or medical-assisted therapies as a legislative solution, which Anslinger was also clear to explicitly denounce. “The idea of the government poisoning its citizens with

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226 ERLEN & SPILLANE, supra note 156, at 61.
227 ERLEN & SPILLANE, supra note 156, at 64.
228 ERLEN & SPILLANE, supra note 77, at 66.
229 ERLEN & SPILLANE, supra note 77, at 70-73.
230 ERLEN & SPILLANE, supra note 77, at 61, 66.
231 ERLEN & SPILLANE, supra note 77, at 61.
232 ERLEN & SPILLANE, supra note 77, at 129 (citing Anslinger’s 1959 television interview on the Monitor talk show).
233 ERLEN & SPILLANE, supra note 77, at 127.
narcotics is nonsense. Why don’t they set up bar rooms for alcoholic . . . ? Why not furnish everybody with what they want, bullets, or department stores for kleptomaniacs, and so on…”

Anslinger presented anecdotes and “fabricated horror stories connecting drug use with violent crime” as testimony in several congressional hearings, and they “weighed heavily” in Congress’s decision to enact major narcotics legislation, including the Boggs Act of 1951 and the Narcotic Control Act of 1956 (“NCA”).

By 1956, Anslinger had accomplished his goals of persuading Congress to pass legislation requiring stiff mandatory minimum sentencing for possession and drug sale. The NCA even allowed for the jury to recommend the death penalty for a conviction of drug sales to a minor. As rhetoric expert Dr. Rebecca Carroll put it, “After twenty-six years, Anslinger was the recognized authority on narcotics. By controlling the discussion on narcotics, Anslinger controlled the policy on narcotics.”

Not until mandatory minimums became a reality did organized interest groups make a concentrated effort to publicly challenge the legitimacy of the United States’ criminal justice approach to the nation’s drug problems or attempt to redefine the problem of addiction as a medical disease. During the late 1950’s, the American Bar Association (“ABA”) and the AMA led the way in the attempt to redefine addiction as a health issue by testifying at congressional hearings and forming a formal, joint committee to study narcotic drugs. The ABA-AMA Committee hoped that their research would add credence to their criticisms of the United States’ criminal justice approach to addiction and would open up a dialogue between the Committee, the

234 Id. at 127 (citing Anslinger’s 1959 television interview on the Monitor talk show).
235 Id. at 66.
237 Id. at § 107(i).
238 ERLEN & SPILLANE, supra note 77, at 112.
239 ERLEN & SPILLANE, supra note 77.
Narcotics Bureau, and Congress regarding alternative legislative solutions for the drug problem.\textsuperscript{240}

Instead, it enraged Anslinger, who wrote them letters dismissing the evidence in their 1958 Interim Report\textsuperscript{241} as inconsistent and lacking in factual accuracy.\textsuperscript{242} Anslinger had devoted his career to ensuring that the FBN was the federal agency responsible for addressing problem drug use and a problem definition that attributed the cause of drug use to psychological or medical causes would shift power to health agencies as fixers of the problem. Not only would the FBN’s appearance as the fixers of drug use be impacted, but so would the funding allocations that accompanied the delegated powers to fix the problem. If drug abuse is a health problem, then funding would flow away from law enforcement agencies, like the FBN, and towards health agencies. As such, Anslinger was invested in maintaining the “addiction as deviance” narrative.

As such, Anslinger refused the Committee’s multiple requests to meet and used the media to communicate his disgust for the Interim Report.\textsuperscript{243} Later that year the FBN released official Comments on the Narcotic Drug Interim Report of the ABA-AMA, a compilation of previously published texts that supported the FBN’s narratives—none of which directly addressed the claims made in the Interim Report.\textsuperscript{244} The FBN, under Anslinger’s direction, did what it did best: battle the evidence with stories. The ABA-AMA released their final report in 1961, which

\textsuperscript{240} The Committee was especially interested in exploring the expansion of Medication Assisted Treatments (MAT). ERLEN & SPILLANE, supra note 77.

\textsuperscript{241} The report summarized the two approaches to addressing problem drug use: the punitive approach and the health approach. See generally THE JOINT COMM. OF THE AM. BAR ASS’N & AM. MED. ASS’N ON NARCOTIC DRUGS, NARCOTIC DRUGS: INTERIM REPORT (1958) [hereinafter ABA-AMA]. It advocated that the federal government fund an experimental pilot program that prescribed opioids on an outpatient basis as treatment for addiction. Id. at 11. The report included a detailed appendix outlining Britain’s approach to treating addiction, a harm reduction approach that favored MAT. Id.

\textsuperscript{242} ERLEN & SPILLANE, supra note 77.

\textsuperscript{243} Id.

\textsuperscript{244} ADVISORY COMM. TO THE FED. BUREAU OF NARCOTICS, COMMENTS ON NARCOTIC DRUGS: INTERIM REPORT OF THE JOINT COMMITTEE OF THE AMERICAN BAR ASSOCIATION AND THE AMERICAN MEDICAL ASSOCIATION ON NARCOTIC DRUGS, (1959). See also ERLEN & SPILLANE, supra note 77.
they titled “Drug Addiction, Crime or Disease?” However, as Rufus King, one of the authors of the report, later wrote in his book entitled The Drug Hang-Up: the “ABA-AMA, [was] No Match for HJA.”

Although the ABA-AMA tried to redefine addiction as a disease, they did not have a high-ranking government official supporting their narrative. Rather, a high ranking administrative officer who had established himself as a narcotics expert directly opposed their narrative. Aside from not having the necessary support from an official, support that Baumgartner, et al., argue is an important predictor of successful problem redefinition, the ABA-AMA made an erroneous assumption: that gathering scientific or empirical evidence to support claims and arguments was the key to refuting the dominant causal story that problem drug use was a character flaw. Essentially, they brought facts to a battle of stories.

After all, Anslinger’s dominance in the drug policy discourse did not result from his use of “facts” or scientific evidence to support his arguments. Anslinger invested his energy in telling a compelling narrative that resonated with his audience and with legislators who were interested in assuaging their constituents’ fears. His narratives were consistent, his description of the target population elicited images that made his solutions more persuasive, and he artfully utilized the media to communicate his stories. The ABA-AMA Committee, on the other hand, did not even produce enough copies of the Interim Report for mass circulation, and they ran out of copies soon after it was published. Initially, they made enough prints to provide copies to the FBN and some ABA and AMA members for review, but the Committee wanted to make sure

245 ABA-AMA, supra note 244.
246 ERLEN & SPILLANE, supra note 77.
247 See generally ERLEN & SPILLANE, supra note 77.
248 BAUMGARTNER, supra note 55, at 78.
249 ERLEN & SPILLANE, supra note 77.
that the Interim Report was factually accurate and approved by the Board before copies got into the hands of the media, libraries, schools, and even all of the members of the ABA and AMA.\textsuperscript{250} This decision allowed Anslinger to control the discourse by criticizing the Interim Report in the media, when few had the opportunity to read the Interim Report for themselves.\textsuperscript{251} Further, Anslinger insisted that the FBN widely circulate its Comments to the Interim Report as soon as it was published in 1958, making sure to send copies to the media,\textsuperscript{252} while the ABA-AMA Interim Report did not become widely distributed until 1961 as an attachment to the Final Report.\textsuperscript{253} By the time the report was available, legislators had already made their judgments. Anslinger understood that the key to success was to ensure that the FBN narrative dominated, while the ABA-AMA was more concerned with ensuring that they had their facts straight—even if it meant delaying its reports’ entrances into the discourse. As well-researched as the Interim and Final Reports may have been, lawmakers dismissed them even before they became widely available to the public, and with their dismissal, the efforts to redefine addiction as a disease died. In the legislative process, evidence is only one input into the decision-making process and, in this case, it was no substitute for a well-crafted story.

VI. LESSONS LEARNED: CONCLUDING REMARKS

As legal scholars, we devote many of our printed words to analyzing legislation that has been enacted or proposed. We propose “better” legislative proposals or argue that current proposals or enacted legislation are inadequate. Little legal scholarship analyzes or suggests how to convince legislators to enact model legislative solutions. Even when making such

\textsuperscript{250} Id.
\textsuperscript{251} ERLEN \& SPILLANE, supra note 74, at 120-129.
\textsuperscript{252} Id. King argued that the FBN purposely made their publication appear similar to the Interim Report by printing it on the same colored paper and formatting the cover similarly in an effort to confuse readers into thinking that they were reading the Interim Report and not the comments to it. Id.
\textsuperscript{253} Id.
suggestions, they often ignore the politics of the legislative process, the institutions that are involved, and the problem definition process that comes before, and drastically influences, the types of legislative proposals that lawmakers consider. In the academy, we place so much emphasis on the numbers, the facts, and the evidence, as if the side with the best evidence and the most publications in the highest-ranked journals wins. If the endgame is to contribute to the legislative process, however — if the goal is to help lawmakers reform our ineffective and costly criminal justice approach to problem drug use and replace it with any one of the model public health-oriented drug policies that many developed nations have effectively implemented, then continuing to focus on compiling more evidence will not help us reach our objective, because the existence of evidence alone does not change policy. The AMA and ABA had sufficient evidence to support their policy position, yet Harry Anslinger silenced them with his story. Arguably, the AMA was more successful in achieving their objectives in the late 1800s and early 1900s, when they had little evidence to support their narrative that addiction was a disease, than they were when they had a well-researched and documented report in the late 1950s. As groups like the Parents Groups of the 1970s and 1980s have shown us, the power lies within the narrative.

Although narratives may trump evidence, there is still strength in numbers in the sense that more voices in unison are stronger than a single voice. The coalitions that have formed around common narratives throughout drug policy history have shown us that the more narrators that tell the same story, the more likely that the narrative will dominate the legislative discourse. In each instance, groups had choices or alternatives as to how they wanted to craft their narrative, yet each compelling narrative had some commonalities. They each drew from cultural norms and beliefs in order to make their narratives believable. Their descriptions of their characters coincided with that population’s social construction. And, their causal theory framed the
solution they supported. Not only did these groups have commonalities in their narrative structure, they also shared an understanding of the power of narratives in the legislative process. They used their narratives to persuade other groups, legislators, and even high-ranking administrative officials to support their causal explanations and their legislative proposals.

Concerned citizens, including legal scholars, have at their disposal several strategies that they can use to take advantage of the current political window of opportunity that bi-partisan and public support for the addiction-as-a-disease narrative has created. Since a plethora of evidence supporting the efficacy of a public health-oriented approach already exists, proponents of the public health approach can focus their efforts on affecting the legislative process by using some of the strategies that this Article outlines. Namely, proponents can begin by (1) identifying preferred public health solutions, (2) strategically crafting a compelling causal story that aligns with the desired public health solutions and accounts for cultural norms and beliefs, (3) forming coalitions with other proponents that support the narrative and its aligning solutions, and (4) using the narrative to persuade high-ranking government officials in both the executive and the legislature to support public health solutions.

Moreover, advocates for the public health approach will need to broaden the problem definition of the Opioid Epidemic specifically, and problem drug use in general, to sufficiently address current and future problem drug use. For example, as with other health outcomes, the social determinants of health influence addiction and overdose death rates. If advocates supported a policy narrative that attributes problem drug use, at least in part, to social, economic and environmental factors, a multi-modal public health-oriented solution would have a greater likelihood for political success. Such a narrative does not negate the “addiction-is-a-disease

\[^{254}\text{COURTWRIGHT, supra note 57; MASSING, supra note 110; MUSTO, supra note 57; YSA ET AL., supra note 4.}\]
\[^{255}\text{See generally ANDERSON ET AL., supra note 3.}\]
narrative," but rather builds on it to focus on both treatment and establishing a system of supports that ensures the greatest likelihood for lifelong treatment success. Advocates can add to the credibility of such a narrative by pointing to the evidence that demonstrates that such multi-modal approaches are not only more effective, but are also more cost-effective in the long term.256

Since legal professionals and legal scholars are already predisposed to seeking policy change through the judicial system, this Article has focused on another avenue by which legal scholars and professionals can contribute to the problem definition discourse and influence policy outcomes—the legislative process. Although this manuscript focuses on affecting the legislative process, narrators can apply the problem definition strategies it presents to the implementation and interpretation phases of lawmaking. Moreover, although this discussion focuses on the issue of problem drug use, pressure groups can apply these strategies to other issues, like gun violence, for which groups desire to redefine the problem and effect policy change.

For a multi-modal public health approach to become a legislative staple in American policy, advocates of such an approach must learn from the failures and successes of past organized interest groups and focus on building a dominant and compelling narrative to supplement existing scientific evidence and seek support for such a narrative from coalitions and high-ranking government officials. After all, it is not the evidence, but the problem redefinition and its accompanying narratives that drive policy change.257

256 YSA ET AL., supra note 4.
The opioid epidemic has claimed more than 300,000 lives in the United States since 2000 and could claim another half million over the next decade. Although heroin and illicitly manufactured fentanyl account for an increasing proportion of opioid-involved overdoses, the majority of persons with opioid addiction started with prescribed painkillers. The search for solutions has spread in many directions, and one tentacle is probing the legal accountability of companies that supply opioids to the prescription market. Even as the federal government, among others, pursues civil and criminal actions against physicians and pharmacies to address inappropriate prescribing and dispensing of opioids, a variety of lawsuits have been filed and continue to be filed against opioid manufacturers and distributors.

These lawsuits commenced in the early 2000s but have increased in frequency and profile in recent years (see table). The earliest suits against opioid manufacturers — typically Purdue Pharma, the maker of OxyContin (oxycodone) — were personal injury claims brought on behalf of persons with addiction who overdosed.

Opioid products, they alleged, were defectively designed because companies failed to include safety mechanisms, such as an antagonist agent or tamper-resistant formulation. Manufacturers also purportedly failed to adequately warn about addiction risks on drug packaging and in promotional activities. Some claims alleged that opioid manufacturers deliberately withheld information about their products’ dangers, misrepresenting them as safer than alternatives.

These suits faced formidable barriers that persist today. As with other prescription drugs, persuading a jury that an opioid is defectively designed if the Food and Drug Administration approved it is challenging. Furthermore, in most states, a drug manufacturer’s duty to warn about risks is limited to issuing an adequate warning to prescribers, who are responsible for communicating with patients. Finally, juries may resist laying legal responsibility at the manufacturer’s feet when the prescriber’s decisions and the patient’s behavior contributed to the harm. Some individuals do not take opioids as prescribed or purchase them illegally. Companies

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<td>Nov. 5, 2004 (settled)</td>
<td>Aggressively marketing OxyContin to state residents, many of whom became addicted</td>
<td>$10 million paid over 4 yr to support drug abuse and education programs, law-enforcement initiatives, and medical programs on drug abuse</td>
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<td>Concealing from prescribers the extent to which OxyContin’s qualities could lead to addiction</td>
<td>No fault admitted</td>
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<td>State of Oregon ex rel. Hardy Myers v. Purdue Pharma L.P. et al.</td>
<td>May 8, 2007 (settled)</td>
<td>Unlawfully marketing OxyContin for off-label uses</td>
<td>$19.5 million Purdue pledged not to promote OxyContin for off-label uses Requires Purdue to maintain abuse- and diversion-detection program, report problem prescribing, and have field sales personnel undergo special training before selling OxyContin</td>
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<td>Misbranding OxyContin as “less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications”</td>
<td>No fault admitted</td>
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<td>Commonwealth of Kentucky, ex rel. Jack Conway v. Purdue Pharma L.P. et al.</td>
<td>Oct. 4, 2007 (filed) Dec. 23, 2015 (settled)</td>
<td>Committing Medicaid fraud by misrepresenting the risks and benefits of OxyContin, thereby costing Kentucky Medicaid millions in drug and treatment costs Engaging in false advertising by means of false and misleading package inserts, promotion, and marketing Reaping unjust enrichment by profiting from OxyContin while state paid associated medical and drug costs</td>
<td>$24 million paid over 8 yr, to be spent on addiction treatment No fault admitted Judge granted media request to unseal the court documents to make Purdue practices known to the public</td>
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<td>State of West Virginia, ex rel. Patrick Morrisey v. Cardinal Health, Inc.</td>
<td>June 26, 2012 (filed) Jan. 9, 2017 (settled)</td>
<td>Violating West Virginia Controlled Substances Act by failing to diligently respond to suspicious orders Engaging in unfair and deceptive practices, in violation of the West Virginia Consumer Credit and Protection Act Creating a public nuisance because diversion of drugs led to increased crime and consumption of law-enforcement and health care resources Reaping unjust enrichment while state expended substantial resources on prescription opioid epidemic</td>
<td>$20 million paid by Cardinal Health (distributor) $16 million paid by AmerisourceBergen (distributor) $2.4 million paid by Miami-Luken (distributor) No fault admitted</td>
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<tr>
<td>The People of the State of California v. Purdue Pharma L.P. et al.</td>
<td>May 21, 2014 (filed) May 24, 2017 (settled with Teva)</td>
<td>Engaging in false advertising by deceptively marketing opioid drugs meant for short-term use as appropriate for chronic pain Engaging in unfair competition, in violation of the California Unfair Competition Law Creating a public nuisance under California law by engaging in deceptive marketing that led to an epidemic of opioid abuse</td>
<td>$1.6 million paid by Teva Pharmaceuticals, to be spent on combating the ongoing opioid epidemic impacts in Santa Clara and Orange Counties Bars Teva from deceptive marketing No fault admitted by Teva Charges against Purdue, Endo Health Solutions, Janssen, and Actavis remain unresolved, although litigation stayed by state court judge pending outcome of FDA studies related to risks of long-term opioid treatment</td>
</tr>
<tr>
<td>The People of the State of Illinois v. Insys Therapeutics, Inc.</td>
<td>Aug. 25, 2016 (filed) Aug. 18, 2017 (settled)</td>
<td>Violating the Illinois Consumer Fraud Act by engaging in the unfair and deceptive practices of deliberately marketing Subsys, the synthetic opioid approved for breakthrough cancer pain, for off-label purposes to high-volume opioid prescribers and paying prescribers to prescribe Subsys under a sham speaker program</td>
<td>$4.45 million No fault admitted Prohibits Insys from engaging in any false, misleading, or deceptive marketing and from promoting off-label use of its opioid drugs in Illinois Requires Insys to promote its opioid Subsys only to prescribers who are oncologists or who are enrolled in an applicable FDA Risk Evaluation and Mitigation Strategy</td>
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PERSPECTIVE

Drug Companies' Liability for the Opioid Epidemic

n engl j med 377;24 nejm.org December 14, 2017

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<td>Commonwealth of Massachusetts v. Insys Therapeutics, Inc.</td>
<td>Oct. 5, 2017 (filed and settled)</td>
<td>Violating the Massachusetts Consumer Protection Act by engaging in unfair and deceptive acts of misleading health care professionals about the appropriate use of Subsys, including by promoting the drug for off-label uses and paying kickbacks to health care professionals to induce them to prescribe Subsys</td>
<td>$500,000 No fault admitted Prohibits Insys from engaging in any unfair or deceptive marketing practices of Subsys in Massachusetts, including for off-label purposes or by paying kickbacks to prescribers Prohibits Insys from promoting Subsys to any health care professional unless he or she provides cancer care or is enrolled in an applicable FDA Risk Evaluation and Mitigation Strategy</td>
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<td>United States of America v. The Purdue Frederick Company, Inc., et al</td>
<td>May 10, 2007 (filed) June 25, 2007 (settled)</td>
<td>Violating FDCA by misbranding OxyContin with the intent to defraud or mislead</td>
<td>$600 million paid by Purdue $34 million paid by three of Purdue's top executives Parties admitted to misleading physicians and patients about product's addictiveness and misbranding it as abuse-resistant</td>
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<td>United States of America v. Cardinal Health, Inc.; United States of America v. Kinray, LLC</td>
<td>Dec. 23, 2016 (settled)</td>
<td>Violating CSA by failing to report suspicious orders of controlled substances to pharmacies in Maryland, Florida, and New York Violating Washington record-keeping laws</td>
<td>$44 million, consisting of $34 million pursuant to Cardinal settlement and $10 million pursuant to Kinlay (acquired by Cardinal in 2010) settlement Cardinal admitted failure to report suspicious orders to the DEA</td>
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<tr>
<td>United States of America v. McKesson Corporation</td>
<td>Jan. 5, 2017 (settled)</td>
<td>Violating CSA by failing to maintain effective controls against diversion of controlled substances, including opioids, and to report suspicious orders to the DEA Violating 2008 administrative agreement with federal government to monitor sales and report suspicious orders to the DEA</td>
<td>$150 million Requires McKesson to suspend sales of controlled substances from distribution centers in Colorado, Ohio, Michigan, and Florida for 1–3 yr Because McKesson admitted failure to report suspicious pharmacy orders, it agreed to enhanced compliance with earlier 2008 agreement (which had also included a $13.25 million settlement)</td>
</tr>
<tr>
<td>United States of America v. Mallinckrodt, Inc.</td>
<td>July 11, 2017 (settled)</td>
<td>Violating CSA by failing to notify DEA of suspicious orders, as well as failing to implement an effective system to detect such orders</td>
<td>$35 million Allows DEA to analyze data Mallinckrodt collects on orders from customers No fault admitted</td>
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<td>Canada-wide class proceedings v. Purdue Pharma et al.</td>
<td>June 8, 2007 (commenced) Aug. 24, 2017 (settlement approved)</td>
<td>Failing to disclose the known risk of addiction and withdrawal associated with OxyContin and OxyNEO to a class of persons who were prescribed and ingested these products from Jan. 1, 1996, through Feb. 28, 2017</td>
<td>$20 million (Canadian) settlement proposed and accepted by three of four jurisdictions overseeing the cases, consisting of $2 million to provincial health providers, $4.5 million in legal fees, and ~$13,000–$17,000 per class member</td>
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* CSA denotes Controlled Substances Act; DEA Drug Enforcement Agency; FDA Food and Drug Administration; and FDCA Food, Drug, and Cosmetic Act.
may argue that such conduct precludes holding manufacturers liable, or at least should reduce damages awards.¹

One procedural strategy adopted in opioid litigation that can help overcome defenses based on users’ conduct is the class action suit, brought by a large group of similarly situated individuals. In such suits, the causal relationship between the companies’ business practices and the harm is assessed at the group level, with the focus on statistical associations between product use and injury. The use of class actions was instrumental in overcoming tobacco companies’ defenses based on smokers’ conduct. But early attempts to bring class actions against opioid manufacturers encountered procedural barriers. Because of different factual circumstances surrounding individuals’ opioid use and clinical conditions, judges often deemed proposed class members to lack sufficiently common claims.³

The tide may turn for such lawsuits, however. As the population harmed by opioids grows and more information about the populations is documented, it becomes easier to identify subgroups with similar factual circumstances and legal claims — for example, newborns with neonatal abstinence syndrome. A class action brought against Purdue Pharma in Canadian court by persons who were prescribed and ingested OxyContin and OxyNEO (controlled-release oxycodone), which alleged claims similar to those in many U.S. cases, is on the verge of being settled for $20 million, if all involved provinces agree (see table).

**Notwithstanding the $600 million federal settlement with Purdue in 2007 — one of the largest in history with a drug company — opioid litigation has yet to financially dent the $13-billion-a-year opioid industry.**

Perhaps the most promising development in opioid litigation has been the advent of suits brought against drug makers and distributors by the federal government and dozens of states, counties, cities, and Native American tribes. Because the government itself is claiming injury and seeking restitution so that it can repair social systems debilitated by opioid addiction, these suits avoid defenses that blame opioid consumers or prescribers. They also garner substantial publicity.

Government strategies include traditional types of enforcement actions based on the federal Food, Drug, and Cosmetic Act, which prohibits introducing “misbranded” drugs into interstate commerce. However, governments have recently embraced several more creative strategies, borrowing from playbooks used for suing tobacco and firearm companies.

The first strategy focuses on the public scourge created by the opioid epidemic. Governments allege that opioid companies unreasonably interfered with the public’s health by oversaturating the market with drugs and failing to implement controls against misuse and diversion, thereby creating a public nuisance. State attorneys general made similar arguments about firearm manufacturers, which allegedly knew that the high volume of guns they were supplying could find buyers only on the black market.

The second strategy paints opioid companies’ business practices as deceptive. In these fraud claims, sometimes brought in connection with Medicaid claims or consumer protection laws, governments charge that companies made false representations about their products’ addictiveness and effectiveness, all calculated to mislead the state, prescribers, and the public. This argument proved powerful in suits against tobacco companies.

A third strategy calls out companies’ lax monitoring of suspicious opioid orders. The federal Controlled Substances Act requires drug suppliers to maintain effective controls against, and to notify the Drug Enforcement Agency of, potentially illegitimate orders.

Whereas tobacco lawsuits benefited from leaked evidence that tobacco companies were aware of nicotine’s addictiveness and sought to underestimate it and to manipulate nicotine levels in tobacco products, no comparable whistleblower evidence has emerged with regard to opioids. Without such evidence, it is harder to establish an intent to deceive. Nevertheless, other information may help prove that companies knew that what
they were doing was harmful: admissions of liability in some settlements; documents obtained in government investigations, investigative reporting, and litigation; and marketing practices that persisted despite mounting evidence linking opioids to adverse health outcomes.  

A final strategy highlights the profits that opioid companies have reaped at the government’s expense through allegedly unfair business practices. In these “unjust enrichment” claims, governments argue that opioid companies should have to disgorge such profits. This argument has intuitive appeal, as it did in litigation over tobacco, firearms, and lead paint, because attorneys can point to huge pecuniary gains enjoyed while the government was saddled with vast medical and law-enforcement costs. Such claims have struggled to find legal footing in cases involving other products because courts typically require evidence that the government conferred a benefit on the company. For opioids, though, government payment for excessive prescriptions under public insurance programs directly contributed to companies’ profits. 

Already, two large settlements have occurred in cases that included unjust enrichment claims, although pharmaceutical companies avoided admitting fault (see table).

Notwithstanding the $600 million federal settlement with Purdue in 2007 — one of the largest in history with a drug company — opioid litigation has yet to financially dent the $13-billion-a-year opioid industry. Moreover, opioid litigation victories have all taken the form of settlements, in which companies usually have not admitted any fault. Even when litigation costs have no prospect of exceeding the economic benefits of continuing to produce a dangerous product, though, litigation can have value as a public health strategy and may mitigate some harms of the opioid epidemic.

The funds obtained in several government suits have provided desperately needed resources for opioid addiction treatment and law enforcement. Future payouts, reasonably likely to increase in frequency and magnitude, could also be earmarked for other support services for persons with addiction — such as housing and employment assistance — and for distributing the overdose-reversal drug naloxone. Experience suggests that the challenge will be ensuring that the windfalls to state governments are not diverted to unrelated purposes.

Litigation could also help alleviate the opioid epidemic by changing industry practices and building public awareness. Settlement agreements may include commitments to modify particular marketing and distribution practices, as in the case of McKesson (see table). Lawsuits may bring to light harmful, unethical, and even illegal business practices that sour public opinion of opioid companies and prompt patients to ask more questions about what their doctor prescribes. Finally, snowballing litigation helps build the case for greater regulation. Win or lose, lawsuits that very publicly paint the opioid industry as contributing to the worst drug crisis in American history put wind in the sails of agencies and legislatures seeking stronger oversight. Together, litigation and its spillover effects hold real hope for arresting the opioid epidemic.

Disclosure forms provided by the authors are available at NEJM.org.

From the Department of Health Management and Policy, University of Michigan School of Public Health, Ann Arbor (R.L.H.); and Stanford Law School and the Department of Health Research and Policy, Stanford University School of Medicine, Stanford, CA (M.M.M.).

Preventing Opioid Misuse with Prescription Drug Monitoring Programs:
A Framework for Evaluating the Success of State Public Health Laws

REBECCA L. HAFFAJEE*

The United States is in the midst of a prescription opioid overdose and misuse epidemic. Although many factors have contributed to the escalation of prescription painkiller misuse, it parallels increases in the supply and prescribing of opioids. Prominent state-level regulatory interventions, such as the establishment of prescription drug monitoring programs (“PDMPs”), recognize prescribers as opioid gatekeepers. Prescribers, who are uniquely situated to distinguish between appropriate use and misuse of opioids, are a natural target for regulation. PDMPs also target patients who seek to obtain high volumes of prescription opioids for illicit purposes.

PDMP policies are widespread but heterogeneous, largely uninformed by robust evidence or a systematic assessment of best practices. Whether these programs successfully reduce opioid misuse and overdoses remains unclear. As well, PDMPs present a number of legal and ethical challenges that, along with intervention effectiveness, warrant careful policymaker consideration going forward. This Article articulates and synthesizes for the first time key criteria intended to assist state regulators in dynamically evaluating and justifying PDMPs and other public health laws. The criteria focus on the legality of the policy, approaches to measure its effectiveness, and normative considerations that should be factored into good laws. Such a framework is crucial for policymakers given the complexities and magnitude of this public health challenge, the rich arsenal of policy options from which to choose, and the slow and uncertain progress in combating prescription painkiller misuse. Concluding recommendations include implementing PDMPs with the following features: timely and complete data, strong incentives for prescriber participation, user guidelines and education, integration into clinical work flow, and robust confidentiality and privacy protections. Ongoing evaluation of programs to identify features appropriate for retention and replication is also crucial if PDMPs are to fulfill their potential to curb prescription opioid overdose and misuse.

* Rebecca L. Haffajee, J.D./M.P.H., graduated from Harvard Law School and Harvard School of Public Health in 2006. She practiced regulatory health care law and is currently a doctoral candidate in the Ph.D. Program in Health Policy (Evaluative Science and Statistics concentration), Graduate School of Arts and Sciences, Harvard University (anticipated 2016). For their highly insightful and thoughtful comments and feedback in developing this Article, the Author would like to thank Michelle Mello, Glenn Cohen, Frank Wharam, Alan Zaslavsky, and James Drabick.
INTRODUCTION

The United States is in the midst of a prescription opioid misuse crisis. Although only five percent of the world’s population lives here, we consume over eighty percent of the world’s opioid supplies.\(^1\) Drug overdoses, over half of which are related to prescription drugs, are now the leading cause of injury and death in the United States.\(^2\) In 2014, opioids were involved in sixty-one percent of drug overdose deaths, or

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28,647 deaths. The crisis has escalated to such levels over the past two decades that federal officials now characterize prescription drug misuse and overdose as a national “epidemic.”

Prescription opioid deaths are a consequence of nonmedically indicated use of opioids. This practice, also termed prescription opioid misuse and abuse (this Article uses the term “misuses to capture both), consists of the unintentional or intentional use of medication without a prescription, in a manner other than as prescribed, or for the feeling or experience it causes. The prevalence of prescription opioid misuse is striking. In 2013 alone, 15.3 million Americans aged twelve and older used prescription drugs nonmedically, and 6.5 million had done so in the prior month. Moreover, prescription opioids may serve as gateway drugs. There is some evidence that addicts switch to even deadlier substances, such as heroin, when they can no longer access, afford, or tamper with prescription painkillers.

The rise in prescription painkiller misuse is clearly correlated with the increasing supply and prescribing of opioids. The overall sale of


opioid analgesic painkillers, which increased nearly four-fold between 1999 through 2010, parallels observed increases in opioid-related overdose deaths, emergency department visits, and treatment admissions. In 2012 alone, providers issued 259 million opioid prescriptions—enough for every adult to have their own bottle of pills.

A heightened focus on pain management starting in the 1990s liberalized opioid prescribing. But in responding to the public health problem of under-treatment of pain, prescribers paradoxically have played a major role in creating another public health problem: the growth of prescription drug misuse. Twenty-five percent of nonmedical prescription painkiller users obtained their drugs directly from a doctor’s prescription, while seventy percent of users accessed drugs from family or friends—almost ninety percent of whom had gotten their prescription from a doctor. In other words, the vast majority of misused prescription drugs are sourced directly or indirectly from prescribers.

Prescribers are uniquely situated to distinguish between appropriate use and misuse of opioids and prescribe accordingly. Several state regulatory interventions—most prominently, the establishment of prescription drug monitoring programs (“PDMPs”)—recognize prescribers as opioid gatekeepers. PDMPs also target “doctor shoppers” (patients with particularly high opioid consumption patterns), and diverters (individuals who transfer their prescribed drugs to others for illicit use). PDMPs have been adopted in all but one state, and the Centers for Disease Control and Prevention describes them as “among the most promising state-level

12. See Jones et al., supra note 9, at 802–03 (observing that those at highest risk of overdose, or those who use prescription opioids nonmedically on a chronic basis (that is, for 200 or more days per year), were at the highest risk to obtain their drugs directly from a doctor (twenty-seven percent of the time)).
interventions to improve opioid prescribing, inform clinical practice, and protect patients at risk."14

Although early evidence is emerging regarding the impact of these interventions on opioid prescribing, misuse, and overdoses, the rapid proliferation of heterogeneous PDMPs has been largely uninformed by robust evidence or a systematic assessment of best practices. Instead, state replication of PDMPs has exemplified disorganized policymaking in the face of a serious public health crisis. Moreover, PDMPs present a number of legal and normative challenges that, along with intervention effectiveness, warrant careful policymaker consideration going forward. Thus, existing PDMPs offer an opportunity to reflect upon how state public health policymaking in this area can follow a more deliberate path towards success.

This Article argues for the use of state PDMPs with the following features: timely and complete data; strong incentives for prescriber participation; user guidelines and education; integration into clinical workflow; and strong confidentiality protections—including a requirement that law enforcement officials and licensing boards access individual-identifying data only with a court-issued warrant or subpoena. Ongoing evaluation of PDMPs to improve understanding of best practices is also needed. To arrive at these recommendations, this Article articulates and synthesizes, for the first time, key criteria intended to assist state regulators in dynamically evaluating and potentially justifying public health laws. The criteria focus on the following: (1) the form that regulation should take based on analysis of the policy’s legality; (2) measurement of law effectiveness; and (3) normative considerations that ought to be factored into good public health policy. Such a streamlined framework is a critical tool for state regulators, given the complexities and scope of prescription opioid misuse, the rich arsenal of policy options available to address it, and slow and uncertain progress in combating this problem. Although used to guide PDMP policymaking, this framework also can be applied to interventions designed to address public health threats that exhibit similar characteristics to prescription drug misuse—that is, those of significant magnitude and that may be addressed using a number of available policy options, the success of which is not yet obvious or common knowledge.15


15. The framework may also be used after identifying “critical opportunities” for public health lawmakers, or areas “in which law is under-performing as a public health tool in relation to the problem of interest.” Law can under-perform because legal interventions are few (or nonexistent) or because they are executing poorly, such as causing undesirable consequences. A critical opportunity satisfies three criteria: (1) it targets a significant public health threat; (2) its etiology is well-understood to support the use of law as an intervention; and (3) one or more plausible legal interventions are available to address the threat but are not being used to their full advantage. Michelle M. Mello et al., Critical Opportunities for Public Health Law: A Call for Action, 103 AM. J. PUB. HEALTH 1979, 1979-80 (2013).
This Article proceeds as follows. Part I describes the current prescription drug misuse crisis, establishing it as a public health threat of substantial magnitude that evolved from a history of ebbing and flowing in opioid prescribing in the United States. Part I also outlines the panoply of regulatory interventions available to address this epidemic, including, most prominently, PDMPs implemented by state governments. Part II then lays out a framework for evaluating public health laws implemented by the states, which bear great responsibility to protect population health, and applies it to PDMPs. Key criteria are articulated that probe legal powers to regulate (including legal barriers to implementation), the effectiveness of the law at achieving identified primary and secondary health outcomes, and salient ethical issues raised by public health regulation. Finally, specific recommendations for PDMPs, generated by application of the evaluative framework, are set forth, with the goal of maximizing the chances that these policies will be a public health success.

I. PRESCRIPTION DRUG MISUSE: A PUBLIC HEALTH EPIDEMIC

The current prescription drug misuse and overdose epidemic evolved from over a century of ebbing and flowing in prescription drug use in America. This is the third wave of misuse, following two earlier eras of problematic opioid use and regulatory responses. The first escalation in misuse occurred in the late 19th century during a time when opioids were altogether unregulated. Opioids, including heroin, were commonly prescribed for menstrual pain, among other maladies, often resulting in iatrogenic morphine addiction. Regulation ensued, in the form of the 1906 Pure Food and Drug Act, which required the content of drugs (including opioids) to be listed on their labels, and the 1914 Harrison Narcotics Act, which regulated physicians by mandating that they write prescriptions for opioids, taxing them for such prescriptions, and requiring that they maintain records of drugs dispensed. The Act also restricted the quantity of opiates that could be contained in medicines. Regulation and increased medical education and treatment options, had the intended effect of reducing opioid overprescribing.


17. Id.

18. Id.; Andrew Kolodny et al., The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction, 36 ANN. REV. PUB. HEALTH 559, 561 (2015) (discussing the limited options, other than opium and morphine, available to physicians in this era when treating pain symptoms).


The second wave of misuse came in the mid-1950s, as reports of increases in opioid use and overdose deaths proliferated across the country.\footnote{22} Regulatory responses included laws permitting involuntary hospitalizations of addicts, the establishment of methadone clinics for treating addiction under the Controlled Substances Act (“CSA”), and formation of the Drug Enforcement Administration (“DEA”) to coordinate federal anti-drug efforts.\footnote{23}

In the decades after this second wave, the under-treatment of pain was increasingly recognized as a serious public health challenge that necessitated changes to prescribing behavior. The United Nations even declared access to pain medication a human right in 1961.\footnote{24} This swing toward the liberalization of opioid prescribing contributed substantially to the current misuse and overdose epidemic. In response, various stakeholders—including state and federal regulators, insurers, drug manufacturers, and providers—have adopted a panoply of interventions targeting the supply of, demand for, and misuse of opioids.

A. The Liberalization of Opioid Prescribing for Pain

Under-treatment of pain is itself a serious public health challenge in the United States. An Institute of Medicine committee estimated that every year chronic pain affects about 100 million people and costs up to $560–635 billion in lost productivity and medical treatment.\footnote{25} Starting in the 1980s, inadequate treatment of chronic pain received heightened scrutiny. Before this time, physicians prescribed narcotics for short-term, acute pain, or for pain related to cancer or end-of-life care.\footnote{26} Two medical journal articles—the first published in 1980 in the New England Journal of Medicine, and the second in Pain in 1986—opened the door to more liberal prescribing of painkillers.\footnote{27} Both studies concluded that narcotics can be safely prescribed for chronic pain to many patients with little risk of inducing addiction.

In 1995, Purdue Pharma introduced an extended-release, highly potent form of the painkiller oxycodone, known as OxyContin, which marked the onset of increased opioid use.\footnote{29} Around the same time, drug manufacturers began to market their opioid drugs for chronic, non-

\footnotesize{22. Frakt, supra note 16.}
\footnotesize{23. Id.}
\footnotesize{24. Id.}
\footnotesize{25. INST. OF MED. OF THE NAT’L ACADEMS., RELIEVING PAIN IN AMERICA: A BLUEPRINT FOR TRANSFORMING PREVENTION, CARE, EDUCATION, AND RESEARCH (2011). The Institute of Medicine is now known as the National Academy of Sciences.}
\footnotesize{27. Id.; Frakt, supra note 16.}
\footnotesize{28. Id.}
\footnotesize{29. Kolodny et al., supra note 18, at 562.}
cancer pain via advertisements in well-respected journals, through continuing medical education courses for doctors, and by contributing financial support to not-for-profit organizations, such as the American Academy of Pain Management, the American Pain Society, and the Federation of State Medical Boards.\textsuperscript{30} Highly-regarded physicians—such as Dr. Russell Portenoy, co-author of the \textit{Pain} study and director of the American Pain Society—served as the faces behind many of these drug company promotions.\textsuperscript{31} In 1996, the American Pain Society launched an aggressive campaign entitled “Pain as the Fifth Vital Sign,” the message of which was embraced by the Veterans Affairs health system and The Joint Commission, which accredits health care organizations, including hospitals.\textsuperscript{32} In 2004, the Federation of State Medical Boards passed a model policy on the use of controlled substances to treat pain.\textsuperscript{33} The policy encouraged state medical boards to consider under-treatment of pain an equally serious violation of the standard of care as over-treatment.\textsuperscript{34}

Additionally, over the past several decades, more subtle forces have encouraged doctors to generously prescribe opioids. Patient satisfaction assessments pervade the modern practice of medicine (and even impact payment under pay-for-performance schemes), thereby motivating certain physicians to prescribe opioids if requested by patients.\textsuperscript{35} The medical insurer practice of reimbursing well for prescription pain medications further reinforces the use of opioids to treat subjective pain.\textsuperscript{36} Cumulatively, stakeholder group activities, financial incentives, and patient satisfaction considerations contributed significantly to sharp increases in opioid prescribing observed in the 1990s–2000s and laid the foundations for misuse.

During this same period, a number of academics proposed legal strategies to promote opioid prescribing for pain. Building upon one prominent case in which a California court found a physician to have committed elder abuse by failing to prescribe drugs adequately to manage a patient’s pain,\textsuperscript{37} some academics advocated for increased state court recognition of tort claims against physicians who under-prescribe

\textsuperscript{30} Id.; Frakt, supra note 16.
\textsuperscript{31} Gounder, supra note 26.
\textsuperscript{32} Kolodny et al., supra note 18, at 562.
\textsuperscript{33} Garcia, supra note 10, at 43.
\textsuperscript{34} Id.; Gounder, supra note 26.
\textsuperscript{35} Anna Lembke, \textit{Why Doctors Prescribe Opioids to Known Opioid Abusers}, 367 \textit{NEW ENG. J. MED.} 1580, 1580–81 (2012).
\textsuperscript{37} Garcia, supra note 10, at 42–43.
painkillers\textsuperscript{38} or institutions that fail to satisfy a standard of care for effective pain relief.\textsuperscript{39} Others have recommended the development of a comprehensive, coordinated, national policy to address the inadequate management of pain, rather than the patchwork of state and federal policies in existence.\textsuperscript{40} Still others have questioned the appropriateness of criminal liability for prescribers under the CSA and instead supported an increased role for state medical boards in policing physician controlled substance prescribing.\textsuperscript{41} Many of these viewpoints, however, relied on older science that supported the effectiveness of opioids for treating chronic, non-cancer pain—a clinical viewpoint that is now regularly challenged and up for debate.\textsuperscript{42} Concerns with under-prescribing now must be balanced with those about over-prescribing, given our current epidemic of prescription drug misuse.

B. The Rise of Prescription Painkiller Misuse

Prescription opioid misuse in the United States has risen to epidemic proportions in recent years. Nonmedical use\textsuperscript{43} of prescription drugs occurs in four therapeutic classes (pain relievers, tranquilizers, stimulants, and sedatives); opioid pain relievers, however, are the most commonly misused medication by far.\textsuperscript{44} The percentage of Americans aged twenty and older who nonmedically use pain relievers in a month has held relatively stable at around seven percent over the past decade, after increasing from five percent between 1999–2002.\textsuperscript{45} However, this statistic fails to capture an increase in the intensity of use and misuse. For


\textsuperscript{40} Amy J. Dilcher, \textit{Damned If They Do, Damned If They Don’t: The Need for a Comprehensive Public Policy to Address the Inadequate Management of Pain}, 13 ANNALS HEALTH L. 81, 135 (2004).


\textsuperscript{43} Substance Abuse & Mental Health Servs. Admin., supra note 6, at 15–18.

\textsuperscript{44} Steven M. Frenk et al., \textit{Prescription Opioid Analgesic Use Among Adults: United States, 1999–2012} 1–2 (2015).
example, from 1999–2002 to 2011–2012, the percentage of opioid analgesic users who used a stronger-than-morphine equivalent opioid (per dose) in the past thirty days increased from seventeen percent to thirty-seven percent.  

Moreover, adverse health consequences resulting from prescription drug misuse—including overdose events, emergency department (“ED”) visits, and inpatient admissions—have escalated dramatically. Fatal opioid overdoses exploded from 1.4 per 100,000 people in 1999 to 9.0 per 100,000 people in 2014.  

The rate of emergency department visits involving nonmedical use of prescription drugs—primarily of opioids—more than doubled from 214 visits per 100,000 people in 2004 to 458 in 2011. About half of these deaths and ED visits also involved at least one other drug, including benzodiazepines, cocaine, or heroin.  

Prescription opioid use and misuse persists among people from diverse demographic backgrounds, albeit certain groups exhibit slightly higher rates of use and overdose risk. Adults aged forty and older are slightly more likely to use opioid analgesics than adults aged twenty to thirty-nine; women are slightly more likely than men to use opioids; and non-Hispanic white adults are more likely to use prescription painkillers than Hispanic adults. People at heightened risk for opioid overdose include women, those consuming high daily doses of opioids, those taking medication for chronic pain, “doctor-shoppers,” users of multiple abusable substances, and those with substance abuse or other mental health issues.  

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46. Id. at 2.  
47. Chen et al., supra note 3, at 2; Rudd et al., supra note 3, at 1378.  
49. Id.; Warner et al., supra note 3, at 1.  
51. Frenk et al., supra note 45, at 3–6.  
52. Clinical definitions of “doctor shoppers” differ. See Scott G. Weiner et al., Characteristics of Emergency Department “Doctor Shoppers,” 48 J. Emergency Med. 424, 425 (2014) (defining “doctor shoppers” as patients that had eight or more Schedule II-V prescriptions filled from eight or more providers in one year); Douglas C. McDonald & Kenneth E. Carlson, Estimating the Prevalence of Opioid Diversion by “Doctor Shoppers” in the United States, 8 PLOS ONE 1, (2013) (using different thresholds to define “doctor shoppers” to estimate opioid diversion prevalence). See Joseph Logan et al., Opioid Prescribing in Emergency Departments: The Prevalence of Potentially Inappropriate Prescribing and Misuse, 51 Med. Care 646 (2013) (identifying the following as indicators of potential inappropriate use: opioid prescriptions overlapping by one week or more; overlapping opioid and benzodiazepine prescriptions; high daily doses of greater than or equal to 100 morphine milligram equivalents; long-acting/extended-release (“LA/ER”) opioids for acute pain; and overlapping LA/ER opioids).  
53. Kate M. Dunn et al., Opioid Prescriptions for Chronic Pain and Overdose: A Cohort Study, 152 Annals Internal Med. 85, 87–91 (2010); Amy S.B. Bohnert et al., Association Between Opioid
There is little room for optimism. Evidence from 2011–2013 did indicate a leveling off in opioid prescribing rates and overdoses nationally, which some researchers attributed to the August 2010 reformulation of OxyContin to a more tamper-resistant form. However, more recent evidence shows that national prescription opioid overdose death rates again significantly increased from 2013–2014, suggesting that existing policy interventions may not be sufficient to tackle the epidemic. Over this same period, moreover, heroin abuse rates increased, suggesting that some—though not all—prescription drug misusers switched to an illegal, cheaper, and deadlier alternative when they could no longer access prescription opioids.

C. Regulatory Responses

Federal and state policymakers, among others, have responded with a multitude of interventions to address opioid misuse and overdoses. Table 1 catalogues prominent interventions and identifies the stakeholders that typically take these measures. Although not exhaustive, this list illustrates the many strategies available and the complex array of implementers. These strategies are characterized within the public health prevention paradigm used for epidemiologic responses to other communicable and non-communicable diseases. Opioid addiction—compulsive opioid seeking and use despite the often negative consequences—is the chronic disease that can result from prescription opioid misuse.

Addiction prevention strategies can be organized into categories that focus on: (1) primary prevention of new cases of opioid addiction; (2) secondary prevention to identify and treat early cases of addiction; and
(3) tertiary prevention to effectively treat those already addicted.\(^60\) The goal of primary prevention is to reduce the incidence of disease—in this case, to prevent the initiation of opioid addiction. Prescriber guidelines are an example of primary prevention, because they seek to encourage more informed opioid prescribing. Secondary prevention measures aim to identify and treat a serious health condition after onset but before serious complications ensue,\(^61\) such as detecting doctor shoppers by means of a PDMP. Finally, tertiary prevention measures provide therapy and rehabilitation once a disease is firmly established.\(^62\) Access to the opioid antagonist drugs (such as naloxone) is an example of tertiary prevention.

Undoubtedly, some combination of these prevention measures is required to comprehensively address prescription opioid-related morbidity and mortality—but which specific interventions are most worthwhile to pursue? This Article focuses on a specific type of intervention: prescription drug monitoring programs, which will be referred to as “PDMPs” throughout. Other prevention measures are unquestionably key components to comprehensively addressing the epidemic, but PDMPs are a popular, state-level, legal mechanism that have gained the reputation of having incredible promise for addressing opioid misuse.\(^63\) They primarily target prescribing, a significant upstream driver of prescription opioid misuse because it serves as the prerequisite to most opioid addiction—whether by initial prescription, repeat prescriptions, or obtaining drugs from friends or family members or diverters.\(^64\) And, PDMPs have experienced widespread—albeit disorganized—roll-out among the states, such that policies exhibit widely varying features not rigorously informed by evidence or systematic criteria for determining their success.

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60. Id. at 565–69.
61. Id.
62. Id.
63. Chakravarthy et al., supra note 13, at 424.
64. Wilson M. Compton et al., Prescription Opioid Abuse: Problems and Responses, 80 Preventive Med. 5 (2015). See Jones et al., supra note 9, at 802–03 (underscoring the need to target prescribers, as they commonly source opioids to frequent users).
### Table I. Interventions to Curb Prescription Drug Misuse

<table>
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<th>Stage</th>
<th>Objective</th>
<th>Examples of Interventions</th>
<th>Implementing Stakeholders</th>
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</thead>
<tbody>
<tr>
<td><strong>Primary prevention</strong></td>
<td>Prevent initiation of prescription opioid addiction</td>
<td>Opioid prescriber education and guidelines*</td>
<td>• State and local governments • Health care providers • Federal government o U.S. Food and Drug Administration (“FDA”): Risk Evaluation and Mitigation Strategy (“REMS”) required of extended-release/long-acting (“ER/LA”) opioid drug sponsors</td>
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<td>Pain management clinic (“pill mill”) regulation*</td>
<td>• State governments • Federal government o Drug Enforcement Agency (“DEA”)</td>
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<td></td>
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<td>Opioid drug approval*</td>
<td>• Federal government o FDA:REMS required for ER/LA opioids</td>
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<td>Abuse-deterrent drug formulations*</td>
<td>• Opioid drug developers</td>
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<td></td>
<td></td>
<td>Medication take-back or disposal programs*</td>
<td>• Federal government o DEA • State or local governments • Retail pharmacies</td>
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<tr>
<td><strong>Secondary prevention</strong></td>
<td>Identify and treat prescription opioid addiction after onset but before serious complications develop</td>
<td>Prescription drug monitoring programs**</td>
<td>• State governments • Insurers</td>
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<td></td>
<td></td>
<td>Urine testing for drugs**</td>
<td>• Health care providers • Insurers</td>
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<td>Drug supply management **</td>
<td>• Insurers • Pharmacy benefit managers</td>
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<td></td>
<td>• Formulary development • Quantity limits • Reimbursement incentives</td>
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<td></td>
<td></td>
<td>Anti-“doctor shopping” laws*</td>
<td>• State and local governments</td>
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65. Under the Food and Drug Administration Amendments Act (“FDAAA”) of 2007, REMS was introduced as a risk-management strategy intended to reduce known or serious safety hazards associated with a drug or biologic product. The FDAAA grants the FDA authority to require sponsors to submit a REMS prior to drug approval if it determines that such a measure is necessary to ensure that drug benefits outweigh risks, or after approval if new safety information emerges to necessitate such a strategy. Inst. of Med., Ethical & Sci. Issues in Studying the Safety of Approved Drugs 42–43 (2012). See infra note 152 for a discussion of the REMS for ER/LA opioid medications.

66. “Pill mills” are those facilities where pain management is the primary practice component, or which provide pain treatment to a majority (greater than fifty percent) of patients, or both. Ctrs. for Disease Control & Prevention, Menu of Pain Management Clinic Regulation 1 (2012).
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<th>Examples of Interventions</th>
<th>Implementing Stakeholders</th>
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<tr>
<td>Tertiary prevention</td>
<td>Address firmly established opioid addiction through therapeutic or rehabilitative measures</td>
<td>Opioid addiction treatment</td>
<td>• Insurers</td>
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<td>Access to opioid overdose reversal drugs</td>
<td>• Health care providers</td>
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<td></td>
<td></td>
<td>Syringe exchange programs</td>
<td>• Governments (federal, state, local)</td>
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<td>• Insurers and PBM’s</td>
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* These interventions can also be considered secondary prevention measures.

** These interventions could be considered primary, secondary, or tertiary prevention measures, because they aim to identify either misusers or diverters and prevent them from accessing opioids (which can then be passed on to “unexposed” persons) and can be used to direct misusers into treatment programs.

1. State PDMPs

State PDMPs are the most prevalent state policy mechanism used to address prescription drug misuse, with forty-nine states and the District of Columbia having enacted programs. PDMPs digitally store controlled substance dispensing information in a centralized, statewide database and make that information accessible to “authorized users,” including prescribers, pharmacists, and sometimes law enforcement officials and state medical boards. When they query the system about a patient, authorized users typically see the dose, supply, and prescriber of scheduled drugs that the patient has recently filled. Authorized users can only access the data with log-in credentials provided upon registering with the PDMP.

PDMPs seek to satisfy many goals, most prominently to support providers in facilitating the legitimate medical use of controlled substances, while avoiding prescription drug misuse. Armed with PDMP-supplied information about a patient, prescribers and pharmacists can communicate

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67. “Doctor shopping” is defined as when a patient obtains controlled substances from multiple healthcare providers without the prescribers’ knowledge of the other prescriptions. Ctrs. for Disease Control & Prevention, Doctor Shopping Laws 1 (2012).


69. Prescription Drug Monitoring Program Ctr. of Excellence at Brandeis, Briefing on PDMP Effectiveness 3 (2014).


with the patient about his or her prescription histories, address potentially dangerous co-prescribing of substances, refrain from supplying opioids to a doctor shopper or diverter, comfortably provide prescription drugs to an individual who doesn’t raise concerns about misuse, and direct individuals into substance abuse treatment therapy when clinically indicated. When enough providers share dispensing information and access patient profiles via PDMPs, opioid misusers and diverters have a harder time “gaming” the system by seeking drugs from multiple providers or pharmacies. As well, PDMPs are intended to help regulators investigate clinicians with inappropriate prescribing and dispensing patterns as well as patients with drug fill behaviors indicative of misuse or diversion. In sum, PDMPs aim to improve individual as well as population health, by improving prescribing and dispensing decisions made for each patient, and by limiting the negative externalities generated by the over-supply of opioids.

State legislatures create PDMPs by statute and outline program details by regulation, often leaving many of the operational particulars to the executive agency in which the program is housed. Advances in information technology facilitated state implementation of electronic PDMPs in the 1990s–2000s. These programs succeeded earlier, less-widespread paper prescription monitoring systems (also known as carbon copy or triplicate paper programs), the first of which was created in California in 1939. Since the first electronic PDMP was established in Oklahoma in 1990, these programs have rapidly proliferated. In 2001, sixteen states had authorized the creation of a program by statute; and by June 2012, forty-nine states and one territory had passed such laws (with forty-one states having an operational program). Today, every state except Missouri has an operational PDMP.

72. See supra note 52 for clinical definitions of “doctor shoppers.”
73. Haffajee et al., supra note 70, at 891.
74. Finklea et al., supra note 71, at 3.
75. See G. Caleb Alexander et al., Rethinking Opioid Prescribing to Protect Patient Safety and Public Health, 308 JAMA 1865, 1865-66 (2012) (suggesting that a public health approach to the treatment of pain calls for greater clinical judiciousness in prescribing of opioids given the harmful effects that clinicians’ treatment decisions have on other individuals beyond the patient being treated).
76. PDMPs are most commonly housed within health agencies or boards of pharmacy, although some are housed within law enforcement or other agencies. The housing agency distributes PDMP data to individuals authorized under state law to receive the information. Richard A. Deyo et al., Measures Such as Interstate Cooperation Would Improve the Efficacy of Programs to Track Controlled Drug Prescriptions, 32 Health Aff. 603, 604 (2013).
77. Id.
78. Id.
80. Id. at 5.
PDMPs vary widely along a number of dimensions, including: who can query the data (and for what purposes); whether unsolicited reports are sent to users; whether prescribers and/or dispensers can delegate access to an authorized agent; whether notification of a patient is required when his/her data is accessed; the extent to which data is shared with other states; how frequently the data is updated; and whether training is required for users. PDMPs increasingly monitor (or track) drugs that are included in Schedules II through V of the DEA’s controlled substances schedules. Recent innovations gaining traction with states include mandates that clinicians query the data for information regarding a patient, under specified circumstances. Also on the PDMP policy horizon is the integration of PDMP data into clinical

82. See id. for an updated comparison of program features. See generally Deyo et al., supra note 76, at 605–07 (describing the variations in program design and controversies surrounding prescription drug monitoring programs).

83. Forty-eight states include prescribers, dispensers, licensing boards, and law enforcement officials as “authorized users.” Only eighteen states require law enforcement to access the data only with a warrant, subpoena, or other judicial process, whereas thirty states allow such access pursuant merely to an active investigation. Nat’l All. for Model State Drug Laws, supra note 68, at 25–26, 31.

84. Forty-five states send unsolicited reports to individuals varying from prescribers, to law enforcement officials, to licensing officials. The triggers for and information included in these reports vary widely. Id. at 45.

85. In thirty-four states, prescribers and/or dispensers can delegate access to an agent who can log into the system on their behalf. Agents can include a physician’s assistant, nurse practitioner, pharmacy technician, or other health personnel. Id. at 21.

86. Patients must be notified when their PDMP data is accessed in eleven states. Id. at 9.

87. Although forty-five states have authorized interstate data sharing, only thirty-two states currently share data. Id. at 34. Interstate Data Sharing, Prescription Drug Monitoring Program Training & Tech. Assistance Ctr. (Aug. 2015), http://www.pdmpassist.org/pdf/Interstate_Data_Sharing.pdf (last visited Aug. 5, 2016).

88. Over half of state PDMPs update the data weekly or less frequently, while only one program offers real-time data. Nat’l All. for Model State Drug Laws, supra note 68, at 12–13.

89. PDMP training is required of authorized users in only thirteen states, although most states offer optional training. Id. at 36.

90. Schedule I drugs have high misuse potential and are not prescribed legally (they currently have no medically accepted use in the United States)—thus, drugs such as heroin or ecstasy cannot be tracked. Schedule II drugs are those with a high potential for misuse but a medically accepted use, such as oxycodone, morphine, and stimulants. Schedule III drugs are those with moderate misuse potential and a medically accepted use, such as buprenorphine. Schedule IV drugs are those with low misuse potential and a medically accepted use, such as benzodiazepines and hypnotics. Finally, Schedule V drugs are those with the lowest potential for misuse and a medically accepted use, such as cough syrups with codeine and anti-diarrheals. Controlled Substances Act, 21 U.S.C. § 801 (West 2016).

91. Nat’l All. for Model State Drug Laws, supra note 68, at 3, 40 (identifying twenty-four states as having some form of mandate, although conditions and exemptions vary widely). See Haffajee et al., supra note 70, at 891–92 (outlining the pros and cons of requiring prescribers to participate in querying PDMP systems, and arguing that while mandates may be called for, given the magnitude of prescription drug misuse and early indications of mandate effectiveness, more robust evidence and guidelines to support their implementation are necessary to avoid potentially dire unintended consequences—such as under-prescribing of opioids for legitimate pain).
workflow (such as electronic medical records) and improved interstate sharing of data to track those individuals who travel across state lines in pursuit of prescription drugs.\footnote{92. Nat’l All. for Model State Drug Laws, supra note 68, at 3.}

PDMPs are perhaps so attractive because they hold the potential to both facilitate legitimate prescribing of controlled substances, and also mitigate prescription drug misuse.\footnote{93. Id.; Clark et al., supra note 79, at 5.} The appropriate prescribing of controlled substances can reduce their misuse and diversion. At the same time, law enforcement, licensing board, and surveillance efforts can protect the public’s health by limiting diversion.\footnote{94. Clark et al., supra note 79, at 5.}

Despite these best intentions, we do not have a firm understanding of PDMPs’ effectiveness, nor of the potential for unintended PDMP consequences or other legal or ethical quagmires. Interest groups, however, have attempted to identify a number of PDMP “best practices” to help guide their implementation. They include the following: a comprehensive list of drugs monitored; unsolicited reporting to providers; medical provider education on PDMP use; a wide array of authorized users; real-time or frequent data collection; interstate sharing of data; and disclosure of de-identified data for research purposes.\footnote{95. Id.} These characteristics appear to be identified largely based on face validity and anecdotal or associative observations, rather than rigorous evidence.\footnote{96. Id.; Nat’l Conference of Ins. Legislators, Proposed Best Practices to Address Opioid Abuse, Misuse and Diversion §§ 1–4 (2013).} In short, justification for these features is wanting. The framework presented herein can assist in systematically analyzing PDMP effectiveness, legality, and normative appeal, with the goal of identifying desirable features that, if adopted, could facilitate the achievement of public health goals and increase the likelihood that these policies will succeed.

II. A Framework for Evaluating PDMP Success

State policymakers stand to benefit from an evaluative framework that can be used to assess the success of PDMP efforts at curbing prescription drug misuse for several reasons. First, the rapid escalation and magnitude of the prescription drug misuse and overdoses—with forty-four people in the United States now dying every day from prescription painkiller overdose—\footnote{97. Drug Overdose Deaths in the United States Hit Record Numbers in 2014, Crs. for Disease Control & Prevention, http://www.cdc.gov/drugoverdose/epidemic/index.html (last visited Aug. 5, 2016).} are remarkable and somewhat
unprecedented. Such a crisis warrants a robust and effective response, which has led to rapid dissemination across the states of new legal approaches, including PDMPs, before their effects have been thoroughly evaluated. Second, the intervention possibilities—from various PDMP features to other types of interventions altogether (see Table 1 for a non-exhaustive list)—are numerous and could be overwhelming to policymakers. Third, some indications of a leveling of opioid prescribing and misuse from 2011–2013 are encouraging, but naturally beg the question: Can we attribute any of these changes to state PDMPs?

It is incumbent upon policymakers at all levels to implement the most prudent set of interventions possible to target prescription opioid misuse, given current knowledge and limited resources. The states are a reasonable and critical locus for policymaking.

This Article does not mean to imply that states are the exclusive or always optimal level at which to regulate. Indeed, the federal government is very involved in regulation of controlled substances, particularly under the CSA and via FDA drug approval (see Table 1). However, the states have broadly regulated to address prescription drug misuse and overdose using their plenary powers to police the health, safety, and welfare of their citizens. As compared to the federal government, states are closer in proximity to these issues: They can better tailor prevention strategies to the specific nature of and variation in prescribing and misuse risks across their jurisdictions, and are directly accountable to their citizens when it comes to adverse health and related consequences. Moreover, states have typically assumed authority over the practice of medicine and other health professions as well as health more generally, and thus the

98. See Garcia, supra note 10, at 43.

99. See Joanna Shepherd, Combating the Prescription Painkiller Epidemic: A National Prescription Drug Reporting Program, 40 Am. J.L. & Med. 85, 86-87 (2014) (advocating for a national prescription drug reporting program that builds upon pharmacy benefit manager networks to crack down on prescription drug misuse); see also Roger S. Magnusson, Mapping the Scope and Opportunities for Public Health Law in Liberal Democracies, 35 J.L. Med. & Ethics 571, 572 (2007) (noting that public health regulatory functions are “shared” between different tiers of government, and together these elements at the national and sub-national levels create a range of specific laws, processes, and remedies for improving health outcomes).

100. States have initiated many prominent laws to address prescription drug misuse and overdose beyond PDMPs. Other legal strategies include pain clinic (or “pill mill”) laws; drug dose and limit laws; physical examination requirements; doctor shopping laws; tamper-resistant form requirements; prescription drug identification laws; and Good Samaritan laws that provide protection to those who reasonably assist others experiencing misuse or overdose. See Public Health Law Program: State Laws on Prescription Drug Misuse and Abuse, Ctrs. For Disease Control & Prevent., http://www.cdc.gov/phlp/publications/topic/prescription.html (last visited Aug. 5, 2016).


102. See Barsky v. Bd. of Regents, 347 U.S. 442, 449 (1954); Michelle M. Mello & Kathryn Zeiler, Disease Prevention and Health Outcomes, Empirical Health Law Scholarship: The State of the Field, 96 Geo. L.J. 649, 654 (2008) (noting that states have been the primary site of lawmaking for important
prescribing of controlled substances (the source of most prescription drugs that are misused) falls squarely within their purview. This Article addresses the balance of regulation between state and federal governments as it relates to how states can best target PDMPs, but it does not cover non-governmental-based initiatives.

The separation of public health powers among different branches of government, albeit fundamental to the way policies are conceived and carried out, is not a focus of this Article. “State policymakers” or “state regulators,” as referred to herein, signify members of both the legislative and executive branches of state governments. Members of the legislature, who are elected and politically accountable to the public, are typically responsible for creating health policy and allocating resources required to carry it out. Executive agencies, most notably departments of public health, assume increasingly expansive public health functions in the states—ranging from proposing laws to the legislature, to issuing rules to carry out policy, to enforcing policy. The framework proposed views state policymakers as a monolithic group, capable of dividing and delegating public health powers as between themselves efficiently and in accordance with administrative law requirements.

This discussion also focuses on state public health laws, namely PDMPs, rather than other types of interventions. Law is increasingly recognized as an important determinant of health and a valuable and effective tool in the public health arsenal. Law has been shown to have a powerful impact in a number of public health domains, such as motor aspects of health markets, including public health-related areas such as seatbelt and workplace wellness, tobacco and alcohol, and unhealthful food and beverages in schools).

103. See infra Part II.A.2.
104. Gostin, supra note 101, at 83.
105. Id. at 161.
106. Id. at 83-84, 166–69.
107. “Public health law” has been famously defined by Lawrence O. Gostin as “the study of the legal powers and duties of government to assure the conditions for people to be healthy (that is, to identify, prevent, and ameliorate risks to health in the population), and the limitations on the power of the state to constrain the autonomy, privacy, liberty, proprietary, or other legally protected interests of individuals for protection or promotion of community health.” Id. at 4. Themes that emerge from this definition and that will recur throughout this Article include: “(1) government power and duty, (2) coercion and limits of state power, (3) government partners in the ‘public health system,’ (4) the population focus, (5) communities and civic participation, (6) the prevention orientation, and (7) social justice.” Lawrence O. Gostin, A Theory and Definition of Public Health Law, 10 J. Health Care L. & Pol’y 1, 1 (2007).
108. Magnusson, supra note 99, at 572 (observing that law is only one of a multitude of “modes” of regulation that reflect different strategies toward compliance and enforcement).
vehicle safety, particularly when based on robust evidence. Specifically, state laws are starting to proliferate in public health: The adoption of legal interventions in a number of areas (PDMPs included) over the past several decades has followed a steep curve from initial adoption in one jurisdiction to nearly fifty-state saturation. Non-legal interventions are also critical to addressing opioid misuse and the public’s health more generally, but the use of PDMP laws—“on the books” (such as constitutions, statutes, rules, and judicial opinions) and as implemented in practice—by policymakers to address opioid misuse constitutes the focus of this discussion.

This Article articulates a framework to assist state lawmakers’ decisionmaking when considering whether and how to respond to a significant public health threat, and uses it to directly guide PDMP implementation. This framework, which can be generalized to contexts beyond prescription drug misuse, sets forth key criteria with which to justify and assess public health laws—both when considering initial policy enactment and in evaluating regulations once implemented. The goal is to identify the optimal form that a public health law should take once a serious public health challenge has been identified. Broadly, the evaluative criteria include: (1) legal powers to regulate and barriers to implementation; (2) effectiveness of regulation; and (3) ethical and normative considerations.

This evaluative framework integrates and builds upon earlier public health law scholarship, including work on evidence-based lawmaking and justificatory conditions for public health legal interventions. Mello and Zeiler outline an ideal iterative process of research and policymaking that a health law, informed by evidence, would take—a so-called “lifecycle” for an empirical health law success story. In their lifecycle, society first identifies a significant public health risk factor derived from

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111. Id.
112. Burris et al., supra note 109, at 174–75. “Legal interventions,” as discussed herein, may include a full range of government use of legal authority, such as adoption of new laws, amendments or clarifications to existing laws, and removal of laws thought to be ineffective. Mello et al., supra note 15, at 1980.
113. Gostin has outlined at least five models, or levers, for legal intervention designed to prevent injury and disease and promote the public’s health: (1) the power to tax and spend; (2) the power to alter the informational environment; (3) direct regulation of individuals (such as motorcycle helmet laws), professionals (such as licenses), or businesses (such as inspections); (4) indirect regulation through the tort system; and (5) deregulation. Lawrence O. Gostin, Public Health Law: A Renaissance, 30 J.L. Med. & Ethics 136, 137–38 (2002). This Article deals primarily with the first three intervention levers, or affirmative regulatory acts engaged in by policymakers.
114. See generally Mello & Zeiler, supra note 102; Burris et al., supra note 109 (discussing the newly founded Public Health Law Research Program and its mission, structure, and goals).
115. See generally Gostin, supra note 101 (discussing the legal foundations of public health research).
116. See Mello & Zeiler, supra note 102, at 668–69.
clear epidemiological evidence.\textsuperscript{117} Risk factors are exposures or attributes that are associated with an increased likelihood of developing a disease or injury.\textsuperscript{118} Significant risk factors can be characterized as variables that greatly increase the risk of developing a disease, or those that are associated with severe harm. Second, in response to such risks, policymakers, researchers, or other key stakeholders may propose and experiment with innovative legal solutions, among other types of policy responses.\textsuperscript{119} Third, these experiments should be evaluated by researchers and policymakers, ideally in cooperation. Finally, those public health laws identified as successful should be retained, strengthened, and replicated in additional jurisdictions, while those deemed unsuccessful should be abandoned (or amended) in favor of policy alternatives.\textsuperscript{120}

Lawrence Gostin has articulated certain prerequisite conditions for public health laws, reminding us that regulation is not justified merely in the name of population health.\textsuperscript{121} Such laws must be defended given that they incur public and private costs and can impact the legitimacy of future policymaking.\textsuperscript{122} Gostin thus proposes five criteria with which to evaluate whether a public health regulation is warranted: (1) significant risk; (2) effectiveness; (3) economic cost; (4) burden on individuals; and (5) fairness.\textsuperscript{123}

Figure 1 lays out the four stages articulated in Mello and Zeiler’s lifecycle,\textsuperscript{124} but goes a step further to specify the specific criteria with which to actually evaluate policy experiments and the ways in which these criteria should be applied to justify any particular law’s existence. Innovative concepts incorporated into this figure include: (1) that evaluative criteria should be applied both at the law adoption stage as well as the retrospective evaluation (of existing policy) stage; (2) that the evaluation should be an ongoing process, rather than a one-time occurrence; and (3) that states should revisit a policy upon each round of evaluation to consider whether to retain, amend, or abandon a law.

Moreover, the specific evaluative criteria set forth in Figure 1 differ from Gostin’s in several key regards. First, whereas Gostin does not focus on a particular level of authority or jurisdiction, these criteria are intended to organize state policymaker inquiries with respect to implementing public health laws. Second, the criteria explicitly recognize legality as a consideration to be incorporated into evaluation. Third, they re-

\textsuperscript{117} Id. See Gostin, supra note 101, at 55.
\textsuperscript{119} Mello & Zeiler, supra note 102, at 669.
\textsuperscript{120} Id.
\textsuperscript{121} Id., supra note 101, at 43–76.
\textsuperscript{122} Id.
\textsuperscript{123} Id. at 55.
\textsuperscript{124} Mello & Zeiler, supra note 102, at 668.
characterize and substantially expand upon the inquiries regarding policy effectiveness and ethical appeal, drawing upon principles of research design and practice-based public health ethics, respectively. The key evaluative criteria further detailed below do not necessarily need to be “satisfied” per se, but should be considered carefully and compared between policy options, if multiple exist. Performing favorably under these criteria lends credibility to public health laws and enhances state policymaker and stakeholder confidence in their value. Consideration of these criteria also may help to address issues of antiquity, inconsistency, redundancy, and ambiguity that can render state public health laws ineffective.\(^{125}\) In the discussion that follows, the three criteria will be outlined and directly applied to PDMPs in an effort to organize and inform this policymaking agenda.

\(^{125}\) Gostin, supra note 113, at 136–37 (discussing entrenched problems with state public health laws—that is, that they are often outdated, built up in layers over varying periods of time, and very fragmented among the fifty states—that call for reform so that law conforms with modern scientific and legal standards, is consistent across jurisdictions, and is more uniform in how it addresses different types of health threats).
Figure 1. Framework for Evaluating State Public Health Laws

Society identifies a significant public health risk

Researchers/policymakers propose a public health law solution

States implement public health laws that perform well under

Researchers/policymakers evaluate public health laws

States replicate, retain, modify, or abandon laws

Evaluative Criteria
A. Legal powers to regulate
B. Effectiveness of regulation
   1. 1st outcomes: intended improvements in population health
   2. 2nd (intermediate) outcomes: measures of mechanisms/pathways through which the laws operate to impact population health
C. Ethical considerations
   1. Proportionality
   2. Minimal infringement
   3. Fairness
   4. Public accountability
A. Legal Powers to Regulate

A threshold inquiry for state policymakers when considering PDMPs and other public health laws is whether the requisite legal powers to regulate exist, and/or whether legal barriers may frustrate implementation. This inquiry drives to the heart of longstanding debates about the appropriate balance of public health powers between different levels of government, and constitutional limits on such powers in the name of civil liberties. Legal powers, duties, and restraints, to use Gostin’s terms, define the space available for public health intervention and should be considered dynamically, given the potential for changes in judicial interpretation of these parameters. State policymakers should specifically ask: (1) whether they have the affirmative constitutional power to act to promote or protect the public’s health; (2) whether the actions planned or taken exceed their powers by encroaching upon regulatory territory already occupied by the federal government; and (3) whether the law in question infringes upon protected individual rights.

In general terms, state implementation of PDMPs stands on solid legal footing. Nevertheless, the ways in which PDMPs are designed raise a number of legal issues that warrant consideration, including the federal government’s possible role in program implementation, privacy issues associated with the retention of personal health information in the databases, and the use of the data by law enforcement and licensing boards.

1. Federalism and the Power to Regulate the Public’s Health

Federalism divides available lawmaking power between two levels of government: federal and state. The federal government acts with limited, enumerated powers granted by the Constitution, while the remaining powers, including the police power, are left to the states. State governments have long held the authority, and sometimes duty,

126. Gostin, supra note 101.
128. Gostin, supra note 101, at 78.
129. Hodge, Jr., supra note 127, at 311. The Tenth Amendment states: “The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved for the States respectively, or to the people.” U.S. Const. amend. X.
130. The Constitution is largely cast in negative terms, particularly with respect to public health protection among the states. See, e.g., DeShaney v. Winnebago Cty. Dep’t of Soc. Servs., 489 U.S. 189 (1989) (holding that the Wisconsin State Department of Social Services had no affirmative duty to provide protection to a four-year-old boy who was beaten severely and incurred permanent brain damage after the Department received reports of the abuse and took no action). There are, however, certain instances whereby the Constitution creates an affirmative duty for the government to protect people from harm or provide health services, including: (1) for persons held in state custody (such as prisons and mental institutions) who have been deprived of their liberty and are thus unable to care
to protect and preserve public health, a critical role which dates to the
Federalist Papers and preceded the Constitution.\textsuperscript{131} As articulated in what
is widely viewed as a leading judicial decision in public health, \textit{Jacobson v. Massachusetts}, decided in 1905, state police powers include broad
powers to pursue reasonable regulations that promote the public health,
safety, welfare, or morals.\textsuperscript{132} While \textit{Jacobson} dealt with infectious
disease—namely, the right of the City of Cambridge, Massachusetts to
require smallpox vaccination—the police power articulated therein
serves as the basis for a vast array of state public health laws ranging into
areas of non-communicable disease and injury.\textsuperscript{133} Beyond the police
power, states also possess \textit{parens patriae} powers to act as guardians of
those who cannot protect themselves legally, namely children and
incompetent persons.\textsuperscript{134}

Although \textit{Jacobson} is settled law and the states possess significant
power to police and protect the public’s health, they do not exclusively
inhabit the domain.\textsuperscript{135} Rather, the federal government has a role to play
in the areas in which it has clearly articulated jurisdiction under the
Constitution. Federal public health powers typically are found in the U.S.
Congress’s powers to tax, spend, regulate interstate commerce, and
employ the means reasonably necessary to achieving other federal
objectives (implied under the Necessary and Proper Clause).\textsuperscript{136} If there is
overlap between federal and state laws in these arenas, then federal law
supersedes (or preempts) that of the states—even where states have

\footnotesize{for themselves; or (2) if the state increased the threat of harm, and is responsible for creating danger.
\textsuperscript{Gostin, supra note 101, at 87.}\textsuperscript{131}  \textsuperscript{131}Wendy E. Parmet, \textit{After September 11: Rethinking Public Health Federalism}, 30 J.L. Med. &
Ethics 201, 202 (2002) (noting that the \textit{Federalist Papers refer to the “domestic police” of the states as
among the powers not available to the federal government}); Hodge, Jr. \textit{supra note 127, at 314;
Gibbons v. Ogden, 22 U.S. 1, 87 (1824) (“[t]he constitution gives nothing to the States or to the people.
Their rights existed before it was formed, and are derived from the nature of sovereignty and the
Massachusetts}, to say that “[t]he safety and the health of the people of Massachusetts are, in the first
instance, for that Commonwealth to guard and protect. They are matters that do not ordinarily
concern the National Government.”).\textsuperscript{133} \textsuperscript{133}Wendy E. Parmet \textit{et al., Individual Rights Versus the Public’s Health—100 Years After
\textsuperscript{134} \textsuperscript{134}This power is typically invoked by a state to make decisions on behalf of those who cannot
make decisions for themselves, or to justify the state’s more general interest in societal welfare and
health. See \textit{Gostin, supra note 101, at 95–98.}\textsuperscript{135} \textsuperscript{135}Parmet, \textit{supra note 131, at 202.}\textsuperscript{136} \textsuperscript{136}U.S. Const. art. I, § 8. For a more in-depth discussion of the federal enumerated powers
relevant to public health, see \textit{Gostin, supra note 101, at 98–109; Parmet, supra note 131, at 203–07;
Hodge, Jr., \textit{supra note 127, at 328–330; Lawrence O. Gostin, Public Health Theory and Practice in the
Constitutional Design, 11 Health Matrix 265, 271–72 (2011); James G. Hodge, Jr., \textit{Implementing
Modern Public Health Goals Through Government: An Examination of New Federalism and Public
acted appropriately within their police powers. In short, the federal government can serve as a limiting factor to state public health regulation.

The pendulum of power to regulate to promote the public’s health has swung between state and federal governments over the course of the twentieth century. First came the era of expansive state powers post-*Jacobson*. Next, federal authority in the public health arena increased during the New Deal era when the Supreme Court broadened its interpretations of the commerce, taxing, and spending powers with national interests in mind—evidencing the so-called “death” of federalism. Most recently, state powers have been newly invigorated by a series of cases that restrict federal power. Specifically, the Court has curtailed Congress’s power to “commandeer” the states to carry out federal programmatic objectives, and has limited the scope of the commerce power. Although national public health goals are unifying, they must be accomplished without infringing on state sovereignty.

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137. U.S. Const. art. VI, cl. 2 (“This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land . . . .”). See Gostin, *supra* note 101, at 80 (discussing the different types of federal preemption, including “express preemption,” where a federal statute explicitly declares that it preempts state or local law; and “implied preemption,” where Congress’s intent to supersede state or local law is clearly implied in legislative language or history. Implied preemption is further subdivided into two categories: (1) field preemption, whereby federal regulation is so encompassing as to dominate an entire field and leave no space for state or local action; and (2) conflict preemption, whereby compliance with state law would frustrate or make impossible compliance with federal law). Federal action in an area of public health regulation need not necessarily invalidate any state regulation, however. Federal laws often serve as a floor, above which state regulation can impose more stringent standards. See, e.g., Interim Final Rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008, 75 Fed. Reg. 5,410, 5,418, 5,430 (Feb. 2, 2010) (to be codified at 45 C.F.R. pt. 146).


141. Hodge, Jr., *supra* note 127, at 356 (referring to this trend as signifying a “new federalism” era in which public health action must be balanced among federal and state levels of government).
Again, traditional state functions are central to the public’s health and thus enjoy significant legal protection from federal intrusion.\textsuperscript{142}

2. State and Federal Authority to Monitor Prescription Drugs

Regulating controlled substances to prevent misuse and associated health and safety problems falls squarely within states’ police powers and their \textit{parens patriae} powers to act as guardians for those unable to protect themselves, although the question of federal preemption arises as a potential limitation to that exercise. Several state attorneys general have successfully brought \textit{parens patriae} lawsuits against Purdue Pharma, the maker of OxyContin, under negligent marketing and public nuisance theories to assert their state’s “quasi-sovereign” interests in the health, safety, and welfare of its citizens.\textsuperscript{143} State police power also has been exerted in numerous ways in the context of prescription opioid misuse, including via law enforcement activities to identify doctor shoppers, diveters, and high-volume prescribers, as well as through regulation of health care professionals involved in prescribing and dispensing.\textsuperscript{144} States have significantly expanded their legislative efforts in this area since the 1970s, enacting myriad laws that have generally gone unchallenged as valid exercises of state police powers.\textsuperscript{145} Against this backdrop, there is little debate that PDMP general establishment falls squarely within the purview of state authority, to the extent PDMPs regulate the clinical practices of prescribing and dispensing of narcotic medicines. That said, and as discussed in Part II.A.4, PDMPs do raise certain privacy objections related to the storage and use of prescription data.\textsuperscript{146

\textsuperscript{142} Id.
\textsuperscript{144} See Barsky v. Bd. of Regents, 347 U.S. 442, 449 (1954) (“It is elemental that a state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there. . . . The state’s discretion in that field extends naturally to the regulation of all professions concerned with health.”). The authority of the states to regulate the practice of medicine is longstanding and extends to the field of narcotic prescribing. See Edward P. Richards, \textit{The Police Power and the Regulation of Medical Practice: A Historical Review and Guide for Medical Licensing Board Regulation of Physicians in ERISA-Qualified Managed Care Organizations}, 8 ANNALS HEALTH L. 201, 201–23 (1999) (providing a history of the police power and the regulation of medical practice).
\textsuperscript{145} See Public Health Law Program: State Laws on Prescription Drug Misuse and Abuse, supra note 100 and accompanying text. Certain states have sought to regulate the supply of a certain controlled substance, for example when Governor Deval Patrick of Massachusetts issued a public health emergency declaration that empowered the public health commissioner to use emergency powers to prohibit the prescribing and dispensing of hydrocodone-only medication (Zohydro, Zogenix), which had been recently approved by the FDA. This type of action, however, encroaches upon the federal government’s supreme role in drug safety approval—specifically, the FDA’s—and was found unconstitutional when challenged by Zogenix. See Rebecca Halfajee et al., \textit{What Is a Public Health “Emergency”?}, 371 NEW ENG. J. MED. 986, 986–88 (2014).
\textsuperscript{146} See infra Part II.A.4.
Although the states implement PDMPs with the requisite police power authority, the federal government possesses concurrent authority to regulate prescription drugs together with the states, a power derived from the Commerce Clause.\textsuperscript{147} Under the Commerce Power, the U.S. Congress may regulate: (1) the channels of interstate commerce; (2) the instrumentalities of commerce (including persons and things in interstate commerce); or (3) economic activities that have a substantial effect on interstate commerce.\textsuperscript{148} The Supreme Court has found narcotic drugs to satisfy all three prongs of this test, as they are “things” that flow through an interstate supply chain (from manufacturer to distributor to pharmacy to patient), the distribution of which impacts this interstate flow.\textsuperscript{149}

Congress’s regulation of controlled substances dates back to the early 1900s.\textsuperscript{150} But, it truly expanded with the enactment of the CSA in 1970 and creation in 1973 of the DEA, an agency charged with policing the issuance and dispensing of controlled substances, including prescription drugs.\textsuperscript{151} To prescribe controlled substances in Schedules II through V, licensed prescribers must register with the DEA every three years and follow other administrative requirements.\textsuperscript{152} To avoid criminal liability under the CSA, a prescriber may issue controlled substance prescriptions only “for a legitimate medical purpose” when “acting in the usual course of his professional practice.”\textsuperscript{153}

\textsuperscript{147} U.S. Const. art. I, § 8, cl. 3.

\textsuperscript{148} Perez v. United States, 402 U.S. 146, 150 (1971).


\textsuperscript{150} See Shepherd, supra note 99, at 101.

\textsuperscript{151} See DEA Mission Statement, Drug Enf’t Admin., http://www.dea.gov/about/mission.shtml (last visited Aug. 5, 2016). In addition, the federal government also established the FDA, which in 2012 used its powers to require ER/LA opioid manufacturers to develop a REMS given that the potential risks of the drugs outweighed the benefits. The REMS policy requires these drug developers to manage the risk of accidental or intentional abuse and risks to patients who are prescribed the drugs but do not clinically need them, primarily by financing the education of prescribers and patients regarding opioid risks and proper prescribing, storage, and disposal practices. Valerie Blake, Fighting Prescription Drug Abuse with Federal and State Law, 15 AM. MED. ASS’N J. ETHICS 443, 443–44 (2013). See generally John F. Peppin et al., Issues and Critiques of the Forthcoming Risk Evaluation and Mitigation Strategy (REMS) for Opioids in Pain Management, 27 ISSUES L. & MED. 91 (2011) (suggesting that REMS is unlikely to reduce the bulk of prescription drug abuse that occurs with non-patients); Hilary Homenko, Rehabilitating Opioid Regulation: A Prescription for the FDA’s Next Proposal of an Opioid Risk Evaluation and Mitigation Strategy (REMS), 22 HEALTH MATRIX 273 (2012).


\textsuperscript{153} 21 C.F.R. § 1306.04(a) (2013). Prescribers may also be held liable under certain state controlled substance acts for unauthorized prescribing practices.
Despite this expansive federal oversight of controlled substances and jurisprudence relating to the Commerce Power, the federal government has not chosen to use its Commerce Power to create any national prescription monitoring program or curtail state plenary powers to do so.\(^{154}\) Instead, it supports the states in monitoring prescription drugs, thereby lending additional support to the idea that Congress has little intention of preempting state PDMP creation. Specifically, the U.S. Department of Justice has encouraged state PDMPs by creating the Harold Rogers Prescription Drug Monitoring Program in 2002 to fund program creation, the National Alliance for Model State Drug Laws to help with policy coordination, and a Prescription Drug Monitoring Program Center of Excellence at Brandeis University to identify best practices.\(^{155}\) None of this federal activity would be construed as commandeering of the states, as the funds and support provided for PDMPs relate directly to these programs and do not require program establishment or operation.\(^{156}\)

The federal government, however, has not ceded this entire arena to the states. As a reciprocal gesture for its support for PDMPs, the federal government has elicited state cooperation with investigative activities relating to prescription drug misuse. The DEA has requested certain state PDMP data pursuant to administrative subpoenas, as authorized under the CSA, to investigate drug crimes—an action that raised supremacy issues that ultimately went unresolved in Oregon Prescription Drug Monitoring Program v. United States DEA.\(^{157}\) In this case, the DEA was attempting to use its administrative subpoena power to access Oregon PDMP records for an individual patient and for all drugs prescribed by two physicians, absent a warrant.\(^{158}\) The Oregon PDMP refused to comply with these subpoenas on the basis that doing so would violate Oregon law, which says that PDMP data constitutes protected health information and law enforcement can only access the data

154. In other words, the federal government has neither expressly preempted state PDMPs nor enacted other controlled substance monitoring laws that would impliedly preempt state creation of PDMPs. See Barnes & Arndt, supra note 149, at 292–95 (discussing circuit court decisions that reaffirm the constitutionality of CSA regulations, but that have also found such regulations do not invalidate state police powers to regulate medicine).

155. Deyo et al., supra note 76, at 604–05.


157. Or. Prescription Drug Monitoring Program v. United States Drug Enf’t Admin., 998 F. Supp. 2d 957, 960 (D. Or. 2014). The DEA appealed the district court’s ruling and is awaiting a decision from the Ninth Circuit Court of Appeals. The ultimate outcome of the case could influence the standards across jurisdictions regarding DEA (and state law enforcement) access to PDMP data. The CSA empowers the Attorney General, and executive agencies acting pursuant to his/her authority (including the DEA), with broad authority to issue administrative subpoenas for information “relevant or material” to an investigation relating to his/her functions “with respect to controlled substances.” 21 U.S.C. § 876(a) (West 2012).

pursuant to a **valid court order based on probable cause** for an authorized drug-related investigation involving an individual.\(^{159}\) In a former instance when the Oregon PDMP objected to a DEA request for PDMP data (pursuant to an administrative subpoena) on all Schedule II through IV controlled substance prescriptions issued by a particular physician over a seven month period, a U.S. magistrate judge found Oregon’s court order requirement to be preempted by the CSA.\(^{160}\) In *Oregon Prescription Drug Monitoring Program*, the court never reached the supremacy issue presented, however, instead deciding that the DEA’s use of administrative subpoenas violated the Fourth Amendment, as discussed below in Part II.A.4.

Given the concurrent jurisdiction of federal and state governments to monitor prescription drugs, what is the appropriate balance of powers—particularly when presented with a complex and serious public health problem like prescription opioid misuse? Strong arguments can be made for federal intervention, given markedly heterogeneous programs across states, limited state resources, and the interstate components of drug prescribing and dispensing involved. State PDMPs exhibit widely varying features, most of which appear chaotically conceived and uninformed by rigorous studies of effectiveness (as most programs were adopted before much of an evidence base existed). State authorities may lack the resources or expertise to operationalize PDMPs optimally, even with federal assistance.\(^{161}\) Furthermore, prescription drug misuse is not confined within state borders, as demonstrated by growing evidence of doctor shopping across state lines\(^{162}\) and mail order pharmacies that can send controlled substances across states.\(^{163}\) All of these factors weigh in favor of uniform federal standards that could, in theory, more comprehensively and deliberately address prescription drug misuse.\(^ {164}\)

While the federal government has the authority and a set of justifications to have its own PDMP, the creation of such a program would require a major overhaul of deeply entrenched state programs. State PDMPs represent huge investments; replacing them with a federal system would seem wasteful and counter-productive just as we are

\(^{159}\) Id.; Or. Rev. Stat. § 431.966(2)(a)(C) (West 2016).

\(^{160}\) *Or. Prescription Drug Monitoring Program v. United States Drug Enf’t Admin.*, 998 F. Supp. 2d 957, 960 (D. Or. 2014). In other words, the magistrate judge found the DEA’s investigatory authority reigned supreme over Oregon state law’s data access requirements. *Id.*

\(^{161}\) *Clark et al., supra* note 79, at 57–62; *Gostin, supra* note 101, at 81.


\(^{163}\) See Anupam B. Jena et al., *Prescription Medication Abuse and Illegitimate Internet-Based Pharmacies*, 155 *ANNALS INTERNAL MED.* 848 (2011).

\(^{164}\) *Gostin, supra* note 101, at 81; *Parmet, supra* note 131, at 208.
beginning to detect what may be promising health results.\textsuperscript{165} State governments (and local governments to which they may delegate power) are closer to the issues and have more flexibility than the federal government to cater the programs to their citizenry’s public health needs, opinions, and geographies—all of which can serve to enhance PDMP results.\textsuperscript{166} Certain states may wish to implement specific features or PDMPs in combination with other interventions for a greater impact. For example, Florida chose to combine a PDMP with regulation of pill mills, given the high concentration of these practices.\textsuperscript{167} States can also function as “laboratories” to test new interventions and inform evidence-based policy in other jurisdictions.\textsuperscript{168} The progressive, widespread adoption of PDMPs from the 1990s through 2000s provides rich heterogeneity in programs across states to allow for natural experiments that test different features for the best results. In sum, leaving state PDMPs intact for continued evaluation and potentially improvement seems preferable. As a stronger evidence base about effective PDMP practices emerges, there will be room for increased federal influence to achieve some consistency across programs: The federal government should condition future state PDMP funding on adoption of these identified practices.\textsuperscript{169} But at the moment, while states seem to be an appropriate level at which to implement PDMPs, policymakers face tough decisions with respect to the form that these laws take, as guided by consideration of individual liberties, effectiveness, and other ethical dimensions.

### 3. Constitutional Limits on Public Health Regulation

Although state governments have broad authority to act in ways that limit private interests in favor of the greater community,\textsuperscript{170} these infringements do have legal bounds. Individual liberty, autonomy, privacy, and economic freedom enjoy protection from certain government

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\textsuperscript{165} See infra Part II.B.3 for a discussion of the PDMP effectiveness literature.

\textsuperscript{166} See Gostin, \textit{supra} note 101, at 81; Hodge, Jr., \textit{supra} note 127, at 356.

\textsuperscript{167} See, e.g., Lainie Rutkow et al., \textit{Effect of Florida's Prescription Drug Monitoring Program and Pill Mill Laws on Opioid Prescribing and Use}, \textit{10 JAMA Internal Med.} 1642 (2015) (finding that Florida's PDMP and pill mill laws were associated with modest decreases in total opioid volume supplied, as well as in morphine milligram equivalents per transaction and opioid prescriptions).

\textsuperscript{168} Mello & Zeiler, \textit{supra} note 102, at 654, 671–79 (discussing that state-based law provides the opportunity for evaluation thanks to time-varying adoption of reform across jurisdictions, often for reasons unrelated to the outcome variable of interest. The federal National Minimum Drinking Age Act, which tied the minimum drinking age to national highway funds, was adopted after studies of state innovations attributed beneficial health impacts to higher drinking ages).


\textsuperscript{170} Parmet, \textit{supra} note 109, at 401–11 (discussing the interdependency of health and the public good nature of many interventions as justifications for public health interventions, such as the individual mandate in the Affordable Care Act).
Intrusion under the Bill of Rights, as well as state constitutions and laws,\textsuperscript{171} in addition to articulating the breadth of state authority to protect the public’s health, \textit{Jacobson} was the first case to carefully articulate a framework for the protection of individual liberties in the exercise of police power, which has been elaborated upon and developed in subsequent case law interpreting the Constitution.\textsuperscript{172} The permissibility of public health laws turns on scientific justification and the manner in which they are applied.\textsuperscript{173} Specifically, public health powers are constitutional only if exercised in accordance with the following legal principles: (1) extraterritoriality; (2) necessity; (3) reasonableness; (4) due process rights; and (5) equal protection principles.\textsuperscript{174} Freedom of expression principles further impose significant barriers to public health regulation. For general framing purposes, the above principles are outlined in brief and then applied in detail as relevant to PDMPs.

For any given public health law, state policymakers should undertake a careful constitutional analysis to anticipate private objections that could frustrate implementation. First, states can regulate matters within their borders, but not extraterritorially.\textsuperscript{175} Second, the exercise of police power should be necessary to prevent an actual or looming threat to public health, rather than a potential or hypothetical one.\textsuperscript{176} Third, the exercise of state power must be reasonable. Here a policymaker would ask two questions: (1) will the legal action taken plausibly be effective in achieving its objective (that is, are the means reasonably related to the ends)? and (2) are there any obviously less burdensome alternatives that could have been implemented instead?\textsuperscript{177}

Furthermore, individual rights to due process and equal protection are constitutionally protected and must be considered in the affirmative.

\textsuperscript{171} Gostin, supra note 101, at 85–86, 114–16. State constitutions and laws also provide parameters for policymaker actions, but are too plentiful to be addressed comprehensively in this Article.

\textsuperscript{172} See generally Wendy K. Mariner et al., Jacobson v. Massachusetts: It’s Not Your Great-Great-Grandfather’s Public Health Law., 95 AM. J. PUB. HEALTH 581 (2005) (tracing the evolution of conceptions of state police powers and individual liberty over the century since \textit{Jacobson}, finding that the Court’s recognition of the relative importance of liberty has strengthened over time).

\textsuperscript{173} Parmet et al., supra note 133, at 654.

\textsuperscript{174} Although the facts in \textit{Jacobson} did not require the Supreme Court to articulate equal protection as a constitutionally required limitation, this standard had previously been articulated in \textit{Jew Ho v. Williamson}, Gostin, supra note 101, at 128 (citing Jew Ho v. Williamson, 103 F. 10 (N.D. Cal. 1900)).

\textsuperscript{175} The police power is a state’s “recognized [] authority [] to enact . . . all laws that relate to matters completely within its territory and which do not by their necessary operation affect the people of other states.” Jacobson v. Massachusetts, 197 U.S. 11, 25 (1905).

\textsuperscript{176} Gostin, supra note 101, at 126–27 (the subject of compulsory intervention must pose an actual, demonstrable threat to the community); \textit{Jacobson}, 197 U.S. at 39 (not requiring that the vaccination be administered against anyone who “with reasonable certainty” can show that he is not the “fit subject of vaccination . . . by reason of his then condition, [which] would seriously impair his health or probably cause his death.”).

\textsuperscript{177} See \textit{Jacobson}, 197 U.S. at 31; Gostin, supra note 101, at 127.
government exercise of public health powers. Individuals are free from unwanted intrusions—including searches and seizures—in places in which they have a legitimate expectation of privacy (such as their body or property).\footnote{Gostin, supra note 101, at 403. The Fourth Amendment guarantees “the right of the people to be secure in their persons, houses, papers, and effects against unreasonable searches and seizures,” and is extended to state governments via the Fourteenth Amendment. U.S. Const. amend. IV. See Wilson v. Health & Hosp. Corp. of Marion Cty., 620 F.2d 1201 (7th Cir. 1980) (finding that health official searches absent warrants or consent violated individual’s reasonable expectation of privacy under the Fourth Amendment).} Under the Fourth Amendment, a search is usually found unreasonable absent a warrant from a judge showing probable cause,\footnote{See, e.g., Ferguson v. City of Charleston, 532 U.S. 67 (2001) (finding that state hospital performance of urine tests on pregnant women without their consent to obtain evidence for law enforcement purposes constituted an unconstitutional search under the Fourth Amendment. No special need was recognized given that the testing was linked to the state’s general interest in law enforcement.); Loder v. City of Glendale, 927 P. 2d 1200, 1230 (1997) (striking down mandatory drug tests for all city employees seeking promotions because they had already been tested, whereas drug tests for new applicants were permissible given the lack of prior knowledge of their drug use).} with limited exceptions.\footnote{See, e.g., Greene v. Edwards, 263 S.E.2d 661, 663 (1980) (holding that people with communicable tuberculosis must be afforded counsel, written notice, and the right to confront the witnesses against them).} The concept of liberty is also protected under the Fifth Amendment\footnote{The Fifth Amendment to the U.S. Constitution states: “No person shall . . . be deprived of life, liberty, or property, without due process of law.” U.S. Const. amend. V. The Fifth Amendment has been extended to the states under the Fourteenth Amendment to the U.S. Constitution.} and can be framed as two separate obligations: procedural due process and substantive due process. Procedural due process entitles individuals to fair procedures—typically, notice, a fair hearing, and counsel\footnote{See, e.g., Hunt v. Manypenny, 436 U.S. 343 (1978); Nurse v. City of Chicago, 740 F.2d 1115 (7th Cir. 1984) (finding that the city’s refusal to terminate an employee on the basis of a false diagnosis violated substantive due process).}—when the government deprives them of life, liberty, or property.\footnote{See, e.g., Lawrence v. Texas, 539 U.S. 558, 562 (2003) (finding a liberty right to engage in private acts, particularly intimate acts in nonpublic locations, such as the home).} Substantive due process relates to the protected zone of individual liberty or privacy, where the government cannot enter without adequate justification.\footnote{The concept of liberty is also protected under the Fifth Amendment.} And finally, any state government-drawn distinction between similarly situated persons—for example,
between persons of different races and ethnicities—requires justification based on equal protection principles. The level of scrutiny applied by courts in considering substantive due process and equal protection claims varies depending on the nature of the burdened right or interest.

Although not raised in Jacobson or yet in the context of PDMPs, freedom of speech is relevant to the evaluative framework and policymaking calculus in other public health law contexts, such as regulating the advertising of tobacco products. State regulators should be mindful that courts afford exceptional protection to speech, and the trend has been toward increasing protection of commercial speech, in particular. Indeed, the First Amendment is, of late, arguably the most significant constitutional barrier to state and federal public health regulation in the contexts of both compelled speech and speech restrictions.

4. Liberty Issues Raised by PDMPs

Although states are generally within the purview of their police powers in creating PDMPs, certain features of these heterogeneous programs have the potential to infringe upon individual rights and freedoms and may, therefore, be subject to legal challenge. PDMPs, as typically implemented, meet the extraterritoriality and necessity

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185. See, e.g., Yick Wo v. Hopkins, 118 U.S. 356, 372 (1886) (striking down a facially neutral ordinance restricting the washing of clothes in public laundromats after 10:00 p.m. on the basis that it was being enforced with discriminatory intent—only against Chinese owners); Jew Ho v. Williamson, 103 F. 10, 26 (N.D. Cal. 1900) (finding that the quarantine of an entire district in San Francisco in order to contain a bubonic plague epidemic was used as a guise to discriminate against Chinese people who populated most of the area, the health of whom was actually placed at greater risk by the quarantine).

186. The Fourteenth Amendment also provides that no state shall “deny to any person within its jurisdiction the equal protection of the laws.” U.S. Const. amdt. XIV.

187. For further discussion of substantive due process, equal protection, and levels of constitutional review, see Gostin, supra note 101, at 135–42.

188. Id.; see, e.g., Sorrell v. IMS Health Inc., 554 U.S. 522, 554–55 (2011) (finding that a Vermont state statute banning the sale, use, or transmission of prescriber-identifiable data (absent prescriber consent) violated data miner free speech rights); Thompson v. W. States Med. Ctr., 535 U.S. 357, 376–77 (2002) (holding that a provision of the FDA Modernization Act, which exempts certain compounded drugs from having to satisfy drug approval requirements if the drug is not advertised or promoted, unconstitutionally restricts pharmacists’ commercial speech); Lorillard Tobacco Co. v. Reilly, 553 U.S. 525, 555–56 (2001) (holding that Massachusetts’ outdoor and point-of-sale advertising restrictions targeting smokeless tobacco and cigars violated the First Amendment); R.J. Reynolds Tobacco Co. v. Food & Drug Admin., 696 F.3d 1205, 1221–22 (D.C. Cir. 2012) (holding that the FDA rule requiring graphic warning images on cigarette packages and advertisements violates the First Amendment).

189. For academic discussion of this evolving and expansive body of law, see David Orentlicher, The Commercial Speech Doctrine in Health Regulation: The Clash Between the Public Interest in a Robust First Amendment and the Public Interest in Effective Protection from Harm, 37 AM. J.L. & MED. 299 (2011); Micah L. Berman, Manipulative Marketing and the First Amendment, 103 GEO. L.J. 497 (2015).
requirements for public health laws originally articulated in Jacobson. Each program operates within its state’s borders, collecting data on controlled substances dispensed within the state and permitting prescriber, pharmacist, and sometimes regulator use of that data. Some interstate sharing of information to authorized users (typically, prescribers or pharmacists) or PDMPs in other states occurs, but any information transmitted across state boundaries is usually shared reciprocally, subject to the originating state’s requirements for authorized use, and intended to complement public health efforts in both states. Furthermore, sharing of data across state lines can be justified given the sometimes interstate nature of prescribing, drug fills, and diversion. With regard to necessity, there is little debate that the exercise of police power is necessary to address opioid misuse and overdose, a public health threat of significant and increasing magnitude.

Further, the programs appear reasonable in the Jacobson sense of the term. PDMPs bear a real and substantial relation to the protection of public health and safety: They aim to inform optimal prescribing as well as to address patients and prescribers with outlier fill and prescribing patterns, respectively. Given that the vast majority of drugs misused originate from prescribers, either directly or indirectly, prescribing is a reasonable level at which to intervene to address the epidemic. Also, because a small percentage of prescribers source the majority of opioids, and because a small percentage of patients receive disproportionately large amounts of opioids, outliers in each of these categories are reasonable targets for intervention. If challenged, a court would likely view a state’s decision to implement a PDMP in lieu of or in addition to other available interventions that target prescription drug misuse (such as pain clinic laws) with deference, finding it neither arbitrary nor totally unreasonable.

190. See Jacobson v. Massachusetts, 197 U.S. 11, 25 (1905) for a definition of states’ “police power.” See supra note 175 of this Article for such a definition.
193. Id.
194. See Gostin, supra note101, and text accompanying note 176; Jacobson v. Massachusetts, 197 U.S. 11 (1905); see also Part I, supra for a discussion of the public health significance of opioid misuse.
195. See supra note 175 and accompanying text.
196. See supra notes 11–12 and accompanying text.
198. Laws that regulate “pill mills,” or pain management clinics that source large quantities of prescriptions, aim to prevent these facilities from inappropriately prescribing controlled substances. Such laws typically provide for state oversight of pill mills and contain other requirements pertaining to ownership and operation of the facility. For instance, a law may set forth personnel and operational requirements,
The heart of challenges to PDMPs revolves around informational privacy rights. These rights can be located in the Fourth and Fourteenth Amendments, as well as in federal and state confidentiality laws. Because statewide prescription dispensing data is aggregated in a database that can be widely accessed by many types of authorized users, PDMPs present new possibilities for security breaches in which private information is disclosed to the general public, as well as for law enforcement and licensing body use of the data. The potential for broad data access raises privacy concerns among patients and prescribers and could reduce their drug seeking and prescribing behaviors, respectively. Some such behavior changes may be desirable, given that a central purpose of PDMPs is to have a deterrent effect on over-prescribing, doctor shopping, and diversion. But other behavioral changes may be unintended and undesirable, such as the chilling of appropriate prescribing or patient access to legitimately needed painkillers. Courts seek to balance the competing state and individual privacy interests in determining the legality of PDMPs and access to prescription information contained therein.

The Supreme Court addressed the right to informational privacy in prescription records under the Due Process Clause of the Fourteenth Amendment in *Whalen v. Roe*. In *Whalen*, the Court considered whether New York’s paper prescription monitoring program (which also collected the prescription information in a computerized database) violated individual interests in (1) avoiding disclosure of personal matters, and/or (2) independence in important decisionmaking. The Court admitted that the monitoring program could have a chilling effect on opioid prescribing and use. Nonetheless, it found that the program adequately safeguarded physicians’ and patients’ right to informational privacy, emphasizing the extensive security protections in place to keep private information from being disclosed and the fact that the decision whether to prescribe or use a drug is still left to patients and doctors. Subsequent state courts have considered the right to informational privacy in prescription records housed in individual pharmacies, rather than statewide databases, and relied on the *Whalen* precedent to find no inspection and licensure procedures, standards of care, and/or patient billing procedures. See Ctrs. for Disease Control & Prevention, supra note 66.

199. See infra Parts II.B–C for additional consideration of unintended consequences of PDMPs under the evaluative framework.
201. *Id.* at 591, 599–600.
202. *Id.* at 600–02, 604 (noting protections, including a receiving room protected by a locked wire fence and alarm system, limited access to a small number of people, and serious penalties for unlawful release). The Court also found that any physician claim regarding potential disclosure of patient information was “derivative from, and therefore no stronger than, the patients”—in other words, rejecting physician privacy rights violations in this context. *Id.* at 604.
constitutional violations. Although not yet squarely addressed by any court, it seems unlikely an electronic PDMP would infringe upon Fourteenth Amendment privacy rights if adequate safeguards were in place to protect the data from public disclosure.

Patient (and prescriber) Fourth Amendment privacy rights are also implicated by warrantless searches of PDMP data by law enforcement officials and other regulators. In almost all states, professional licensing bodies and law enforcement officials can access PDMP data for the respective purpose of conducting administrative searches and pursuing criminal investigations against patients, prescribers, or pharmacists. What differs from state to state is whether these officials can access the data simply pursuant to an active investigation, or whether they need to satisfy the more stringent standards of accessing the information only with a court-issued search warrant, subpoena, or order. While the stated goals of PDMPs vary—and many programs explicitly do aim to prevent criminal activities such as diversion and doctor shopping—a common primary goal is to improve health care by reducing drug misuse and facilitating appropriate prescribing. If law enforcement and licensing officials are given access to the files absent any probable cause or reasonable restrictions around terms of access, PDMPs could easily turn into tools primarily used to troll for criminal or medical misconduct. This shift in emphasis could induce a chilling effect on prescribing and prescription drug use in ways that actually interfere with optimal medical care.

The Whalen Court did not decide whether a centralized state database housing prescription records implicates the Fourth Amendment.

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203. See, e.g., State v. Wiedeman, 835 N.W.2d 698, 714 (Neb. 2013) (finding no violation of the Fourteenth Amendment after “weighing the State’s significant interest in the regulation of potentially dangerous and addictive narcotic drugs against the minimal interference with one’s ability to make medical decisions and the protections from broader dissemination to the general public”); Stone v. City of Snow, 593 N.E.2d 294, 301 (Ohio 1992) (holding that the Ohio statutes permitting warrantless inspection of prescriptions, orders, and records to law enforcement officials and regulators did not violate doctor, patient, or pharmacist rights to privacy as they did not allow disclosure to the general public and included adequate safeguards).

204. In a Whalen v. Roe concurrence, Justice Brennan did express concerns with the computerized storage of sensitive information, leaving open the possibility that the Court would view electronic PDMPs, whereby data are shared across a wide network of authorized users, as a heightened invasion of privacy. David B. Brushwood, Maximizing the Value of Electronic Prescription Monitoring Programs, 31 J.L. Med. & Ethics 41, 43 (2003). But see Dilcher, supra note 40 (suggesting it is unlikely that the Supreme Court will invalidate electronic PDMPs on general privacy grounds).

205. Nat’l All. for Model State Drug Laws, supra note 68, at 5, 25–26. In a handful of states, the PDMP is actually housed within a law enforcement or professional licensing agency, as opposed to a health agency, thereby giving these regulators and officials’ unfettered access to the records. Id. at 25–26.

206. Id.


208. Id.
right to privacy. However, other state and federal courts have addressed this right in the context of pharmacy-housed prescription records, generally finding that although patients have a subjective expectation of privacy in their prescription records, they do not have a privacy right that society is prepared to recognize as objectively reasonable—as is also required to invoke Fourth Amendment protections. Some courts have justified patients’ (and prescribers’) reduced expectation of privacy in pharmacy records on the basis that most states have laws that explicitly allow certain officials access to these records without a warrant. Other courts have recognized pharmaceuticals as a pervasively regulated industry and thus applied the three-pronged test set out in New York v. Burger to determine whether a warrantless search is reasonable. In applying the Burger test, courts have typically found that allowing searches of prescription data furthers substantial and well-established government interests in regulating prescription drugs, and that notice requirements are met if these searches are conducted during reasonable hours. Most courts have found the warrant exception applies to administrative inspections of pharmacy records, such as those conducted by pharmacy boards, though some also have applied it to searches conducted pursuant to criminal investigations.

209. The Court declined to address the Fourth Amendment arguments brought by physician and patient plaintiffs because the case did not “involve affirmative, unannounced, narrowly focused intrusions into individual privacy during the course of criminal investigations.” Whalen v. Roe, 429 U.S. 589, 604 n.32 (1977).


213. In its close level of regulation, the pharmaceutical industry is distinguishable from certain other areas of health. See, e.g., Tucson Woman’s Clinic v. Eden, 379 F.3d. 531, 551 (9th Cir. 2004) (holding that an Arizona regulation that required abortion clinics to submit to warrantless inspections by the Arizona Department of Human Services violated the Fourth Amendment. The Ninth Circuit determined that the administrative search exception was inapplicable because abortion services are not a closely regulated business).

214. New York v. Burger, 482 U.S. 691 (1987). To determine whether a warrantless search is reasonable, three criteria must be met: (1) there must be a substantial government interest in regulating this area; (2) the regulatory scheme must further that government interest; and (3) the regulation must provide a constitutionally adequate substitute for a warrant—in other words, it must provide comprehensive notice to the target of the search and appropriately limit the time, place, and scope of the search. Id. at 702.


PDMPs, however, raise unique issues with respect to unfettered searches, particularly when conducted by law enforcement or licensing officials, which justify different data access standards from those applied to pharmacy-housed records. PDMPs centralize all dispensing data generated within a state (and sometimes across states), rather than that from a single pharmacy. Most are fully electronic and searchable, for instance by prescriber, pharmacy, or patient name—or conceivably by controlled substance or prescribing volume. Under the mosaic theory, the aggregation of prescription information in PDMPs should be covered by a reasonable expectation of privacy under the Fourth Amendment, even if each individual pharmacy-housed record may not be.\(^{217}\) Moreover, although the third-party doctrine suggests that when certain records are turned over and maintained by third-parties, they are no longer private and not protected by the Fourth Amendment when exposed to others, significant support for patients' expectation of privacy in medical records exists.\(^{218}\) Because PDMP data, by virtue of their comprehensive nature, are akin to medical records, there is a strong argument that such records are entitled to some measure of protection from unfettered access by government officials.

Indeed, the heightened Fourth Amendment privacy concerns associated with PDMPs were recognized in *Oregon Prescription Drug Monitoring*. In this leading case in the area, the American Civil Liberties Union (“ACLU”) intervened on behalf of the PDMP to raise arguments about individual physician and patient Fourth Amendment privacy rights

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\(^{217}\) See Benjamin J. Priester, *Five Answers and Three Questions After United States v. Jones* (2012), the Fourth Amendment “GPS Case”, 19–28 (Mar. 28, 2012), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2030390 (noting five Justices’ express support for the “mosaic theory” in *U.S. v. Jones*, or the idea that the aggregation of information may be covered by a reasonable expectation of privacy, even though each discrete piece of information standing alone would not. The mosaic theory, which suggests the Fourth Amendment protection can be triggered when the sheer quantity of information becomes great, applies both to information presented to the public and that turned over to a third-party, like PDMP data. However, the precise parameters of how this theory will be applied by the Court remain uncertain). For additional arguments in favor of the mosaic theory, see Wayne A. Logan, “*Mosaic Theory*” and *Megan’s Laws*, 2011 Cardozo L. Rev. De Novo 95 (2011).

\(^{218}\) See, e.g., State v. Skinner, 10 So. 3d 1212, 1218 (La. 2009) (finding that the Fourth Amendment requires a search warrant before a search of medical or prescription records for criminal investigative purposes can be undertaken); Doe v. Broderick, 225 F.3d 440, 451 (4th Cir. 2000) (holding that a patient at a methadone clinic had a legitimate expectation of privacy in the records on file there, given their intimate and private nature).
in their PDMP information. Notwithstanding federalism issues discussed above in Part II.A.2, the federal district court decided in favor of the ACLU and held that the Fourth Amendment was violated by the DEA’s use of administrative subpoenas (rather than a court-issued warrant) to obtain PDMP records for an individual patient’s prescriptions and for all drugs prescribed by two physicians.\footnote{Or. Prescription Drug Monitoring Program v. United States Drug Enf’t Admin., 998 F. Supp. 2d 957, 966, 967(D. Or. 2014).} The court found that both patients and physicians have subjective and objective expectations of privacy in PDMP records for the Schedule II through IV drugs at issue.\footnote{Id. at 964–67.} The court found that although patients must expect that medical personnel will access their prescription files, it is reasonable for patients to expect that law enforcement will not have access to the PDMP records—given the intensely personal nature of the data (often revealing a person’s medical condition and treatment patterns) and information on the PDMP’s website that emphasized the protection of confidential information.\footnote{Id. at 966–67. The district court found it “difficult to conceive of information that is more private or more deserving of Fourth Amendment protection” than prescription drug information that would reveal if a patient is being treated for gender identity disorder—as would be captured by PDMP records. Prescribing records of this kind are protected against government intrusion by a “heightened privacy interest rendering the use of administrative subpoenas unreasonable.” Id. The court also dispensed with the DEA’s assertion that the “third-party doctrine” undermines the patient/prescriber expectations of privacy because (1) PDMP records are inherently personal and private; and (2) doctors and patients do not voluntarily convey the information to the PDMP rather it is required by law that all dispensing information be included. Id.} Although the district court’s decision is not binding in other jurisdictions and a few state courts have held alternately,\footnote{Williams v. Commonwealth, 213 S.W.3d 671, 676–78 (Ky. 2006) (finding that the Kentucky statute authorizing warrantless searches of PDMP data is facially constitutional and does not amount to a “search” because only limited data of Schedules II-V controlled substances that did not reveal a patient’s medical condition or treatment were conveyed); Lambert v. Larizza, Case No. 13-314-2-CICI (Fla. Cir. Ct. Feb. 13, 2014) (holding that the production of PDMP prescription records for 3300 patients to state and federal law enforcement officials pursuant to a warrantless request did not violate Florida's constitution because there is a reduced expectation of privacy in prescription records); Florida Judge Rules Government Can Search Prescription Drug Monitoring Database, THOMSON REUTERS (Feb. 21, 2014), http://blog.legalsolutions.thomsonreuters.com/practice-of-law/florida-judge-rules-government-can-search-prescription-drug-monitoring-database/ (discussing the ruling in Lambert v. Larizza). See Jodie Tillman, California High Court to Consider Limits on Regulators’ Access to Prescription Database, L.A. DAILY NEWS (Apr. 26, 2015), http://www.dailynews.com/general-news/20150426/california-high-court-to-consider-limits-on-regulators-access-to-prescription-database (last visited Aug. 5, 2016) (describing the decision of a California state appeals court that found medical board use of PDMP data to identify a physician with outlier prescribing trends that led to his administrative probation does not violate the patients’ rights to privacy under the state constitution. The court found that medical records are not comparable to prescription records from a privacy standpoint, as the latter are subject to regular scrutiny by law enforcement and regulatory agencies).} PDMPs are beginning to follow Oregon Prescription Drug Monitoring guidance by increasingly requiring
a search warrant or a court-issued subpoena for law enforcement officials to access PDMP data.\textsuperscript{223}

Privacy protections for PDMP data can also be located in non-constitutional sources, such as the Health Insurance Portability and Accountability Act ("HIPAA")\textsuperscript{224} and state privacy laws. The HIPAA "Privacy Rule" creates a national standard for the protection of individually identifiable health care information from disclosure by "covered entities" (or health care providers), with limited exceptions that may apply to PDMP data.\textsuperscript{225} For example, a covered entity may disclose health information that identifies a patient without receiving permission from that individual for enumerated exceptions germane to PDMPs, including: disclosures required by law; public health activities; health oversight activities; law enforcement purposes; and for treatment, payments, and health care operations.\textsuperscript{226} Moreover, HIPAA does not preempt state law (including state privacy and PDMP laws) if the Secretary of Health and Human Services determines that the state provision serves a compelling public health need or has as its principal purpose the regulation of any controlled substance, among other aims.\textsuperscript{227} All of this suggests that HIPAA should not prevent the sharing of information via PDMPs—either by dispensers when initially logged into the PDMP or to authorized users of PDMPs—so long as the information shared is limited to the minimum necessary to achieve the intended purpose.\textsuperscript{228}

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{223} Nat'l All. for Model State Drug Laws, supra note 68, at 2; Devon T. Unger, Minding Your Meds: Balancing the Needs for Patient Privacy and Law Enforcement in Prescription Drug Monitoring Programs, 117 W. Va. L. Rev. 345, 386 (2014) (arguing that patients have a legitimate interest in personally identifiable PDMP data and that the Fourth Amendment requires law enforcement to obtain a warrant before accessing such data). Still, thirty states allow law enforcement to conduct searches of PDMP data merely pursuant to an active investigation, and many allow licensing boards to do the same. Nat'l All. for Model State Drug Laws, supra note 68, at 25–26.
\item \textsuperscript{224} Unger, supra note 223, at 262–64.
\item \textsuperscript{225} 45 C.F.R. §§ 160, 164 (2012). “Covered entities” include medical or health care service providers, such as physicians and pharmacists, who electronically transmit individually identifiable information in connection with financial or administrative activities related to health care. Id. §§ 164.501, 164.506, 164.512.
\item \textsuperscript{226} 45 C.F.R. §§ 164.501, 164.506, 164.512 (2012).
\item \textsuperscript{227} HIPAA does not preempt state law (including a PDMP law) if the Secretary of Health and Human Services determines that the provision serves a compelling public health need, or has “as its principal purpose the regulation of the manufacture, registration, distribution, dispensing, or other control of any controlled substance;” or “provides for the reporting of disease or injury . . . or for the conduct of public health surveillance, investigation, or intervention.” 45 C.F.R. §§ 160.203(a)(1)–(2), 160.205(c). See Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and Prescription Drug Monitoring Programs (PDMPs), Nat'l All. for Model State Drug Laws (2010), http://www.namsdl.org/library/BB52D3BB-1372-636CDD90AC7AAB8D724F (last visited Aug. 5, 2016).
\item \textsuperscript{228} 45 C.F.R. § 164.502(b)(1). At least one federal lawsuit charges that access by a local police department of a man’s prescription history without probable cause, a subpoena, or court order is a violation of HIPAA. Mollie Bryant, Brandon Denies Police Violated HIPAA, The CLARION-LEDGER (Jan. 25, 2016),
\end{itemize}
\end{footnotesize}
Moreover, some states include explicit privacy protections in their PDMP laws. These steps are advisable for all programs and include: exempting PDMP data from public records requests; imposing criminal or civil penalties for unauthorized disclosure of PDMP data; limiting authorized users of the data to a select set of professionals; and explicitly requiring that the housing entity comply with all relevant state and federal privacy and confidentiality laws. States should also put in place substantial data security protections to avoid disclosure of PDMP information, especially if data is shared across state lines. These measures include password-protected access (and careful authentication of all users), data encryption software, preventing unauthorized downloads of the data, and monitoring for potential security breaches.

While some states set forth stricter conditions for law enforcement and licensing official access PDMP files, as compared to pharmacy-housed files, the majority still allow warrantless searches. The Oregon Prescription Drug Monitoring decision to require law enforcement officials to obtain a warrant based on probable cause strikes a reasonable balance between facilitating federal and state law enforcement drug investigations and protecting physician-patient interests and medical privacy. These data access requirements should also be extended to licensing bodies given their analogous role to law enforcement and ability to sanction medical professionals by revoking or suspending medical licenses. Otherwise, unfettered access to prescription records by law enforcement and licensing officials runs a higher risk of hampering prescribing and/or opioid use to an extent that compromises legitimate pain management. State rules that require the data be housed within a health agency and limit PDMP authorized users to those who use the data for clinical purposes—and provide the data (absent a warrant) to others (such as researchers, law enforcement, or licensing bodies) only on a de-identified basis—run the least risk of running afoul of privacy laws or interfering with the doctor-patient relationship. Moreover, requiring law enforcement and licensing bodies to obtain a warrant does not substantially interfere with their duties and is therefore reasonable.


230. Thirty-eight states currently have such penalties for disclosing or obtaining PDMP data without authorization. Id. at 42. However, enforcement of these penalties is not well-documented.

231. Nat’l All. for Model State Drug Laws, supra note 68; Unger, supra note 223, at 379–82 (proposing that all data be personally de-identified before disclosure to law enforcement officials).


233. See People v. Curco Drugs, Inc., 350 N.Y.S.2d 74, 84 (N.Y. Crim. Ct. 1973) ("[O]btaining of a warrant would not have seriously undermined the [statute allowing administrative inspections of
In summary, states seem to be the appropriate level for PDMP implementation and a federal PDMP is neither a realistic option on the horizon nor a necessary one. However, certain features of state PDMPs can infringe upon protected individual rights and should be carefully considered going forward. Given the potential for broad PDMP data access that could hinder optimal medical care by affecting doctor and patient behavior around opioid prescribing and drug seeking, PDMPs should be guarded carefully by the housing entity and available to a limited subset of users under select circumstances. Most notably, law enforcement and licensing officials should only obtain the data pursuant to a warrant based on probable cause. Penalties for unauthorized data disclosure should be clear, strong, and enforced.

B. Effectiveness of Regulation

Even if a PDMP seems likely to withstand privacy challenges, policymakers must further inquire into the effectiveness of a particular approach. This second consideration with respect to public health laws is empirical in nature: Will (or does) the regulation in question—either proposed or already implemented—effectively address the immediate public health threat? State regulators should specifically ask: (1) what are the public health outcomes this law seeks to impact?; (2) do these outcomes align with pre-defined primary and secondary health outcomes we seek to target?; (3) does sufficient, credible evidence exist to suggest that the law will achieve (or has achieved) intended public health outcomes when applied to the context and environment at hand?; and (4) Is the predicted or actual ratio of intended to unintended consequences high enough to warrant implementation?

This Article considers public health laws that are “interventional” in nature, meaning those that are intended to either directly affect health outcomes, or to impact health via mediating factors (such as health behaviors or environments) in the causal chain between laws and health outcomes. Interventional laws are central to answering the question at the core of public health lawmaking: “What are the best legal tools to use to promote health?” Nevertheless, many other types of public health laws, such as those of infrastructural and incidental natures, are critical to pharmacy premises without a warrant]’s purpose of deterring violations. Clearly, it would have been only a minimal interference with their duties to obtain a warrant.”)

234. Anthony D. Moulton et al., The Scientific Basis for Law as a Public Health Tool, 99 Am. J. Pub. Health 17, 17 (2009) (distinguishing “interventional” public health laws, or those designed to address specific health conditions or risk factors, from “infrastructural” public health laws, or those that empower public health agencies and jurisdictions); Burris et al., supra note 109, at 175 (further delineating further a third category, “incidental public health law,” as comprised of those policies that impact population health although they are not on their face oriented toward health).

235. Burris et al., supra note 109, at 186.
effective policymaking, and this framework could be adapted to measure the success of those laws as well.

With respect to interventional laws, the level of certainty required to deem a regulation effective can vary. As a general matter, policymakers should aim to identify robust evidence, generated using optimal designs for establishing causality, to support a particular regulatory approach. In other words, does the law itself cause intended changes in targeted health outcomes? This question can and should be assessed at different stages. If a policy is being newly considered for implementation, regulators can consider evidence generated from comparable contexts to support law initiation. Alternatively, if the law is already implemented, regulators can focus on retrospective evaluations of the specific law as well as literature reviewing similar policies to determine whether the law should be retained, revised, or abandoned in favor of other policy options (Figure 1). Policymakers might also consider a package of laws or a law intervention paired with a different type of policy, such as a PDMP combined with prescriber education initiatives, in which case they should seek evidence to support the interactive effects of these multiple interventions.

Fortunately, in contemporary times, research on the effectiveness of public health law is increasingly available. Public health law research (“PHLR”) may be generated from within the legal academy, where there has been an explosion of empirical work in recent years, or from researchers in other social science fields (such as economics, health services research, political science, or public policy) that “use systematic methods within an explicit theoretical framework to collect and analyze data.” The translation of available scientific evidence (research) into

236. Id. at 175, 186; Burris & Anderson, supra note 101, at 109.
237. See J. Frank Wharam & Norman Daniels, Toward Evidence-Based Policy Making and Standardized Assessment of Health Policy Reform, 298 JAMA 676, 677 (2007) (identifying the need for systematic and ongoing evaluations of new health policies, the lack of which has led to the discovery of unintended consequences years after policy implementation, and presenting a framework for maximizing the effectiveness and ethical characteristics of health policy. The four essential elements identified in the framework include: “(1) [r]eview to ensure that the policy’s fundamental precepts are ethical . . . (2) [t]argeted pilot projects or timely retrospective assessments to address benefits and harms for stakeholders . . . (3) [s]tudies to determine if unintended consequences can be satisfactorily minimized . . . [and] (4) [f]eedback systems to maintain acceptable outcomes after policy implementation.”).
238. Burris et al., supra note 109, at 187.
239. See Nancy E. Kass, An Ethics Framework for Public Health, 91 Am. J. Pub. Health 1776, 1778 (2001) (observing that if a law is one of multiple and varied interventions that together are designed to reduce health risks and poor health, then interventions and studies must be designed with the awareness of the relationship between this program of interventions and ultimate reduction in morbidity and mortality).
240. For example, the Robert Wood Johnson Foundation funded a large Public Health Law Research initiative starting in 2008, to promote the scientific study of the relationship between laws and legal practices, and population health. Burris et al., supra note 109, at 171.
241. Id. at 172. In other words, they engage in “research.” Id.
public health policy and law, though a critical step, has historically been under-emphasized and constitutes a key criterion in the framework for evaluating the success of public health law (Figure 1).\textsuperscript{242} Moreover, evidence included for this translation should be selected with care, based on some hierarchy of rigor and robustness, to avoid regrettable health policy decisions based on inadequate or misleading research.\textsuperscript{243}

1. Outcome Variables of Interest

Intended outcomes that signify improved public health should be pre-defined by policymakers based on policy needs and targeted health risks. Public health targets of interventional laws can be categorized as primary and secondary outcomes, as described below. Other non-health-related or process-oriented benefits of legal interventions may accrue and are important, such as increased employment or community building in the process of carrying out the law, but these benefits are ancillary to the main goals of public health regulation.\textsuperscript{244} At the forefront of policymakers’ minds when considering public health regulation should be stated goals of improving population health.\textsuperscript{245}

\begin{footnotes}
\item\textsuperscript{242} See Jonathan E. Fielding et al., \textit{How Do We Translate Science into Public Health Policy and Law?}, 30 J.L. MED. \& ETHICS 22 (2002); see also Kass, \textit{supra} note 239, at 1780 (noting that due to the all-too-common situation in which PHLR findings are not translated into policy, benefits can fail to accrue from the research. Institutional review boards allow research to proceed with the expectation that a benefit to research subjects or communities will emerge. Without translation into policy, the risk-to-benefit ratio of the research will rarely weigh in favor of research proceeding). But see Burris \& Anderson, \textit{supra} note 101, at 107–08 (discussing the influential nature of PHLR on policymaking, in both a top-down and bottom-up fashion. Research funding so crucial to creating a robust PHLR base, however, has been disproportionately light in comparison to its wide use and impact). Some of this policy translation has failed to occur for reasons outside of the effectiveness evidence, such as budget constraints and public support. See \textit{infra} Part II.C.; see also Stephanie Zaza et al., \textit{Using Science-Based Guidelines to Shape Public Health Law}, 31 J.L. MED. \& ETHICS (SPECIAL SUPP.) 65, 66 (2003) (observing that legislators often shy away from evidence-based decisionmaking simply because they lack the knowledge to understand the science or because they lack confidence in the actual health benefits and effectiveness of a proposed intervention); Beverly Gard et al., \textit{Connecting Public Health Law with Science}, 32 J.L. MED. \& ETHICS (SPECIAL SUPP.) 100, 100 (2004).
\item\textsuperscript{243} See Sumit R. Majumdar \& Stephen B. Soumerai, \textit{“The Unhealthy State of Health Policy Research,”} 28 HEALTH AFF. W900 (2002) (discussing examples where researchers failed to adopt core principles of study design prerequisite to producing valid evidence, such as in the field of health information technology, which arguably led to the adoption of ineffective interventions. Worse, such an evidence-base could lead to the unintended consequence of population harm); see also Stephen B. Soumerai et al., \textit{How Do You Know Which Health Care Effectiveness Research You Can Trust? A Guide to Study Design for the Perplexed}, 12 PREVENTING CHRONIC DISEASE: PUB. HEALTH RESEARCH, PRACTICE \& POL’Y 1 (2015).
\item\textsuperscript{244} Kass, \textit{supra} note 239, at 1778. These incidental benefits may play a role in balancing of benefits and harms when considering whether regulation should be undertaken.
\item\textsuperscript{245} \textit{Id.} ("[A] reduction in morbidity and mortality need not and could not be the goal of every individual public health intervention or program; however, individual public health programs should not be undertaken that are not part of a larger package of programs whose combined goal is the reduction of morbidity and mortality.").
\end{footnotes}
Population health improvements can be measured in terms of primary outcomes or secondary outcomes. Primary outcomes are ideal measures of public health law effectiveness, as these directly reflect population health sought to be addressed by the law. Those considered of value to state policymakers include population-level morbidity and mortality measures. Pre-defined and “clinically significant” improvements in primary outcomes typically include reductions in diagnosed illnesses or deaths. In the PDMP context, primary targeted outcomes that signify improved health include reduced opioid-related overdoses, substance abuse treatment admissions, emergency department visits, and rates of addiction.

Secondary outcomes considered in public health law evaluations include proximal or intermediate outcomes that lie along the pathways of effect. Such proxy outcome variables include changes to environments and behaviors that expose individuals to health risks. PDMP proximal outcomes include changed prescriber and patient behavior, reduced controlled substance supply, and enhanced law enforcement or other surveillance activity. Changes in prescribing behavior indicative of reduced opioid misuse and overdose risk include, for example, lower rates of prescribing of high-morphine-equivalent dosages or less co-prescribing of opioids and benzodiazepines. Reduced rates of doctor shopping and drug diversion reflect changes in patient behaviors and/or law enforcement activity, from which lowered opioid adverse health effects theoretically follow.

While primary outcome measures are the ultimate measure of public health law effectiveness, a focus on intermediate (or secondary) outcomes is often necessary or reasonable for several reasons. First, the time horizon required to detect changes in population health often can be lengthy, because reduced morbidity and mortality attributable to a policy take time to manifest and measure. Take opioid misuse, for instance: Even if a PDMP reduces incident opioid addiction by erecting appropriate barriers to individuals obtaining prescriptions, reductions in population-level overdoses and mortality will take some time to manifest

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246. Burris et al., supra note 109, at 177–78; Kass, supra note 239, at 1777.
247. Id.
249. Logan et al., supra note 52; Wilsey et al., supra note 53; Dunn et al., supra note 53.
250. See Ctrs. for Disease Control & Prevention, supra note 67, for a definition of “doctor shopping.”
251. Burris et al., supra note 109, at 177–79.
252. Id.
because an already-addicted population will continue to experience these adverse health outcomes in the short-term. Also, ultimate health outcomes like opioid-related overdoses and hospitalizations are so rare that they must be observed over some time to detect policy-attributable changes, if there are any. It is thus more practicable and still telling to measure changes in prescribing patterns as a proxy for changes in the environment that ultimately would contribute to reduced opioid-related adverse health outcomes. Second, because ultimate health outcomes are often attenuated from laws or policies, understanding mechanisms that may lead to changes in these outcomes increases confidence that any effects observed are indeed attributable to a particular intervention. Access to and measurement of intermediary variables along the causal pathway avoids exclusive use of sometimes unpersuasive ecological studies, not uncommon to the PHLR literature.\(^5\)

2. *Assessing the Evidence*

Policymakers and researchers should explicitly identify the intended and/or anticipated pathways of effect from law to health outcomes. Research supporting or refuting aspects of this pathway can be located within a causal model,\(^5\) while gaps in the research base may also become apparent. But how can regulators identify empirical research worth including in the evidence base to either support or call into question public health laws? PHLR can be good science, but this is not true across the field. Furthermore, some laws lend themselves to evaluation better than others.\(^5\) Principles of research design can be used to guide policymakers—even those with limited empirical training—in identifying scientific evidence worth incorporating into policy.\(^5\)

A wide array of research methods are available for studying the effects of public health laws,\(^5\) ranging from qualitative research,\(^5\) to observational studies,\(^5\) to quasi-experiments,\(^5\) to randomized controlled...
experiments. Study design types within these broad categories of research can be characterized by the inter-related concepts of rigor, suitability for causal inference, and capacity to control for common biases.

A simplified hierarchy of designs can assist policymakers (ideally in coordination with researchers) in organizing PHLR to assess whether sufficient evidence exists to support law adoption or continued existence. The quantity of evidence is important here, although less so than the quality of evidence used to determine policy effectiveness and the generalizability of the evidence to the context in question. Table 2 suggests a way to organize studies, generally arranged from the strongest to weakest designs for causal inference (that is, to demonstrate that effects were caused by the policy studied). Randomized controlled experiments, the “gold-standard” for inferring a causal relationship between the law and an outcome, are quite rare in PHLR. Thus, natural experiments, or those where the intervention is not randomly assigned, are important to consider. The hierarchy presented is by no means exhaustive of the different types of studies that policymakers may encounter. Rather, it is intended as a starting point to assist in assessing the value of PHLR for policy incorporation.

261. Id. (“An experiment in which units are assigned to receive the treatment or an alternative condition by a random process such as the toss of a coin or a table of random numbers.”).

262. See, e.g., Mello & Zeiler, supra note 102, at 657–62 (providing a helpful catalogue of methodological approaches to the empirical study of health laws, from strongest to weakest designs, and also displaying the rating system used by the U.S. Preventive Services Task Force in considering whether sufficient evidence exists to support a preventive health measure); Soumerai et al., supra note 243, at 15.

263. Kass, supra note 239, at 1778–79 (suggesting that the greater the burdens posed by a program, the stronger the evidence base must be to support that a program will achieve its stated goals).

264. Because the law is “randomly assigned” to an intervention group and not the comparison group, the two groups theoretically are comparable on every other dimension. Therefore, the effects found can be attributed to the intervention rather than confounding variables. Confounding variables are those that could be related to both the intervention and the outcome variable, and could thus explain any changes in outcomes observed.


266. Shadish et al., supra note 259, at 171–206.

### Table 2. Hierarchy of Public Health Law Research Designs

<table>
<thead>
<tr>
<th>Category</th>
<th>Design Type</th>
<th>Brief Description</th>
<th>Strengths</th>
<th>Validity Threats</th>
</tr>
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</table>
| **Experimental**      | Randomized controlled trial      | Experiment in which units are assigned to receive a legal intervention or no intervention by a random process (e.g., toss of a coin or lottery). 268 | • “Gold standard” of evidence for identifying causal relationships.  
• If randomization is successful, the risk of unmeasured confounding variables is minimized. | • External validity (i.e. generalizability to other contexts, populations) is limited.  
• Quite rare in PHLR. |
| **Quasi-Experimental**| Interrupted time series          | Study that specifies a time at which an intervention occurred to “interrupt” the prior situation (e.g., time at which a law is effective) and observes outcomes over multiple time points pre- and post-interruption. 269  
Stronger design if it includes a comparison group or outcome not exposed to interruption. | • Displays graphically baseline trends and any changes in level or trend of the outcome variable at the time of interruption in the intervention group. | • Co-occurring interventions or indeterminate intervention time periods threaten validity.  
• Requires adequate observations pre- and post-interruption to establish seasonality or secular trends. |

267. Study validity can be characterized in a number of ways. This table and accompanying discussion focus on internal validity and external validity. “Internal validity” refers to the validity of inferences about whether observed covariance between treatment (intervention) and outcome variables reflects a causal relationship. “External validity” refers to the validity of inferences about whether the cause-effect relationship holds over variation in persons, settings, treatment variables, and measurement variables. Shadish et al., supra note 259.

268. Id. at 12–13.

269. Id. at 171–206.
<table>
<thead>
<tr>
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<th>Brief Description</th>
<th>Strengths</th>
<th>Validity Threats</th>
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<tbody>
<tr>
<td></td>
<td>Regression discontinuity</td>
<td>Study participants are assigned to a condition (e.g., health insurance coverage) on the basis of a cutoff score (e.g., income). Outcome variable is measured before and after assignment.(^{270})</td>
<td>• Minimizes differences (i.e., confounders) between groups, but for the cutoff score.</td>
<td>• Possible manipulation of the cutoff criteria (e.g., lying about income). • Generalizable only to populations close to the cutoff.</td>
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<td></td>
<td>Difference-in-differences (or) controlled pre-post</td>
<td>Study that compares outcomes before and after the intervention in a group exposed to an intervention compared to a group not exposed.</td>
<td>• Minimizes concern that effects merely reflect secular trends.</td>
<td>• Not accounting for differing baseline trends of groups.(^{271})</td>
</tr>
<tr>
<td><strong>Observational</strong></td>
<td>Uncontrolled pre-post</td>
<td>Study measures outcome variable before and after the intervention, but without a comparison group. Stronger design adjusts for potential confounding variables (i.e., uses multivariate regression).(^{272})</td>
<td>• Can rule out that effects are caused by other confounding variables rather than the law of interest by including these variables in the model.</td>
<td>• Cannot rule out that secular changes in the environment may introduce confounding variables responsible for effects.</td>
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\(^{270}\) Id. at 207–43.

\(^{271}\) Soumerai et al., supra note 243, at 15.

\(^{272}\) Mello & Zeiler, supra note 102, at 659–60; Soumerai et al., supra note 243, at 15.
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<tr>
<td>Cross-sectional designs</td>
<td>Study is descriptive only, measuring outcome variable at one point in time after the intervention (i.e., no baseline measure). Stronger designs adjust for confounding variables (i.e., use multivariate, instead of univariate or bivariate regression).</td>
<td>● Can describe the relationship between two variables. Precision in the measure of this relationship is enhanced if other variables that relate to both (i.e., confounders) are included in the model.</td>
<td>● No baseline measure(s) to provide a basis for comparison to outcome measures after the intervention, so no cause-effect relationship can be identified.</td>
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<tr>
<td>Qualitative Surveys, interviews, focus groups</td>
<td>Systematic content analysis (and sometimes quantitative analysis(s) of questions answered by multiple study participants.</td>
<td>● Can provide rich context to the factors affecting policy effectiveness.</td>
<td>● Subjective and susceptible to response bias.</td>
<td>● Not generalizable given typically small sample sizes.</td>
</tr>
<tr>
<td>Case studies</td>
<td>Description of policy intervention experience using a particular example or set of examples.</td>
<td>● Can provide rich information about particular example(s) of policy effectiveness.</td>
<td>● Example(s) selected may be unique and not generalizable to other contexts.</td>
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In addition to the above categories of designs for individual studies, other types of research aim to aggregate the findings of multiple primary studies and may be very valuable to policymakers. Systematic reviews use explicit methods to identify and critically review research relating to a particular outcome or set of outcomes and evaluate the strength of their findings to arrive at a general conclusion about the literature.\(^{277}\) Meta-analyses apply quantitative statistical analyses to pool and analyze findings from different studies to arrive at effect estimates of similar interventions across the literature.\(^{278}\) There are certain collaborative entities, such as the Cochrane Collaboration, Campbell Collaboration, and The Community Guide (of the Centers for Disease Control and Prevention) pioneering the work in these areas, although relatively few systematic-type

\(^{273}\)  Mello & Zeiler, supra note 102, at 658–60.
\(^{274}\)  Id. at 658.
\(^{275}\)  Id.
\(^{276}\)  Id.
\(^{277}\)  Id. at 661; Moulton et al., supra note 234, at 17.
\(^{278}\)  Id.
reviews are available relative to the numerous and varied types of public health laws in existence.\textsuperscript{279} Finally, “comparative effectiveness” studies do not necessarily encompass a specific study design type, but are defined as those that compare methods to “prevent, treat, and monitor a clinical condition or to improve the delivery of care,” and to inform decisionmaking by policymakers, among others.\textsuperscript{280} This definition can potentially include head-to-head comparisons of community- and population-level interventions to improve health conditions, such public health law approaches to treating prescription opioid misuse.\textsuperscript{281} Comparative effectiveness research, although in its infancy in the United States, is enjoying substantial federal funding\textsuperscript{282} and may be increasingly available and relevant to public health policymaking in the future.

3. PDMP Effectiveness

The body of research investigating PDMP effectiveness is beginning to generate information about whether these policies impact opioid-related primary health outcomes or proximal outcomes. Although the literature is growing and of a respectable size, many studies are not rigorous enough to warrant policy incorporation or replication, when compared against the hierarchy of research designs presented in Table 2. Several more recent studies, though, use long-term data from multiple states and assess specific PDMP features to draw conclusions about PDMP impacts. As these kinds of stronger studies proliferate, a clearer sense of PDMP effectiveness will emerge.

The Appendix Table catalogs key studies of PDMPs that shed light on identified primary and secondary outcomes.\textsuperscript{283} The Table summarizes the results of a search of social science and medical peer-reviewed literature\textsuperscript{284} for studies that measure the effects of state-based, electronic

\textsuperscript{279} See Moulton et al., supra note 234, at 17, for a detailed discussion and catalogue of systematic reviews available for interventional public health laws, as well as identification of notable gaps in the field; see also Mello & Zeiler, supra note 102, at 661.

\textsuperscript{280} Jane Hyatt Thorpe, Comparative Effectiveness Research and Health Reform: Implications for Public Health Policy and Practice, 125 PUB. HEALTH REP. 909, 909 (2010) (quoting the Institute of Medicine’s definition of comparative effectiveness research).

\textsuperscript{281} Id.

\textsuperscript{282} Id. at 909–10.

\textsuperscript{283} See supra Part II.B.1 for identification of these outcomes.

\textsuperscript{284} The helpfulness of unpublished PDMP evaluations, such as those conducted internally by states, for informing policy is limited by the widespread use of uncontrolled designs (that is, the studies fail to include a comparison group for reference when evaluating a particular PDMP) and contexts which are difficult to generalize across states. Further, these evaluations are not subject to the peer-review process. Also, evaluations of PDMPs in other countries, most notably Canada, are not included in the literature presented. Extrapolating results from these studies presents numerous challenges given differing health care systems, prescribing norms, patient behaviors, and PDMP features. See Yoko Murphy et al., Prescription Opioid Use, Harms and Interventions in Canada: A Review Update of New Developments and Findings Since 2010, 18 PAIN PHYSICIAN E605, E610–E611 (2015).
PDMPs. Included in the Table are the published analyses that employ quasi-experimental and observational designs (see Table 2). Although this review does not focus on them, qualitative studies can offer further insights into the relationship between PDMPs and health outcomes, and should supplement policymakers’ considerations. The Appendix Table should not be considered exhaustive of research bearing on PDMPs, but it includes the best candidate studies currently available for drawing causal inferences about the public health effects of PDMPs.

Although some have interpreted the PDMP literature as providing strong evidence of program effectiveness, the story is far from clear. We still lack a robust understanding of whether PDMPs reduce opioid-related overdose deaths, the ultimate health outcome of interest. The best available study uses national mortality data from the Centers for Disease Control and Prevention to find no association between PDMPs and overdose mortality. However, the data used is somewhat outdated (1999–2005) and spans over a period when PDMPs were not very robust. On the other hand, states with PDMPs do seem to experience fewer opioid-related treatment admissions and poisonings, based on two strong quasi-experimental studies. These analyses used national poisoning and treatment admission data cumulatively spanning from 1997 through 2009 and characterized states of study based on the

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285. There is a decent-sized body of literature on paper PDMPs, particularly focusing on their impact on benzodiazepine prescribing. However, this literature is not included in Appendix Table because paper PDMPs were a substantially different intervention from electronic PDMPs and were implemented during a different prescribing era. This literature thus may have limited generalizability to electronic PDMPs. See Tamara M. Haegerich et al., What We Know, and Don’t Know, About the Impact of State Policy and Systems-Level Interventions on Prescription Drug Overdose, 145 DRUG & ALCOHOL DEPENDENCE 34, 37–38 (2014), for a summary of these paper PDMP studies.

286. See, e.g. Prescription Drug Monitoring Program Ctr. of Excellence at Brandeis, supra note 69, at 3; Julie Worley, Prescription Drug Monitoring Programs, a Response to Doctor Shopping: Purpose, Effectiveness, and Directions for Future Research, 33 ISSUES IN MENTAL HEALTH NURSING 319, 326 (2012).

287. See Haegerich et al., supra note 285, at 37–38 (presenting an astute but limited review of the PDMP evaluation literature from 1946–2014). The authors conclude that “later studies . . . have not clearly established significant effects on total opioid prescribing or health outcomes with PDMPs. The largest limitation is the lack of detailed data on prescribing volume and patterns prior to PDMP implementation, which forced the use of cross-section, observational study designs. The effect sizes in the most recent studies have been small, making it conceivable that the differences are due to unaddressed confounding variables. There is yet little data to settle the question of whether specific actions of PDMPs (e.g., proactive reporting) add to their effectiveness.”). No rigorous systematic reviews study PDMP effects.


289. Id.

presence or absence of a PDMP. Reifler et al. went a step further and conducted sub-analyses of “superior” PDMP features—for example, program was in effect for a long time, sent unsolicited reports, and monitored comprehensive drug schedules—to find consistent results. Although further study of all primary health outcomes is warranted, these studies suggest that PDMPs are at least associated with decreased poisonings and admissions.

However, the mechanism of effect (or secondary outcomes) to explain reduced treatment admissions and poisonings is uncertain. The literature findings are mixed as to whether state PDMPs reduce opioid supply or prescribing. Several quasi-experimental studies use national opioid supply data spanning 1997 through 2008 to draw different conclusions regarding whether PDMPs are associated with reduced supply. Another quasi-experimental study conducted by Rutkow et al. found that Florida’s (voluntary) PDMP and pill mill law combined to drive modest decreases in total opioid fills and morphine concentration per dose (but not days’ supply of drugs) among the highest baseline users and prescribers, respectively. This strong analysis nevertheless suffers from an imperfect comparison state—Georgia, which had much lower prescribing at baseline—and an inability to isolate PDMP effects from those of another intervention. Weaker observational studies have drawn mixed conclusions about the effect of PDMPs on prescribing behavior and typically include small sample sizes, which limit their generalizability. Finally, there is very little evidence to suggest that PDMPs reduce doctor shopping or diversion, given that the few studies available on these outcomes do not lend themselves to causal inference.

Although the evidence base in support of PDMPs is growing, it requires significant further exploration and rigor. Weaknesses in the

291. Id.
292. Reifler et al., supra note 290.
293. See Rutkow et al., supra note 167.
294. Id.
literature are numerous. First, many of the more rigorous studies were conducted during a period when PDMPs were much weaker policies—for instance, through the early 2000s, programs typically monitored only Schedule II substances and were seldom queried—and thus need updating. Second, most studies are not rigorous, with no randomized controlled trials and few quasi-experimental studies available. Many studies also lack a comparison group, fail to measure outcomes before a policy went into effect, or include small sample sizes. Third, studies typically do not adequately account for many other, co-occurring prescription drug misuse policy interventions (such as pill mill laws, or opioid drug reformulations), and thus could falsely attribute effects to PDMPs instead of to these policies. Finally, mixed results could be attributable to divergent PDMP policies, which are typically not carefully characterized in studies. Studies could do a much better job of differentiating the PDMP interventions based on policy strength. 

A major drawback in PDMP studies, moreover, is the typical failure to account for actual levels of PDMP use by prescribers, which is still thought to be quite low. The median PDMP registration rate among providers who issued at least one controlled substance prescription was thirty-five percent from 2009–2012, and not all enrolled prescribers regularly query PDMPs. A recent national study found that only fifty-three percent of primary care physicians reportedly use their state’s PDMP. Although studies do suggest that PDMP awareness is high and that use is increasing over time, database queries are still sufficiently low that not incorporating this measure into studies may dilute any potential findings of effect. Also, further investigation is required into whether targeting increased use among a subset of high-volume users is the way to go.


298. Peter Kreiner et al., Bureau of Justice Assistance Prescription Drug Monitoring Program Performance Measures Report: January 2009 through June 2012 (2013). The percentage of prescribers who registered with the program (among prescribers who issued at least one controlled substance prescription in the prior three months) from 2009–2012 ranged from one to eighty-two percent based on the state. Id. at 15–16.

299. Lainie Rutkow et al., Most Primary Care Physicians Are Aware of Prescription Drug Monitoring Programs, But Many Find the Data Difficult to Access, 34 Health Aff. 484, 487 (2015).

prescribers, rather than all physicians or controlled substance prescribers, is warranted.

Because so many varied PDMPs have been implemented, policymakers and researchers should now look to evidence from multi-state, retrospective, comparative evaluations of their effectiveness. This evidence base needs to be updated, using longer-term data from before and after program implementation, now that sufficient time has passed since electronic PDMPs were implemented in many jurisdictions. Identifying appropriate comparison jurisdictions to enable quasi-experimental designs is somewhat of a challenge, given that forty-nine states have adopted their own PDMPs. Thus, time variation in PDMP adoption or implementation of certain features offers opportunities for comparative studies. For instance, the impact of relatively recent “strong” PDMP mandates on reduced opioid prescribing (requiring that prescribers check the systems regularly) shows promise in the handful of states that have adopted this policy lever, but requires additional empirical support. Also, comparison outcomes offer new avenues. For example, researchers can compare opioid prescribing for acute pain or headaches (indications where opioids have been shown to have limited utility) versus that for cancer (where opioid prescribing receives little scrutiny). One would hypothesize that PDMPs would reduce opioid prescribing in the former case, but not the latter.

The literature would benefit from a greater interdisciplinary focus by incorporating prescribers, pharmacists, program administrators, law experts, and health services researchers into informing and designing studies. Prescribers and pharmacists can provide clinical expertise germane to generating hypotheses about which PDMP features are likely to impact prescribing behavior, and to identifying appropriate comparison outcomes (see above example). Law experts can assist in categorizing PDMPs as robust or weak for comparison purposes, based on assessment of their policy features or enforcement. Policymakers can identify key outcomes of interest with regard to PDMP effectiveness. Program administrators can provide PDMP data for study and an understanding of the operational particulars of the programs, such as user-ship. And health services researchers can help to design the best studies feasible using available data.

301. Twenty PDMPs currently require that evaluations be reported to the legislature at least annually regarding the effectiveness of the programs and how they are impacting prescribing. Nat’l All. for Model State Drug Laws, supra note 68, at 11. These types of reporting requirements would offer a prime opportunity for policymakers to work with researchers and program administrators to enhance the evidence base, particularly by conducting studies using comparison states or comparison outcomes.

Finally, comparative effectiveness studies that compare PDMPs to other state interventions targeting opioid misuse, such as pill mill laws or access to opioid antagonists, would provide timely information to regulators regarding how to best invest their limited resources to tackle prescription opioid misuse. If PDMPs are implemented concurrently with other interventions, as was the case in Florida where PDMPs and other policies were pursued in quick succession, it may be practically difficult to separate out PDMP independent effects, and thus co-effects that are less generalizable to other jurisdictions must be considered.\footnote{See Rutkow et al., supra note 299 (studying the interactive effects of the Florida PDMP law and pill mill laws on opioid prescribing and total opioid volume). But see Delcher et al., supra note 297 (attempting to “control” for three co-interventions that impacted Florida—including the Florida pill mill law, DEA pill mill crackdown, and OxyContin reformulation—in the multivariate regression model).} Exploration into all these areas would assist policymakers to most effectively address prescription drug misuse and would serve to facilitate decisions regarding whether to retain, amend, or abandon PDMPs.

C. **Ethical Considerations**

A third broad inquiry for state policymakers asks whether ethical objections advise against public health law implementation or perpetuation. Even if a policy falls within the appropriate legal parameters for state action and seems likely, or is proven, to be effective in addressing the public health problem, there may be ethical objections that, if substantial, should bar its implementation or continued existence.

The community-level focus of public health calls for a set of justificatory considerations distinct from those used in clinical medical settings where the treatment and cure of individual patients are paramount.\footnote{Kass, supra note 239, at 1776 (“[C]odes of medical and research ethics generally give high priority to individual autonomy, a priority that cannot be assumed to be appropriate for public health practice…. A framework of ethics is needed, both to provide practical guidance for public health professionals and to highlight the defining values of public health, values that differ in morally relevant ways from values that define clinical practice and research.”). See Lisa M. Lee, *Public Health Ethics Theory: Review and Paths to Convergence*, 34 J. L. MED. & ETHICS 85, 87 (2012); James F. Childress et al., *Public Health Ethics: Mapping the Terrain*, 30 J. L. MED. & ETHICS 170, 170 (2002); Ross E.G. Upshur, *Principles for the Justification of Public Health Intervention*, 93 CANADIAN J. PUB. HEALTH 101, 101 (2002).} Instead, public health is primarily concerned with the well-being of populations, the broader social and environmental determinants of health, and prevention of ill societal health.\footnote{Upshur, supra note 304, at 101. The Institute of Medicine has defined public health as “what we, as a society, do collectively to assure the conditions in which people can be healthy.” INST. OF MED., THE FUTURE OF PUBLIC HEALTH 19 (1988).} Public health ethics frameworks that are practice-based emerged from an explicit recognition of these distinguishing features and unique moral considerations in public
Rather than try to provide a comprehensive philosophical approach to public health in practice, they rely upon the foundational values of rights (positive and negative) and social justice. Specifically, a code of public health ethics should emphasize the negative rights of citizens to noninterference, affirmative societal obligations to improve the health of the overall population, and the need to fulfill these obligations with special focus on the needs of the most disadvantaged. The principles proposed provide practical guidance for practitioners faced with public health-related ethical quandaries, including policymakers implementing public health laws.

Public health ethics principles set forth by Kass and Childress provide useful guideposts for the ethical implementation of public health laws. These conditions do not explicitly include, but instead complement and assume, favorable performance under those criteria already set forth herein (that is, the legal permissibility and effectiveness of a law designed to address a significant public health threat). Although not an exact algorithm to resolve conflicts between the goal of public health and other moral considerations, the following ethical conditions can help guide determinations about the appropriateness of public health interventions, and include: (1) proportionality; (2) minimal infringement; (3) fairness; and (4) public accountability. A brief discussion of the principles follows, and each is applied to the PDMP context—although it is important to bear

306. Id.
308. Kass, supra note 239, at 1777; Gostin, supra note 101, at 10–11 (discussing the social justice moral impulses that animate public health: (1) to advance human well-being by improving health; and (2) to do so by particularly focusing on the needs of the most disadvantaged. To satisfy these aims succeeds in bringing the good of health to all members of the population).
310. Kass, supra note 239, at 1777 (“Indeed, it is in great part because such power is vested in public health by law that a code or framework of ethics designed specifically for public health is so very important.”).
311. See id.
312. Childress et al., supra note 304.
313. Several of the justificatory conditions included in public health ethics frameworks proposed by other scholars actually overlap with legal requirements set forth in Part II.A supra, and the general requirement of effectiveness set forth in Part II.B supra. For example, James Childress et al. require that a public health policy be necessary, effective, and minimally infringing. Childress et al., supra note 304, at 173. Nancy Kass requires that a public health policy be effective at reducing mortality and morbidity and minimally infringing. Kass, supra note 239, at 1778–80. Richard Upshur requires that the program be minimally restrictive. Upshur, supra note 304, at 102. Minimal infringement is included in the present framework as an ethical principle because, depending on the type of policy, the law requires varying degrees of inquiry into the level of infringement and whether less restrictive alternatives are available. By including minimal infringement as an ethical principle, an inquiry must be made into the reasonableness of the intrusiveness of the law, not merely whether an obviously less restrictive means is available. See infra Part II.A.1.
314. Childress et al., supra note 304, at 173.
in mind that every state PDMP is unique and must be assessed on a case-by-case basis.

1. Proportionality

First, it is critical to demonstrate that the benefits of a public health law outweigh the costs or infringements associated with its implementation. Proportionality requires the weighing of societal benefits against burdens, in order to help assess whether a particular law is the best use of available resources. There are two dimensions of proportionality: one that considers societal benefits against individual burdens and another that considers societal benefits against societal burdens. Individual burdens, such as liberty and privacy, will be further addressed below in the discussion of “minimal infringement.” The societal benefits of PDMPs include changes in the primary and secondary outcomes outlined above: Reducing opioid-related adverse health outcomes, improving prescribing, and reducing diversion or doctor shopping. Societal benefits also include reduced expenditures associated with prescription drug misuse, as well as more intangible but potentially substantial benefits associated with reduced unemployment, absenteeism, and family disruption. Illicit drug use (a large percentage of which involves opioids) costs our nation $11 billion in health care costs and $193 billion annually overall—some of which expenditure could be saved if PDMPs work to curb this practice.

Societal burdens considered should include government costs of implementation and enforcement, as well as the opportunity costs of expending government and private resources, including political capital, instead of pursuing other policies to achieve the same ends. PDMPs are expensive to implement and finding the money to implement them has proven a challenge. Programs are funded by a combination of federal funds, private funds, and state-raised revenues, but often operate at

315. Id.

316. Two tools may be useful to policymakers for comparing costs to benefits. Cost-benefit analysis quantifies the costs and benefits of a course of action, comparing them using the same metric (often monetary value). Trying to quantify the benefits of a course of action can be challenging and controversial. Thus, in health interventions, cost-effectiveness analysis is often favored. Cost-effectiveness analysis divides the impact of a program (such as the percentage reduction in new cases of opioid addiction) by the cost of the program, generating a statistic termed the “cost-effectiveness ratio” (“CER”). CERs can be compared as between different policy interventions or programs. Abdul Latif Jameel, Introduction to Evaluations: Cost-Benefit/Effectiveness/Comparison Analyses, J-PAL, https://www.povertyactionlab.org/methodology/what-evaluation/cost-benefiteffectivenesscomparison-analyses (last visited Aug. 5, 2016). For further discussion of concepts and benefits of cost-effectiveness analysis for use by policymakers, see WORLD HEALTH ORG., MAKING CHOICES IN HEALTH: WHO GUIDE TO COST-EFFECTIVENESS ANALYSIS (T. Tan-Torres Edejer et al., eds., 2003), http://www.who.int/choice/publications/p_2003_generalised_eea.pdf.

317. Individual burdens are the focus of James Childress et al.’s discussion of the proportionality principle. See Childress et al., supra note 304, at 173–76.

impaired capacity when money issues arise. The programs are complex to operate—from the technical components (software is usually proprietary and owned by contracted software vendors) to ensuring confidentiality of information, to checking the accuracy of data inputted by dispensers, to promoting or enforcing use by prescribers, to facilitating optimal law enforcement use of the data. Substantial resources are required to facilitate these tasks. In the current environment, PDMPs constitute the dominant state approach to addressing prescription drug misuse, perhaps at the opportunity cost of investing money and political capital into other opioid misuse prevention efforts. In order to justify these societal costs, the health benefits and cost savings will need to be explicitly proven.

Moreover, unintended effects—both negative and positive—of regulation on population health outcomes or on non-health outcomes should be included in the calculus. There may be substantial negative unintended effects of PDMPs on populations, the extent of which are currently unknown. Although a few studies have suggested that electronic PDMPs will not have a “chilling” effect on appropriate prescribing, whether PDMPs lead some prescribers to cut back on or discontinue appropriate controlled substance prescribing, thereby exacerbating the under-treatment of pain epidemic or other maladies, remains to be seen. Studies of older paper PDMPs found that prescribers did, indeed, cut back on appropriate benzodiazepine prescribing, particularly among racial minorities—albeit this was a somewhat different, more forceful intervention than most electronic PDMPs. Some studies of early electronic PDMPs detected substitution from monitored (Schedule II) to non-monitored (Schedule III) opioids, which lends support to the possibility that PDMPs could change pain management treatment and possibly compromise clinical care. Differentiating between appropriate and inappropriate opioid prescribing, as well as how to best use PDMPs to identify doctor shoppers and diverters, places a substantial onus on prescribers (and pharmacists) in an area where clinical disagreements abound. Also, if opioid addicts are denied pills because prescribers check PDMPs, then they may turn in increasing numbers to heroin—

320. See Bachreri et al., supra note 295; Ringwalt et al., supra note 295.
322. See Paulozzi et al., supra note 288; Simoni-Wastila & Qian, supra note 296.
perverse, negative public health ramification.\textsuperscript{323} Many of these potential unintended consequences of PDMPs are substantial: Research should investigate whether they occur, and safety mechanisms should be instituted to prevent their matriculation. For instance, if opioid addicts are denied prescription drugs, addiction treatment options should be recommended and made available so that they are less likely to turn to heroin.

2. Minimal Infringement

As a corollary to the proportionality requirement, policymakers should seek to minimally infringe upon private interests and adopt the least restrictive means available. This ethical requirement can be viewed as complementary to the legal standards described in Part II.A.\textsuperscript{1} (and in some cases, of a higher threshold). This condition recognizes that there may be a number of means to achieving a public health end, and the least restrictive one should be favored—particularly when using powerful police powers that are presumptively coercive, the unintended consequences of which may be ill understood.\textsuperscript{324} Individual burdens or harms typically will fall into three categories: (1) risks to privacy and confidentiality; (2) risks to liberty and self-determination; and (3) risks to justice (which will be further addressed as a fairness consideration below).\textsuperscript{325} Even where a public health law may appear to restrict an individual’s liberty, its potential to enhance the liberty of other individuals warrants consideration, as positive externalities of public health laws abound.\textsuperscript{326}

PDMPs impose serious individual burdens on prescribers and patients. PDMP infringements on prescribers in their clinical practice are not insignificant, and prescribers have shown resistance to using PDMPs. Commonly cited prescriber objections to use include concerns about compromised patient satisfaction ratings (if checking a PDMP results in delays or denial of controlled substance prescriptions), unreimbursed time associated with using the program, burdensome enrollment procedures, cumbersome systems, and the information being viewed as unnecessary, incomplete, inaccurate, and/or untimely.\textsuperscript{327} To minimally

\textsuperscript{324} Upshur, supra note 304, at 102.
\textsuperscript{325} Kass, supra note 239, at 1779 (discussing the burdens more or less likely to arise from different public health activities). Regulations and legislation rank among the most intrusive approaches to public health—they are coercive because they typically impose penalties for noncompliance. Id.
\textsuperscript{326} Parmet, supra note 109, at 405.
\textsuperscript{327} Deyo et al., supra note 76.
infringe upon prescribers and the physician-patient relationship, these barriers should be reasonably addressed, for example, by automatically enrolling prescribers, improving integration into clinical workflow, and making data complete through frequent updates and interstate sharing (at least among neighboring states). Physicians should not be required to log into multiple, cumbersome systems, particularly absent reimbursement for their time. Use mandates adopted in twenty-two states raise a particularly interesting quandary: They infringe substantially on physicians, but they seem to increase use and possibly reduce opioid prescribing volume and misuse. Robust evidence, therefore, should be generated from within states that have enacted strong mandates (such as New York and Tennessee) to justify this policy lever before it is more universally adopted given significant prescriber objections. At the same time, PDMP features that serve to dis-incentivize prescribers from checking the systems, such as laws that explicitly provide prescriber immunity from liability for failure to check or exemption from any obligation to query the systems, should be abandoned to send the message that PDMPs ought to be checked frequently when prescribing monitored substances.

Infringements on prescribers and patients can also be substantial if their private prescription data are disclosed and/or used for law enforcement or regulatory purposes. As discussed in Part II.A, allowing law enforcement and licensing boards unfettered access to PDMP data—namely, to identify high-volume prescribers, doctor shoppers, or diverters absent a court-issued warrant or subpoena—toes the line, legally speaking. As an ethical matter, even if the law allows wide access in certain jurisdictions, patients and prescribers arguably should be afforded heightened privacy protections to allow uninhibited doctor-patient decisionmaking to occur. Also, strict data security protections, particularly when information flows across states, are necessary to minimize confidentiality concerns felt by opioid prescribers and patients. These include robust technological protections and penalties for disclosure by PDMP authorized users.

Effective PDMPs are likely to benefit third parties, despite other liberty infringements. Preventing addiction facilitates the enjoyment of

328. See Steven E. Weinberger et al., Legislative Interference with the Patient-Physician Relationship, 367 New Eng. J. Med. 1557 (2012) (citing other examples of doctor-patient interferences, such as restrictions on discussions about gun safety imposed in some states).
329. Twenty-one states currently require prescribers and dispensers to register with the PDMP. Nat’l All. for Model State Drug Laws, supra note 68, at 39.
330. See Haffajee et al., supra note 70.
331. Id.
332. Twenty-five states provide such immunity. Nat’l All. for Model State Drug Laws, supra note 68, at 38.
333. Sixteen states absolve prescribers from any obligation to check PDMPs. Id. at 37.
334. See infra Part II.A.4 for PDMP security recommendations.
certain liberties by others, such as avoiding the burden of being exposed to prescription opioids (which increases the likelihood of using and abusing drugs); avoiding caring for, watching suffer, or losing a family member or friend; avoiding exposure to HIV or other diseases spread by sharing infected needles; and avoiding increases in health insurance premiums (or taxes for public programs) generated by the costs of opioid-related hospitalizations or outpatient visits. These benefits suggest that a balance must be struck between making PDMPs minimally intrusive on individual liberties and making them effective—as mentioned in the mandate discussion above.

3. Fairness

A public health law should satisfy a basic requirement of fairness. Although fairness can be articulated using a number of different ethical frameworks, this discussion centers on the distributive justice theory originally conceived by John Rawls, which calls for the equitable distribution of benefits and costs among populations and communities. Kass and Gostin both ground fairness in distributive justice. According to Kass’s framework, distributive justice in public health obligates the government to ensure that interventions address the health of the least advantaged; Gostin goes a step further to assert that the negative consequences of interventions do not fall disproportionately on the least advantaged. Because the least advantaged are more vulnerable to public health threats as well as least likely to enjoy other social determinants of health, they arguably deserve special attention.

In the case of prescription opioid misuse, the least advantaged in society (as measured by socioeconomic status, for example) are more likely to lack robust education about the science and risks of addiction;
switch to cheaper and more easily accessed heroin when prescription pills are no longer available; have limited treatment options for addiction and overdose (such as naloxone access; substance abuse treatment); and lack access to social and other support services to address addiction and its consequences (such as access to clean needles). These considerations mean that PDMPs may be necessary to reduce inequalities, but also that any unintended negative consequences should not disproportionately fall upon the less advantaged. The paper triplicate form of prescription monitoring that preceded electronic PDMPs reduced problematic, as well as non-problematic, benzodiazepine use, and had disproportionate under-prescribing impacts in minority communities. The potential for these unintended consequences of electronic PDMPs should be closely monitored, to see if, for example, certain demographic groups are targeted as potential “doctor shoppers” and prescribed to less often as a result of these programs. Education and guidelines should accompany prescriber use of the systems to promote standardized and conscientious use of the data in a way that promotes good health and does not exacerbate social inequalities.

4. Public Accountability

Finally, the government should strive to be accountable to the public when implementing health laws on their behalf. Any public health law will infringe on some private interests and impose some social cost, and thus should be explained and justified to parties impacted. Policymaking transparency respects stakeholders as moral equals who deserve to be involved in the decisionmaking process. It also is essential to creating and maintaining public trust, an element so crucial to the acceptability and ultimate effectiveness of public health laws as well as the general legitimacy of future policymaking. Public health policies may be particularly susceptible to backlash—in the form of lack of public support, legal challenges, noncompliance, or opposition to future laws—if they are coercive. Policymakers should appreciate that different social groups may view public health laws from different perspectives and endeavor to gain diverse support. In pluralistic societies, where there is reasonable disagreement about principles that ought to guide priority setting in meeting population health needs given limited resources, different viewpoints should be understood and

343. Ross-Degnan et al., supra note 321.
344. Pearson et al., supra note 321.
345. Upshur, supra note 304, at 102; Childress et al., supra note 304, at 173.
346. Childress et al., supra note 304, at 173; Parmet, supra note 109, at 410.
347. Parmet, supra note 109, at 410.
348. Parmet et al., supra note 133, at 654.
respected, and decisionmaking made as clear and accountable as possible.\textsuperscript{349}

PDMP implementation and policies should thus be transparent to the public. Consideration of various features and program amendments should be made with the involvement of relevant stakeholders. The process of effectuating changes to the Massachusetts PDMP provides an example of excellent public accountability in public health lawmaking. In August 2012, Massachusetts enacted a law to automatically enroll practitioners in its existing PDMP and require that they consult the database when prescribing controlled substances to new patients. The Commonwealth solicited extensive feedback and held hearings concerning these changes. Through this process, prescriber objections to the breadth of circumstances for PDMP checks surfaced and were incorporated into the final implementation rules in the form of mandate exemptions.\textsuperscript{350} As a result, the cooperation and mutual respect between public health officials and Massachusetts providers was likely strengthened, which will facilitate future prescription drug misuse prevention endeavors. Prescribers will also be more willing to accept and comply with the PDMP mandate now in effect.

Conclusion

This Article seeks to simplify and systematize the inquiries critical for state policymakers when considering public health laws—like PDMPs—for implementation. Although various scholars have outlined factors that should guide policymaking, for instance in the public health ethics and PHLR literature, this Article is the first to synthesize the factors under three key criteria relevant to state regulation, suggest the policymaking junctures at which they should be applied, and apply them to PDMPs. PDMPs constitute the dominant policy adopted by states to address prescription opioid misuse—a profound public health challenge that is as complex in etiology as in the policy interventions available to combat it. PDMPs exemplify unstructured policymaking uninformed by

\textsuperscript{349}Id.; Upshur, supra note 304, at 102; Norman Daniels, Accountability for Reasonableness: Establishing a Fair Process for Priority Setting Is Easier than Agreeing on Principles, 321 British Med. J. 1300, 1300 (2000) (outlining key elements of a “fair process” for guiding public health decisions, including: transparency about the basis of a decision, appeals to common rationales that fair minded people can accept as relevant to meeting health needs fairly; and procedures for appealing/revising decisions).

\textsuperscript{350}Massachusetts Prescription Monitoring Program, Mass. Exec. Office of Health & Human Servs. (July 2016), https://www.drugabuse.gov/related-topics/trends-http://www.mass.gov/eohhs/gov/laws-regs/dph/proposed-regulations/prescription-monitoring-program.html#statistics (last visited Aug. 5, 2016). For example, the final rule limited mandate coverage to new patient prescriptions for Schedule II/III drugs or benzodiazepines, and included myriad exceptions, such as: prescriptions to hospice patients, inpatients, children, or in emergency situations; emergency department practitioners who do not anticipate writing a Schedule II-V prescription or who prescribe a five-day supply or less; and prescribers who face circumstances that render PDMP use impossible).
evidence or systematic guiding principles, and thus would stand to benefit from a more deliberate and organized path to success. The framework articulated herein guides PDMP recommendations, but is also generalizable to public health threats that exhibit characteristics similar to prescription drug misuse—namely, significant public health problems that can be addressed with a panoply of policy options.

To satisfy legality, effectiveness, and ethical criteria—markers of successful public health policymaking—PDMPs should follow certain guidelines. First, they should include strong confidentiality protections and be searchable by authorized health care practitioners (prescribers and dispensers) only, to comport with legal and ethical privacy requirements. Strong penalties for disclosure of information by authorized users, such as medical license suspensions for prescribers, are important to provide further confidentiality incentives. Law enforcement officials, licensing boards, and researchers should be provided with the data on a de-identified basis or pursuant to a court-issued warrant or subpoena. Second, PDMPs should be designed to infringe minimally on and assist maximally clinical practice. To this end, the data should be as close to real-time as possible, shared across neighboring states, and accurate. The databases should be easily searchable and, as soon as practicable, integrated into electronic medical records. Third, the programs ought to strongly incentivize prescriber participation, first by requiring registration and abandoning laws that provide immunity for failure to check or no obligation to query. Mandates with appropriate exceptions should be considered once further evidence of existing mandate efficacy (and possible unintended consequences) becomes available. Fourth, PDMPs should include user guidelines and education about how to use the data effectively. This would help to somewhat standardize opioid treatments across providers and prevent unintended consequences, such as under-prescribing for pain and burdening certain populations based on doctor shopping or diverter stereotypes. Finally, the existence and features of programs should be publicized to stakeholders, and any changes to their features going forward should incorporate diverse perspectives.

PDMPs undoubtedly show promise and should be pursued by the states, but they are still imperfect laws in need of adjustment and continued study. Effectiveness research should focus on evaluating

351. Researchers receive data on a de-identified basis in thirty-two states at present. Nat’l All. for Model State Drug Laws, supra note 68, at 22.
352. See Unger, supra note 223.
353. See Haffajee et al., supra note 70.
354. The Centers for Disease Control and Prevention has convened an expert panel to develop guidelines on opioid prescribing that will be available in 2016. These guidelines should help to develop additional clinical agreement in the clinical field and may be used to inform PDMP use, once available.
newer, strong PDMP features (such as mandates) using long-term, multi-state designs, when possible, that incorporate comparison groups or outcomes. Increased evidence linking PDMPs to improved prescribing, reduced diversion and doctor shopping, and reduced overdoses, in particular, is needed. Study of the interactive effects of PDMPs and other prescription drug misuse interventions is also desirable, as these interventions are often enacted together. Such evidence will further illuminate PDMP features appropriate for retention and replication. Incorporation of the recommendations articulated herein and ongoing re-evaluation of programs are both critical in order for PDMPs to fulfill their potential to curb the opioid misuse and overdose epidemic in the United States.
APPENDIX TABLE. LITERATURE REVIEW:
PUBLISHED STUDIES OF PDMP EFFECTIVENESS IN ADDRESSING
OPIOID MISUSE, 1990–2015

PART I. STUDY CITATIONS AND DESIGN TYPES

STUDY NO. 1. Delcher et al., supra note 297—Interrupted time series
with comparison groups.

STUDY NO. 2. Paulozzi et al., supra note 288—Multiple parallel time
series, comparing groups without interruption.

STUDY NO. 3. Reifler et al., supra note 290—Controlled pre-post.

STUDY NO. 4. Reisman et al., supra note 290—Multiple parallel time
series display with controlled pre-post regression analysis.

STUDY NO. 5. Jane E. Brady et al., Prescription Drug Monitoring and
Dispensing of Prescription Opioids, 129 PUB. HEALTH REPS. 139 (2014)—Controlled pre-post.

STUDY NO. 6. Paulozzi et al., supra note 288, and see design type above in
STUDY NO. 2.

STUDY NO. 7. Reisman et al., supra note 290, and see design type above
in STUDY NO. 4.

STUDY NO. 8. Rutkow et al., supra note 167—Interrupted time series
with comparison group.


STUDY NO. 10. McAllister et al., supra note 295—Un-controlled pre-post.

STUDY NO. 11. Rasubala et al., supra note 302—Un-controlled pre-post.

STUDY NO. 12. Ringwalt et al., supra note 295—Un-controlled post only.

STUDY NO. 13. Rutkow et al., supra note 167, and see design type above
in STUDY NO. 8.


STUDY NO. 15. Simoni-Wastila & Qian, supra note 296—Cross-sectional.

STUDY NO. 16. Surratt et al., supra note 296—Un-controlled pre-post.

The numbers associated with each study listed on this page can be used to
locate the data source, PDMP measure, findings, and methodological
comments related to that study below in Part II of this APPENDIX TABLE.
# Part II. Data Sources, PDMP Measures, Findings, and Methodological Comments

<table>
<thead>
<tr>
<th>Study No.</th>
<th>Data Source</th>
<th>PDMP Measures</th>
<th>Findings</th>
<th>Methodological Comments</th>
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<tbody>
<tr>
<td>Primary Outcomes</td>
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<tr>
<td><strong>Opioid-Related Overdoses</strong></td>
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</table>
| 1 | Florida Medical Examiners Commission drug-related death data (2003–2012). | Two measures of Florida PDMP: (1) binary indicator for pre- and post-PDMP; (2) continuous variable for number of health provider PDMP queries. | Significant. Oxycodone-caused mortality declined 25% in the month after PDMP. | **Strengths:** Control for three concurrent Florida prescription drug abuse interventions or co-interventions incorporate actual provider use of PDMP into intervention measure.  
**Limitations:** Effect observed is dramatic, particularly given that PDMP was not mandatory and use gradually increased after implementation. Ability to control for co-interventions using model chosen is unclear. Limited generalizability to other states. |
| 2 | Automation of Reports and Consolidated Orders System (“ARCOS”) data for drug distribution (1997–2005). National Center for Health Statistics & CDC drug overdose mortality data (1999–2005). | National sample that characterized states based on the presence at some time during the study period (19) or total absence (31) of a PDMP. | Not significant. PDMPs not associated with lower rates of opioid overdose mortality or lower rates of opioid consumption. | **Strengths:** Only national study to assess relationship between PDMPs and mortality, using supply as an intermediary mechanism.  
**Limitations:** Older study, conducted when PDMPs were not very strong. Combined all states that had PDMP at any time during study period into treatment group. Lacks before-and-after comparisons within states. |
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<tr>
<th>Study No.</th>
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<th>Findings</th>
<th>Methodological Comments</th>
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<tr>
<td><strong>Opioid-Related Treatment Admissions &amp; Poisonings</strong></td>
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<td>3</td>
<td>Research Abuse Diversion &amp; Addiction-Related Surveillance (“RADARS”) Poison Center (2003–2009). Opioid treatment surveillance data (2003–2009).</td>
<td>National sample that characterized states based on the presence or absence of a PDMP, by quarter.</td>
<td>Significant. PDMPs were associated with lower poison center intentional exposures and lower substance abuse treatment admissions.</td>
<td>Strengths: Conducted sub-analyses of superior PDMP features (that is, in effect for a long time, unsolicited reports, monitor drugs through Schedule IV) with consistent results. Limitations: RADARS data are self-reported.</td>
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<td></td>
<td>ARCOS data for opioid shipments (1997–2003). Treatment Episode Data Set (“TEDS”) data for opioid abuse admissions (1997–2003).</td>
<td>National sample that characterized states based on the presence (14) or absence (36) of a PDMP.</td>
<td>Significant. PDMPs were associated with fewer Schedule II opioid shipments and fewer opioid abuse treatment admissions.</td>
<td>Strengths: National sample with measures of both mechanisms (supply) and health (treatment admissions). Limitations: Outdated. Imprecise measures of PDMP laws, which were generally weak during this study period.</td>
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<tr>
<td><strong>Secondary Outcomes</strong></td>
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<td><strong>Opioid Supply</strong></td>
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<td>5</td>
<td>ARCOS data on opioid shipments, quarterly (1999–2008).</td>
<td>National sample that characterized states based on presence or absence of a PDMP, by quarter.</td>
<td>Not significant. State PDMPs not associated with changes in per-capita opioids dispensed.</td>
<td>Strengths: National sample with data over a long time period. Multivariable linear models adjust for demographics and geographic region. Limitations: Effect of PDMP varied hugely between states (66% decrease in Colorado, 61% increase in Connecticut), suggesting that measurement was imprecise.</td>
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<td>STUDY NO.</td>
<td>DATA SOURCE</td>
<td>PDMP MEASURES</td>
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<td>6</td>
<td>(see above)</td>
<td>(see above)</td>
<td><strong>Not significant.</strong> PDMPs not associated with lower rates of opioid consumption. States with PDMPs consumed more hydrocodone (Schedule III, less frequently monitored), suggesting substitution.</td>
<td>(see above)</td>
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<td>7</td>
<td>(see above)</td>
<td>(see above)</td>
<td><strong>Significant.</strong> PDMPs associated with fewer Schedule II opioid shipments.</td>
<td>(see above)</td>
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<td>8</td>
<td>IMS Health LifeLink LRx prescription claims data (July 2010–Sept. 2012).</td>
<td>Florida PDMP and pill mill law concurrent implementation.</td>
<td><strong>Significant.</strong> Florida PDMP and pill mill laws were associated with modest decreases in total opioid volume among highest baseline users.</td>
<td><strong>Strengths:</strong> Excellent data source and robust methods used to detect multiple effects among high prescribers and users. <strong>Limitations:</strong> Comparison group, Georgia, had different levels of opioid use and prescribing at baseline. Difficult to assess whether effects are largely attributable to PDMPs or pill mill laws (or the combination). Results have limited generalizability to other states.</td>
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<td>STUDY NO.</td>
<td>DATA SOURCE</td>
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<td>9</td>
<td>Survey of University of Toledo Medical Center Emergency Department Physicians ED, (June–July 2008).</td>
<td>Ohio PDMP (“OARRS”) consultation.</td>
<td>Significant. Prescribing was altered in 41% of cases: 60% of these cases resulted in fewer or no prescription painkiller being prescribed due to the patient’s number of previous fills; in 39% of these cases, physicians prescribed painkillers when they otherwise would not have.</td>
<td>Strengths: Detailed analysis demonstrates impact of PDMP information on a physician. Limitations: Small sample (n=179), limited to Ohio PDMP, so results have limited generalizability to other states. Results subject to response bias. No comparison group.</td>
</tr>
<tr>
<td>10</td>
<td>PDMP prescribing data of Emergency Department physicians of an urban tertiary care, university teaching hospital (2-week period in Feb. 2014 vs. 2-week period in Dec. 2013).</td>
<td>Florida PDMP (“EFORCSE”) consultation.</td>
<td>Not significant. PDMP data was not associated with any change in average number of controlled substances prescribed per patient.</td>
<td>Strengths: Conducted additional survey of physician impressions of PDMP data, which suggested that they felt it altered their prescribing. Limitations: Small sample (n=710 patients), limited to Florida, so results have limited generalizability. “Historical control” not true comparison group.</td>
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<td>STUDY NO.</td>
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<td>12</td>
<td>North Carolina PDMP data (2009–2011, divided into 6-month blocks).</td>
<td>Two measures of use of North Carolina’s PDMP: (1) number of providers who queried the PDMP, and (2) mean number of days on which providers queried.</td>
<td>(Slightly) significant. Slightly positive association between increased use of PDMP and number of opioid prescriptions filled, suggesting that the PDMP had no “chilling effect” on prescribing.</td>
<td>Strengths: Incorporated measures of PDMP use into intervention measures. Displays time trends. <strong>Limitations</strong>: Post-only study, after PDMP implementation (2005). No comparison group. Registration rates low (27%), so unlikely PDMP use explains overall prescribing trends.</td>
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<td>13</td>
<td>(see above)</td>
<td>(see above)</td>
<td>Significant. Florida PDMP and pill mill laws associated with modest decreases in MME per transaction and opioid prescriptions (1 year post), but not changes in mean days’ supply per transaction. Reductions limited to highest baseline prescribers.</td>
<td>(see above)</td>
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<td>14</td>
<td>Emergency department physicians of patients presenting in two academic medical centers with chief complaint of back pain, dental pain, or headache (Jun. 2011–Jan. 2013).</td>
<td>Massachusetts PDMP consultation.</td>
<td>Significant. After PDMP exposure, emergency department physicians changed plans to prescribe opioids in 9.5% cases: 6.5% patients received opioids that were not previously planned, and 3% no longer received opioids.</td>
<td><strong>Strengths</strong>: Careful survey of physician prescribing plans before and after consulting PDMP. <strong>Limitations</strong>: Small sample (n=38) of physicians, limited to Massachusetts PDMP, so results have limited generalizability. Responses subject to response bias. No comparison group.</td>
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<td><strong>Patient Behavior</strong></td>
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<td>15</td>
<td>Coordination of Benefits MarketScan claims data of Medicare eligible and their dependents (2007).</td>
<td>National sample that characterized patient exposure to PDMP or not (2007).</td>
<td>Significant. PDMPs were associated with decreased utilization of Schedule II opioids but an increase in Schedule III opioids, which were less frequently monitored, suggesting a substitution effect.</td>
<td>Strengths: Multi-variable regression analysis using large sample. Limitations: Medicare population results not generalizable to other age groups. PDMPs not characterized by the strength of features. Cross-sectional design shows association only.</td>
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For the strongest studies, see all studies cited in bold print.
Many State Laws Undermine Harm Reduction Strategies in the Opioid Crisis

Posted on July 20, 2018 by Petrie-Flom Center

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A protest sign seen at an ACT UP demonstration. Syringe exchange programs are a harm reduction policy that could have an impact on the opioid crisis. (Photo by riekhavoc/flickr)

This post is part of a symposium from speakers and participants of Northeastern University School of Law’s annual health law conference, Diseases of Despair: The Role of Policy and Law, organized by the Center for Health Policy and Law.

All the posts in the series are available here.

By Aila Hoss

Despite the increase in rates of opioid overdose death since 1999, the Opioid Use Disorder crisis shows little signs of abating. Recent reports from the Centers for Disease Control and Prevention indicate that overdose death rates have continued to climb in recent years. These sobering reports, along with others highlighting the impact of the crisis on children and families, the increase
in methamphetamine and cocaine use, and the economic costs to businesses, communities and our healthcare system remind us that “opiod addiction isn't the disease; it's the symptom.”

There is “no easy fix” to the social and economic determinants of health, such as poverty and housing insecurity, that are fueling this crisis. However, there are actionable, discrete, evidence-based policy measures that can be taken to reduce the rates of overdose deaths via harm reduction strategies.

Harm reduction strategies are those that minimize the injury associated with drug use, as opposed to decreasing drug use itself. In the context of opioid use disorder, these strategies include increased naloxone training and availability, syringe exchange programs, and overdose immunity protections. The evidence for these strategies have consistently demonstrated that they reduce incidence of HIV, hepatitis C, overdose deaths and do not lead to increased drug use.

And although secondary to the value of creating spaces where individuals with substance use disorder can safely access services, evidence also indicates that syringe exchange programs can also lead to increased access to treatment and are a more cost-effective measure than treating individuals with preventable injuries and illnesses.

Laws authorizing harm reduction strategies are increasingly being adopted in the United States. For example, in 2017, 49 states and DC had a naloxone access law compared to only 11 in 2013. As of 2016, 22 states and DC authorize syringe exchange programs compared to 16 the year before. In 2016, 37 states and DC have an overdose immunity law compared to 12 in 2013. Clearly, substantial progress has been made in codifying harm reduction strategies into state law. Yet, the structure and scope of these laws can also undermine the efficacy of these strategies.

Indiana provides an instructive example. The state law authorizing syringe exchange programs was passed following a devastating HIV outbreak in Scott County. It permits counties to establish syringe exchange programs when there is an epidemic of hepatitis C of HIV due to intravenous drug use and a public health emergency has been declared. Thus, the law aims to use syringe exchange programs to react to a crisis rather than prevent one. Additionally, the law only allows the program to operate for two years. Although the programs can be renewed, this makes them susceptible to political pressure to terminate the program. Only five syringe exchange programs are currently operating in a state with 92 counties, with other programs closing down in recent years.

Indiana’s drug paraphernalia law does not carve out an exception for individuals possessing syringes from syringe exchange programs. Violation of this law is a misdemeanor, but the state legislature recently amended the code to elevate the offence of possessing a syringe to a felony.

In May 2018, the Indiana Court of Appeals affirmed a lower court’s conviction of a man for possessing syringes he secured from a syringe exchange program:

“Thus, while [the defendant] could not be prosecuted for obtaining hypodermic needles from a needle exchange or participating in a needle exchange program, he could be found guilty of
possession of paraphernalia if there was evidence that he intended to use those syringes for unlawful ends.”

The requirement for epidemic and public health emergency, the short duration of the programs, and the ongoing risk of criminal liability for individuals utilizing the programs are all established by law and severely limit the potential public health impact of these programs. And this is not the only example of a harm reduction strategy in Indiana whose law undermines its efficacy.

**Fear of criminal liability is the primary reason discouraging individuals from contacting emergency services in an overdose situation.** Overdose immunity laws provide immunity from criminal liability during these situations and evidence indicates that these laws reduce incidence of overdose deaths. However, the scope of these laws varies substantially across states in terms of the individuals that they protect (bystanders or the individual experiencing the overdose) and the type of protections provided (drug possession, drug paraphernalia, probation violations, and so on).

Indiana’s overdose immunity law applies only to the bystander in the overdose situation and only for drug possession and paraphernalia charges. Uniquely, Indiana’s overdose immunity law only provides protections to bystanders that administer naloxone to the individual experiencing an overdose. Research does not suggest that the average bystander would have naloxone readily available in such a situation, despite laws that seek to increase its access. Here again, a viable, evidence-based harm reduction strategy fails in the face of restrictive legislative language.

Unfortunately, Indiana is not unique. **Many state laws fail to provide immunity for drug paraphernalia for syringes secured from syringe exchange programs** and many of these programs are subject to intense political scrutiny. Similarly, only 18 states provide protection from probation and parole violations in their overdose immunity laws.

A law that supports harm reduction is better than no law at all. But, it is not enough to have law promoting a harm reduction strategy if that law is so narrow in its application that it undermines the success of the strategy. Legislatures, in passing these laws, are clearly committed to advancing harm reduction strategies. In drafting them, however, policymakers must conduct a thorough and thoughtful analysis to ensure that these laws are as impactful as possible.

*Aila Hoss is a Visiting Assistant Professor at Indiana University Robert H. McKinney School of Law. With Professors Nicolas Terry and Ross Silverman, she is serving on a research team funded by the Indiana University Addictions Grand Challenge and co-authored the report Legal and Policy Best Practices in Response to the Substance Abuse Crisis.*

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PUBLIC USE OF RECREATIONAL MARIJUANA: A LEGAL LANDSCAPE OF STATE LAW

Dawn Pepin, JD, MPH, Aila Hoss, JD, Gillian L. Schauer, PhD, MPH, and Carissa Baker Holmes, MPH*

I. INTRODUCTION

In 2012, Colorado and Washington became the first states to legalize recreational marijuana for individuals aged twenty-one years or older and for sale in retail marketplaces.1 Shortly thereafter, in 2014, Oregon,

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1 See Steven W. Bender, Joint Reform?: The Interplay of State, Federal, and Hemispheric Regulation of Recreational Marijuana and the Failed War on Drugs, 6 ALB. Gov’t L. Rev. 359, 370–73 (2013) (explaining how Colorado and Washington legalized the recreational use of marijuana via ballot initiative, as did Alaska, the District of Columbia, and
Alaska, and the D.C. followed suit, with all three jurisdictions legalizing marijuana for users twenty-one years or older, and Oregon and Alaska also allowing marijuana sales in retail marketplaces.\(^2\) Although these jurisdictions have legalized marijuana for recreational use, federal law continues to ban the possession, use and sale of marijuana.\(^3\) However,


\(^{3}\) Under the Controlled Substances Act of 1970, marijuana is illegal and is currently classified as a Schedule 1 controlled substance. 21 U.S.C. § 812 (2012) (stating that Schedule 1 classification means there is “no currently accepted medical use in treatment”); Bender, supra note 1, at 365. As a result, the federal government maintains its authority to prosecute the production, distribution, sale, possession, or use of marijuana. Bender, supra note 1, at 365. In fact, until Attorney General Eric Holder entered office in 2009, raids of medical marijuana facilities by federal officials during the Obama administration were still common practice. Bender, supra note 1, at 378 (quoting Memorandum from David W. Ogden, Deputy Att’y Gen. to Selected U.S. Attorneys (Oct. 19, 2009), available at https://www.justice.gov/opa/blog/memorandum-selected-united-state-attorneys-investigations-and-prosecutions states). In 2009, the Attorney General issued a “Memorandum for Selected United States Attorneys” urging them to prosecute “significant marijuana traffickers” as opposed to those producers of and consumers of medical marijuana. Bender, supra note 1, at 378 (quoting Memorandum from David W. Ogden (Oct. 19, 2009)). Further, in 2013, the Department of Justice (“DOJ”) issued updated guidance confirming that the DOJ limited funds would be used only to address “significant threats” and that cultivation, distribution, sale, and possession would not be prosecuted unless it affected one of the government’s enforcement priorities set forth in the memorandum. See also Memorandum from James M. Cole, Deputy Att’y Gen. to Selected U.S. Attorneys, p. 1 (Aug. 29, 2013) available at
the Obama administration indicated that its position on recreational marijuana would be similar to that of medical marijuana, stating that there are more important uses of federal resources than prosecuting people who are in compliance with state law. In 2014, the Department of Justice ("DOJ") issued a memorandum from Deputy Attorney General James M. Cole in order to provide guidance to the states, and indicated that the DOJ will primarily “address the most significant marijuana-related cases,” which included eight priority areas such as preventing distribution to minors and preventing drugged driving. Thus, under the Obama administration policy, although consumption of marijuana is illegal at the federal level, individuals who act in compliance with state law will not currently be prosecuted for marijuana distribution, possession, cultivation, or sale offenses, provided that they do not threaten federal priorities.

Legalization of recreational marijuana in certain jurisdictions has prompted researchers to study the potential public health implications of recreational marijuana use, including dependence; cognitive impairment and mental health; respiratory issues, including lung


4 Cole, supra note 3; Bender, supra note 2, at 379–80 (quoting Paul Armentano, Will Obama Go After Legal Pot in Washington and Colorado?, ALTERNET (Dec. 19, 2012), http://www.alternet.org/print/drugs/will-obama-go-after-legal-pot-washington-and-colorado (interview by Barbara Walters)).


6 Cole, supra note 3, at 1.


8 See Nora D. Volkow et al., Adverse Effects of Marijuana of Marijuana Use, 370 NEW ENG. J. MED. 2219, 2219–21 (2014).

cancer;\(^{10}\) and occupational health\(^{11}\) and public safety, including motor vehicle accidents.\(^{12}\) The potential harm of secondhand exposure to combusted or aerosolized marijuana due to its use in public places is one such important public health impact. Laws that serve to limit the public use of tobacco have been effective in reducing tobacco-associated diseases.\(^{13}\) This success suggests the potential for parallels between laws limiting the use of marijuana in public in order to reduce secondhand exposure to marijuana and its byproducts.

This article offers a summary of legal provisions in Alaska, Colorado, Oregon, Washington, and D.C. that address the use of recreational marijuana in public, and how they can be used as a tool for other jurisdictions grappling with similar policy issues.\(^{14}\) First, this article provides the landscape of state laws\(^{15}\) that expressly address the public use of marijuana, particularly highlighting the importance of the definition of “public place” in the state’s ability to implement effective prohibitions on public use in all settings. Second, this article provides examples in states that have opted to implement additional public use limitations in certain settings. Next, this article outlines state-based

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\(^{10}\) See Volkow et al., supra note 8, at 2222.

\(^{11}\) See Volkow et al., supra note 8, at 2219; Nat’l Inst. on Drug Abuse, supra note 9; Schweinsburg, supra note 9 (discussing the influence of marijuana use on neurocognitive functioning in adolescents).


\(^{14}\) CDC’s Public Health Law Program (“PHLP”) collected statutes and regulations related to marijuana on January 7, 2016, using WestlawNext, a legal research database. Statutes and regulations were collected in the following jurisdictions: Alaska, Colorado, Oregon, Washington, and the District of Columbia. Quoted language from state statutory and regulatory provisions were pulled directly from WestlawNext. Because this is a constantly evolving area of the law, additional provisions have been added as the authors have become aware of new developments in the law. For summaries on current state marijuana laws not specific to public use provisions, see Marijuana Overview, Nat’l Conf. of State Leg. (Apr. 13, 2016), available at http://www.ncsl.org/research/civil-and-criminal-justice/marijuana-overview.aspx (last visited May 6, 2016); Recreational Marijuana Laws, Pub. Health Law Research (Nov. 1, 2014), available at http://publichealthlawresearch.org/product/recreational-marijuana-laws (last visited May 6, 2016).

\(^{15}\) For the purposes of this article, “states” includes D.C.
smoke-free air law provisions and their potential applicability in the marijuana setting depending upon the law’s definition of “smoke.” Finally, this article ends with a discussion of potential gaps in these legal strategies to address the use of marijuana in certain workplaces and at cannabis clubs.

II. STATE LAWS RELATED TO THE PUBLIC USE OF RECREATIONAL MARIJUANA

The public use of marijuana refers to various types of consumption – such as smoking marijuana or ingesting products that are made with marijuana or its derivatives – in both indoor and outdoor public settings. Alaska, Colorado, Oregon, Washington, and D.C. have enacted laws through ballot measures, statutes, and regulations limiting the public use of marijuana. These statutes and regulations include (1) express prohibition of public use of marijuana; (2) express prohibitions of use in certain facilities; and (3) existing smoke-free air laws with potential application to marijuana use.

A. Express Prohibitions of the Public Use of Recreational Marijuana

One legal lever used to prevent the public use of marijuana is each state’s marijuana public use provision. In general, the marijuana public use provisions specifically define the bounds of marijuana use, while broadly prohibiting consumption of marijuana in public. “Consumption” includes not only smoking or inhaling marijuana, but also ingestion or introducing marijuana into the body in any form. Generally, the term public includes places where a large group of people have access and might specifically include places such as parks, playgrounds, schools, hallways, lobbies, and places of business. However, each state has a different definition of “public,” and even within the same state, the definition within marijuana provisions might differ from the definitions in other sections of the state’s law, such as in

16 See, e.g., ALASKA STAT. ANN. § 17.38.900(3) (West 2016) (defining consumption as “the act of ingesting, inhaling, or otherwise introducing marijuana into the human body”).
17 See id. §§ 17.38.020 (4), .040; COLO. CONST. art. XVIII, § 16(3)(d) (West 2016); COLO. REV. STAT. ANN. § 18-18-406 (West 2016); OR. REV. STAT. ANN. § 475B.280 (West 2016); WASH. REV. CODE ANN. § 69.50.445 (West 2016); D.C. CODE ANN. § 48-911.01(a) (West 2016).
18 Id.
19 Id.
20 See, e.g., ALASKA STAT. ANN. § 17.38.900 (3) (West 2016) (defining consumption in its marijuana statutory code).
21 See, e.g., ALASKA ADMIN. CODE tit. 3, § 306.990 (West 2016).
smoke-free laws. Largely, marijuana public use laws define public use to mean both indoor and outdoor locations. Whereas, smoke-free public use provisions are more likely to be defined to include just indoor spaces, but are also more likely to indicate that restrictions apply in specific indoor settings such as workplaces, bars, and restaurants.

For example, Alaska law legalizes the consumption of marijuana for individuals aged twenty-one years or older, but it does not allow individuals to consume marijuana in public. In Alaska, “in public” is defined as “a place to which the public or a substantial group of persons has access” and “includes highways, transportation facilities, schools, places of amusement or business, parks, playgrounds, prisons, and hallways, lobbies, and other portions of apartment houses and hotels not constituting rooms or apartments designed for actual residence.” The regulations specifically exclude retail marijuana shops from the definition of “in public.”

Under Colorado law, recreational use of marijuana is permitted, but marijuana consumption that is “conducted openly and publicly or in a manner that endangers others” is not allowed. Furthermore, Colorado law states that “a person who openly and publicly displays, consumes, or uses two ounces or less of marijuana commits a drug petty offense.” Colorado’s marijuana law does not define public. However, Colorado’s official state web portal list places such as sidewalks, parks, businesses,

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22 Outdoor spaces are referenced in marijuana public use provisions. See, e.g., OR. REV. STAT. ANN. § 475B.015 (West 2016); OR. ADMIN. R. 845-025-101 (West 2016); WASH. REV. CODE ANN. §§ 69.50.445, 66.04.010 (West 2016). Whereas, the smoke-free provisions may specify that protections are for indoor places. See, e.g., COLO. REV. STAT. ANN. § 25-14-204 (West 2016); ALASKA ADMIN. CODE tit. 3, § 306.990 (West 2016); ALASKA STAT. ANN. § 18.35.305 (West 2016).

23 Id.

24 See ALASKA STAT. ANN. §§ 17.38.900 (3), (4) (West 2016) (defining “consumption” as “the act of ingesting, inhaling, or otherwise introducing marijuana into the human body”), ALASKA STAT. ANN. § 17.38.040 (West 2016); See ALASKA ADMIN. CODE tit. 3, § 306.990(a)(6)(West 2016).


26 ALASKA ADMIN. CODE tit. 3, § 306.990(6)(c) (West 2016) (”in public... does not include an area on the premises of a licensed retail marijuana store designated for onsite consumption...”).

27 COLO. CONST. art. XVIII, § 16; see also COLO. REV. STAT. ANN. § 18-18-406 (West 2016).


29 See, e.g., COLO. REV. STAT. ANN. § 18-1-901 (West 2016) (highlighting that Colorado’s recreational marijuana provisions do not define “public,” however, other sections of the Colorado code define public broadly); Colorado law does define public but does not necessarily apply to the marijuana section. See, e.g., 7 COLO. CODE. REGS. § 1101-9:1-5 (West 2016).
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restaurants, and bars as locations in which marijuana use is prohibited.  

In Oregon, it is “unlawful for any person to engage in the use of marijuana items in a public place,” and such violation results in a fine. A “public place” in Oregon is a place “the general public has access [to],” including common areas of hotels and apartments, roads, schools, public transportation, and outdoor spaces, such as parks and playgrounds, among other areas.

Likewise, under Washington’s marijuana laws, “[i]t is unlawful to open a package containing marijuana, useable marijuana, marijuana-infused products, or marijuana concentrates, or marijuana, useable marijuana, marijuana-infused products, or marijuana concentrates, in view of the general public or in a public place.” In Washington, “public place” is defined to include places such as public roads and highways, public transportation, school buildings and grounds, dance halls, theatres, stores, “those parts of establishments where beer may be sold,” “soft drink establishments,” common areas of hotels, as well as outdoor places, such as playgrounds, parks, and beaches.

Similarly, D.C. makes it “unlawful for any person to smoke or otherwise consume marijuana in or upon a public space.” Although the public use provision does not define “public space,” other provisions in the D.C. code define “public space” as a “publicly-owned property within the property lines of a street, park, or other public property, as such property lines are shown on the land records of the District, and includes any roadway, tree space, sidewalk, or parking within such property

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30 See Laws About Marijuana Use, COLO. OFFICIAL STATE WEB PORTAL, https://www.colorado.gov/pacific/marijuana/laws-about-marijuana-use (last accessed May 16, 2017; see also, Letter from David W. Broadwell, Assistant City Attorney, to the Denver City Council (Aug. 10, 2015), http://big.assets.huffingtonpost.com/denvercityattorneymemo1.pdf (regarding an explanation of initiated ordinance concerning the open and public consumption of marijuana) (demonstrating how local governments have taken action to define “public” under local law).

31 OR. REV. STAT. ANN. § 475B.280 (West 2016); OR. REV. STAT. ANN. §§ 153.012, .008 (West 2016).

32 OR. REV. STAT. ANN. § § 475B.280 (West 2016); OR. REV. STAT. ANN. § 475B.015 (West 2016); OR. ADMIN. R. 845-025-1015 (West 2016).

33 WASH. REV. CODE ANN. § 69.50.445(1) (West 2016). The controlled substances chapter of Washington’s statutory code does not provide a definition of the word “consume.” See id. §§ 69.50.401–465. In the alcohol and beverage control title in the statutory code, where the definition of public use is found, “consume” is defined to include “the putting of liquor to any use, whether by drinking or otherwise.” Id. § 66.04.010(10).

34 Id. § 66.04.010(36). See also WASH. REV. CODE ANN. § 69.50.445(2) (West 2016), “[F]or the purposes of this section, ‘public place’ has the same meaning as defined in RCW 66.04.010, but the exclusions in RCW 66.04.011 do not apply.”

35 D.C. CODE ANN. § 48-911.01(a) (West 2016).
Moreover, D.C.’s law expressly states that it is unlawful to consume marijuana in areas such as streets, parks, sidewalks, parking lots, vehicles in these locations or “[a]ny place the public is invited.” Individuals consuming marijuana in public are guilty of a misdemeanor and are subject to a $500.00 fine or imprisonment for no more than 60 days.

**Table 1:** Marijuana Public Use Laws

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Does state statute or regulation prohibit the public use of marijuana?</th>
<th>Citations</th>
<th>If yes, does the state's marijuana public use law provide a definition of public?</th>
<th>Citations</th>
</tr>
</thead>
</table>

36 See, e.g., id. §§ 10-1101.01(6), 10-1181.01(5).
37 Id. § 48-911.01(a).
38 Id. § 48-911.01(c).
B. Express Prohibitions on Public Use in Specific Facilities

In addition to the states’ general prohibitions on recreational marijuana use in public, all four states and D.C. have express prohibitions on marijuana use in certain facilities. These facilities fall into three main categories: (1) marijuana production, distribution, or retail facilities; (2) childcare facilities or schools; and (3) facilities for intellectually or developmentally disabled persons. Generally, consuming marijuana at these facilities might already be prohibited under the states’ marijuana public use laws; however, states have implemented additional protections for particular facilities. In some circumstances a violation of one of these laws may result in the facility

39 Laws regarding marijuana use prohibitions in detention facilities were not reviewed as part of this research. Laws that ban controlled substances generally in various facilities also were not reviewed as part of this research.

40 See, e.g., COLO. REV. STAT. ANN. §§ 12-43.4-402, -404, -901 (West 2016); 1 COLO. CODE REGS. §§ 212-2-402, .502, .602, .604, .702, .802 (West 2016); WASH. REV. CODE ANN. § 69.50.357 (West 2016).


42 See, e.g., COLO. REV. STAT. ANN. §§ 25.5-10-202(5), 25.5-10-214, 27-10.5-102(27), 27-10.5-301 (West 2016).

43 See § 306.990, supra note 17. See also ALASKA STAT. § 11.81.900 (defining a “public place” to include both schools and businesses); supra notes 27, 28, 29 (interpreting broadly the definition of public place in Colorado); OR. REV. STAT. ANN. § 475B.280 (in Oregon, it is any place in which the public has access); WASH. REV. CODE ANN. § 66.04.010 (West 2016) (in Washington, schools are explicitly listed in the definition of “public place” and public places also include “all other places of like or similar nature to which the general public has unrestricted right of access, and which are generally used by the public.”); D.C.’s definition of public place includes both public land and facilities, but also “[a]ny place to which the public is invited.”; D.C. CODE ANN. §§ 48-911.01, 10-1181.01, 10-1101.01 (West 2016).
The first type of facility where marijuana use may be explicitly prohibited is at marijuana production, distribution, or retail facilities. For example, in Washington, a marijuana retailer and its employees cannot consume any marijuana products on the premises of the facility.45 Similarly, in Colorado the consumption of marijuana at various marijuana retail, production, manufacturing, testing, transportation, and storage facilities is prohibited.46

The second type of facility where marijuana may be expressly prohibited is at childcare facilities. For example, in Oregon no person may smoke marijuana, including medical marijuana, on the premises of a childcare provider’s facility when a child is present or during business hours.47 Similar prohibitions exist for other types of childcare facilities in Oregon, such as childcare homes and centers.48 In Colorado, the Department of Human Services may deny, suspend, revoke, or put on probation a childcare facility’s license if an individual at the facility uses recreational marijuana.49 There may also be additional restrictions on marijuana use among individuals who care for children under state control. For example, in Washington, child-placing agency or adoption services staff may not have contact with children in state care when they are under the influence of marijuana.50 Correspondingly, in Oregon, foster parents must store marijuana and related paraphernalia in a secure location, and marijuana cannot be smoked in sight of “youth offenders.”51

Additionally, all five jurisdictions prohibit marijuana use in schools.52 For instance, in Colorado, the law goes beyond a general

44 See, e.g., COLO. REV. STAT. ANN. § 26-6-108(2) (West 2016).
45 See WASH. REV. CODE ANN. § 69.50.357 (West 2016) (stating that “[n]o licensed marijuana retailer or employee of a retail outlet may open or consume, or allow to be opened or consumed, any marijuana concentrates, useable marijuana, or marijuana-infused product on the outlet premises.”).
46 See, e.g., COLO. REV. STAT. ANN. §§ 12-43.4-402, 4-403, 4-404, 4-901(West 2016); 1 COLO. CODE REGS. §§ 212-2.402, .502, .602, .702, .802 (West 2016).
47 See OR. ADMIN. R. 461-165-0180 (West 2016).
48 See id. 414-350-0090, -205-0100, -300-0070 (West 2016).
49 See COLO. REV. STAT. ANN. § 26-6-108(2) (West 2016) (this prohibition applies to “the licensee, an affiliate of the licensee, a person employed by the licensee, or a person who resides with the licensee at the facility”).
50 See WASH. ADMIN. CODE § 388-145-1650 (West 2016).
51 OR. ADMIN. R. 416-530-0060, -0010 (West 2016) (defining a youth offender as a “person who has been found to be within the jurisdiction of the juvenile court under ORS 419C.005 for an act committed when the person was under 18 years of age.”).
52 See ALASKA STAT. ANN. § 306.990 (West 2016), (naming schools in Alaska’s definition of a public place); OR. REV. STAT. ANN. § 475B.280 (West 2016); WASH. REV. CODE ANN. § 69.50.445(1) (West 2016); WASH. REV. CODE ANN. § 66.04.010 (West 2016); D.C. Code Ann. § 48-911.01 (West 2016) (D.C. broadly defines “public place” to include
prohibition on marijuana use in public by requiring each school district’s board of education to adopt policies prohibiting marijuana use on school grounds by staff and students and that those policies are properly enforced. 53 Further, Washington’s laws ban recreational marijuana use in schools, 54 including on college campuses or during college activities. 55

The third type of facility where marijuana may be expressly prohibited is residential facilities for intellectually and developmentally disabled people. For example, in specific facilities operated by the Colorado Department of Human Services to support people with intellectual and developmental disabilities, 56 the consumption of recreational marijuana on the premises is banned. 57

C. Smoke-Free Laws

Smoking of any kind is harmful to the lungs, and marijuana smoke contains “toxins, irritants, and carcinogens” which are also found in tobacco smoke. 58 Of the four states and D.C. that have recreational marijuana laws, each jurisdiction has some level of smoke-free laws in place, originally passed to protect the public from the harmful effects of tobacco smoke. 59 In Washington, Oregon, Colorado, and D.C., smoking is prohibited at all times in all indoor areas of restaurants, private work places that the general public has access to); Colo. Rev. Stat. Ann § 25-14-103.5(3)(a)(I) (West 2016); see also id. at § 22-32-109.1.


57 Id. at § 27-10.5-301.


sites, and bars, and therefore these jurisdictions have been categorized by CDC as having comprehensive smoke-free laws.60 The U.S. Surgeon General has concluded that there is no risk-free level of secondhand smoke exposure, and therefore comprehensive smoke-free laws are the only way to fully protect people from the harms of secondhand smoke exposure.61 In contrast, Alaska’s smoke-free law requires only the establishment of designated smoking areas in restaurants, and has no statewide restriction for workplaces or bars.62

Smoke-free laws not only provide examples of potential legal interventions that can be used to address public use of marijuana, but also may govern the public use of marijuana in certain instances.63 However, the potential impact of smoke-free laws varies. Each state’s law defines “smoking” differently, and thus, by definition, smoke-free laws might or might not apply to marijuana. Colorado expressly incorporates marijuana into its existing comprehensive smoke-free laws by defining “smoking” as “the burning of a lighted cigarette, cigar, pipe, or any other matter or substance that contains tobacco or marijuana.”64 Similarly, Oregon’s smoke-free laws include both tobacco and marijuana smoke and vapor in its definitions.65 Conversely, D.C. limits its definition of “smoking” to “the act of burning a cigar, cigarette, pipe, or any other matter or substance that contains tobacco.”66

In Alaska and Washington, the matter is not as clear. These two

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62 ALASKA STAT. ANN. § 18.35.300 (West 2016) (“Smoking in any form is a nuisance and a public health hazard and is prohibited in the following vehicles and indoor places, except as allowed under AS 18.35.310: . . . . a food service establishment that has a seating capacity of at least 50 persons’’); ALASKA STAT. ANN. § 18.35.310 (West 2016) (“the prohibition set out in AS 18.35.300 does not apply to . . . a portion of a place or vehicle that is designated as a smoking section under AS 18.35.320’’); ALASKA STAT. ANN. § 18.35.320 (West 2016) (designation of smoking sections).
64 COL. REV. STAT. ANN. § 25-14-203(16) (West 2016).
65 See OR. REV. STAT. ANN. § 433.835 (West 2016); see also Or. ADMIN. R. 333-015-0200 (West 2016).
66 See D.C. MUN. REGS. tit. 20, § 2199 (West 2016).
states do not specifically reference marijuana by definition in their smoke-free laws.\(^{67}\) However, smoking is not specifically limited to tobacco by definition, either.\(^{68}\) In Alaska, the smoke-free laws apply broadly to “smoking in any form.”\(^{69}\) Washington’s smoke-free air laws define “smoking” as “the carrying or smoking of any kind of lighted pipe, cigar, cigarette, or any other lighted smoking equipment,”\(^{70}\) but its smoke-free air laws do reference tobacco smoke elsewhere in the section.\(^{71}\) It could be argued that Alaska and Washington’s broad definitions of smoking includes marijuana, yet it could also be argued that they do not. Express inclusion of marijuana in the definition of “smoking” could serve as a legal tool to prevent the smoking of marijuana in many public places.

Local governments can also have a role in smoke free laws, which in turn can impact the public use of marijuana.\(^{72}\) For example, Colorado’s smoke-free laws expressly state that local governments maintain authority to regulate smoking so long as they do not adopt regulations that are “less stringent” than the smoke-free laws.\(^{73}\) As a result, local governments have taken additional steps to prevent public use of marijuana. As an example, on January 1, 2015, the city of Golden, Colorado, issued an ordinance expanding on the state’s smoke-free law to include marijuana smoke, in areas such as “all city of Golden owned or controlled parks, open space, indoor or outdoor pools and associated spectator areas, indoor or outdoor sport or athletic fields and associated spectator areas, indoor or outdoor water parks and associated spectator areas.”\(^{74}\)

\(^{67}\) ALASKA STAT. ANN. § 18.35.300 (West 2016); WASH. REV. CODE ANN. § 70.160.020 (West 2016).

\(^{68}\) Id.

\(^{69}\) ALASKA STAT. ANN. § 18.35.300 (West 2016); see also id. § 18.35.305.

\(^{70}\) WASH. REV. CODE ANN. § 70.160.020 (1) (West 2016).

\(^{71}\) Id. § 70.160.075.

\(^{72}\) See, e.g., COLO. REV. STAT. ANN. § 25-14-207 (West 2016).

\(^{73}\) Id.

Table 2: Smoke-Free Air Laws

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Does state statute or regulation prohibit or regulate smoking in public?</th>
<th>Citations</th>
<th>Does state smoke-free air laws expressly include marijuana in its definition of smoking?</th>
<th>Citations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorado</td>
<td>Yes</td>
<td>COLO. REV. STAT. ANN. § 25-14-204 (West 2016)</td>
<td>Yes</td>
<td>COLO. REV. STAT. ANN. § 25-14-203 (West 2016)</td>
</tr>
<tr>
<td>Washington</td>
<td>Yes</td>
<td>WASH. REV. CODE ANN. § 70.160.030 (West 2016)</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>District of Columbia</td>
<td>Yes</td>
<td>D.C. MUN. REGS. tit. 20, § 2100 (West 2016)</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

III. DISCUSSION: “PUBLIC USE” IN WORKPLACES AND CANNABIS CLUBS

Although the differences are subtle at first glance, the locations in which smoking is restricted compared to where marijuana is restricted do not mirror one another, leaving some possible gaps. Smoking in public places is prohibited in each jurisdiction, but the definition of “public place” varies by state. Generally, in all states, “public place” is broadly defined to include publically accessible indoor spaces, such as healthcare
facilities,\textsuperscript{75} schools,\textsuperscript{76} and public transportation.\textsuperscript{77} Under most circumstances, marijuana public use laws restrict marijuana use at more places, including outdoor spaces, than the state’s smoke-free laws.

There are, however, some situations in which marijuana public use provisions are less explicit than smoke-free laws about where marijuana may be consumed, such as workplaces and private cannabis clubs.\textsuperscript{78} This section discusses the potential gaps in both marijuana public use provisions and state smoke-free laws that may allow the use of marijuana in locations such as workplaces and cannabis clubs.

A. Workplaces

To date, courts have generally upheld employers’ decisions to ban consumption of marijuana at work and to require drug screening, even in states where marijuana is legal.\textsuperscript{79} In affirming employers’ rights to establish policies regulating the use of and screening for marijuana, states also may have provided employers the discretion to allow marijuana use at work. A news story from Colorado reported that at least one employer is allowing marijuana consumption at work.\textsuperscript{80}

A discussion of Colorado law highlights this potential gap. The state’s marijuana public use provision allows for consumption of marijuana provided that consumption is not “conducted openly and publicly or in a manner that endangers others.”\textsuperscript{81} The regulations state that “a person who openly and publicly displays, consumes, or uses two

\textsuperscript{75} ALASKA STAT. ANN. §§ 18.35.300-365, 305 (West 2016); COLO. REV. STAT. ANN. § 25-14-204 (j) (West 2016); WASH. REV. CODE ANN. § 70.160.020; D.C. MUN. REGS. tit. 20, § 2199 (West 2016).

\textsuperscript{76} ALASKA STAT. ANN. § 18.35.300-365 (West 2016); COLO. REV. STAT. ANN. § 25-14-204 (1)(aa) (West 2016); WASH. REV. CODE ANN. § 70.160.020; D.C. MUN. REGS. tit. 20, § 2199 (West 2016).

\textsuperscript{77} ALASKA STAT. ANN. § 18.35.300-365 (West 2016); COLO. REV. STAT. ANN. § 25-14-204 (c) (West 2016); D.C. MUN. REGS. tit. 20, § 2199 (West 2016).

\textsuperscript{78} ALASKA STAT. ANN. § 18.35.300-365(West 2016); COLO. REV. STAT. ANN. § 25-14-204 (c) (West 2016); D.C. MUN. REGS. tit. 20, § 2199 (West 2016).


\textsuperscript{81} COLO. CONST. art. XVIII, § 16 (3).
ounces or less of marijuana commits a drug petty offense.” However, neither provision defines “publicly.” Without a definition of “public,” employers could argue that a workplace is not a public space. Therefore, with employer approval, the consumption of marijuana at a place of business could be permissible. Further, even though smoking marijuana inside a place of business would be explicitly prohibited through Colorado’s comprehensive smoke-free law, smoke-free laws in Colorado do not apply to the consumption of marijuana in other forms, such as edibles. In addition, Colorado’s smoke-free laws do not prohibit smoking in outdoor spaces, and thus smoking is often allowed outside of a workplace while still on work premises.

Unlike Colorado, the other jurisdictions with legalized recreational marijuana all define what “public use” means in their laws. However, only Alaska explicitly specifies that public use includes use at a place of business. Therefore, even though Washington and D.C. define “public” to include some specific places of businesses, such as hotels, restaurants, or places of amusement, those states do not use broad language to ban marijuana at places of employment as seen in comprehensive smoke-free laws. As a result, similar to Colorado, there are gaps in laws that allow employers to argue that their places of business are private, so employees could consume or smoke marijuana on work premises. Thus, there will likely be more examples of workplaces allowing marijuana consumption on the business premises. Given what is known about the effect of smoking on occupational health and safety, dependency, and respiratory health, in all likelihood, this will continue to be a challenge for states.

B. Cannabis Clubs

The existence of cannabis clubs can be partially attributed to the lack
of clarity in the definition of “public” space under the law. Under Colorado law, the argument for developing clubs is that they are not public places like bars or restaurants, but rather they are private social clubs. Although public use of marijuana is still prohibited in Colorado, the lack of definition of “public” in both the marijuana public use statute and the regulation leaves room for interpretation. Thus, club owners have argued that their clubs are not public places but rather private clubs. Further, even though marijuana smoke is explicitly prohibited at places of employment under Colorado’s smoke-free laws, there is an exception for a place of employment that is “not open to the public and that is under the control of an employer that employs three or fewer employees.” Club owners argue that they are not open to the public, but rather involve paid membership to a social club. In addition, clubs do not charge for marijuana; instead, they collect club dues and members can either access marijuana or bring their own.

While Colorado has made efforts at the state level to both ban and legalize cannabis clubs, the legislative response is happening largely at the local level. For example, in Nederland, Colorado, club owners were able to push for re-zoning to accommodate private clubs. By contrast,

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93 Id. at § 25-14-205.
96 See Jacob Sullum, Colorado Couple to Open First Officially Approved Cannabis
in September 2015, Colorado Springs passed Ordinance No. 15-76, which banned the development of any new marijuana consumption clubs. 97 In March 2016, the city council voted to ban the development of new clubs and to require that existing clubs be phased out. 98 Also, in March 2016, a ballot measure that would allow for cannabis clubs in Denver was submitted to the city. 99

Cannabis clubs have also been developing in Alaska, where retail stores are already exempt from public use laws. 100 Club owners argue that their clubs are not places of business but rather private clubs. 101 As a result, some cannabis clubs were developed. 102 Additionally, in early 2016, new regulations amended the definition of “in public” to exclude “the premises of a licensed retail marijuana store designated for onsite consumption.” 103 While these regulations would make Alaska the first state to legalize marijuana in a public place, as of the date of the writing of this article, “it continues to be a violation of AS 17.38.040 to consume marijuana in a public place, including unlicensed, unregulated marijuana smoking clubs.” 104 The lack of clarity about the status of the exemption


98 See Ordinance No. 15-76; see also Anleu, supra note 94.


101 D.J. Summers, Marijuana Social Clubs Dwindle in Alaska as Legal Confusion Reigns, ALASKA DISPATCH NEWS (Apr. 17, 2016), http://www.adn.com/cannabis-north/article/marijuana-social-clubs-dwindle-alaska-legal-confusion-reigns/2016/04/18/. For examples of cannabis clubs in other states see The Denver Post, supra note 94; Roberts, supra note 94; Anleu, supra note 94; Freed, supra note 94; Watts, supra note 95; Schrader, supra note 95.

102 Id.


104 Marijuana FAQs, Personal Use Questions: AS 17.38.040 Bans Public Consumption. How Is “Public” Defined?, ALCOHOL & MARIJUANA CONTROL OFFICE, https://www.commerce.alaska.gov/web/amco/MarijuanaFAQs.aspx; see also Emily Gray
has contributed to a reduction of cannabis clubs in Alaska. In addition, although the smoke-free provisions in Alaska regulate smoking at places of employment, exemptions allow for the development of smoking sections. Therefore, it is unlikely that, even if Alaska’s smoke-free law applies to marijuana smoke, it would limit development of cannabis clubs. Because of this ambiguity, local governments have begun to take steps to regulate marijuana clubs. For example, the city of Wasilla, Alaska, already bans cannabis clubs, and in January 2016, Anchorage proposed similar regulations within its city limits.

Alternatively, both Washington and D.C. have taken steps to ban cannabis clubs through marijuana public use laws. Washington explicitly makes it illegal to maintain or help someone else to maintain or conduct a marijuana club. Washington’s law also makes it clear that a public place is not just one that charges admission but rather one that receives “any pecuniary gain.” In D.C., a bill that passed on April 5, 2016 clarified that a private club is considered “a place to which the public is invited,” so consuming marijuana at a club is consuming marijuana in public, and is therefore illegal.


See ALASKA STAT. ANN. §§ 18.35.300 (2), .310 (A)(1), .320 (West 2016).


See WASH. REV. CODE ANN. § 69.50.465 (West 2016) (“It is unlawful for any person to conduct or maintain a marijuana club by himself or herself or by associating with others, or in any manner aid, assist, or abet in conducting or maintaining a marijuana clubFalse ‘Marijuana club’ means a club, association, or other business, for profit or otherwise, that conducts or maintains a premises for the primary or incidental purpose of providing a location where members or other persons may keep or consume marijuana on the premises.”).

See id.

In Oregon today cannabis clubs and cafes are now closed. However, initially the law was not as clear. Oregon’s marijuana public use laws prohibit marijuana consumption in a public place.\(^{112}\) “Public place” is often broadly defined as “a place to which the general public has access.”\(^{113}\) When examples are provided, they include common spaces in hotels and public transportation, however, bars and restaurants are not explicitly referenced.\(^{114}\) In addition, until 2015, Oregon’s smoke-free laws did not explicitly include marijuana smoke.\(^{115}\) As a result of the public use law failing to explicitly ban marijuana use in places such as restaurants and bars, in combination with a smoke-free law that failed to include marijuana smoke within its prohibition on smoking in bars and restaurants, some business owners interpreted this as a potential loophole allowing for the consumption of marijuana in cannabis clubs and cafes.\(^{116}\)

Unlike Washington and D.C., Oregon has limited development of cannabis clubs through the use of the state’s smoke-free law rather than its marijuana public use statutes. When marijuana was explicitly added to Oregon’s smoke-free law, smoking and vaporizing marijuana in all places of employment, including cannabis clubs and cafes, became illegal.\(^{117}\) As a result, cannabis clubs and cafes, which are considered places of employment, are now closed.\(^{118}\) Although both tobacco smoke shops and cigar bars are allowed in the state, an amendment to a law considered in 2016 that would have exempted cannabis clubs and cafes did not pass.\(^{119}\)


\(^{115}\) 2015 Oregon Laws Ch. 158 (H.B. 2546).


\(^{119}\) See Or. Rev. Stat. Ann. § 433.850 (2)(c)-(d) (West 2016); SB 1511-4, LC 180 (Or. 2016), https://olis.leg.state.or.us/liz/2016R1/Downloads/ProposedAmendment/8388; see also, Noelle Crombie, World Famous Cannabis Cafe to Close Due to Oregon’s Clean Air Law, OREGONIAN (Feb. 29, 2016), http://www.oregonlive.com/marijuana/index.ssf/2016/02/world_famous_cannabis_cafe_to.html (“Sen. Floyd Prozanski, D-Eugene, introduced an amendment during the Legislature’s 35-day session that would have exempted cannabis cafes from the clean air law, but it did not have enough support to pass.”).
IV. CONCLUSION

Given the serious public health implications of the public use of marijuana, the first states to legalize recreational marijuana have used various legal levers to limit public use. The primary mechanism is through instituting public use limitations in the new marijuana laws. However, the way that public use is defined within these provisions can have a significant impact on the use of marijuana in various settings such as workplaces and cafés. As a result, states have looked to other legal interventions to reduce the public’s environmental exposure to marijuana, including specific prohibitions in certain facilities as well as smoke-free laws.

Looking to the future, as other states consider legalizing recreational marijuana, policymakers might consider these various legal frameworks as potential tools to reduce the public use of marijuana and to identify potential gaps in coverage in certain settings. Policymakers also may want to closely consider the definition of public use within any newly written marijuana public use law in order to ensure that marijuana can be easily regulated in all of the lawmakers’ intended settings. In addition, the comprehensive regulation of marijuana can be achieved with additional laws in other sectors, such as smoke-free air laws.
"Cops in Lab Coats and Forensics in the Courtroom"

Valena E. Beety*

SANDRA GUERRA THOMPSON, COPS IN LAB COATS: CURBING WRONGFUL CONVICTIONS THROUGH INDEPENDENT FORENSIC LABORATORIES (Carolina Academic Press 2015)

“Science is a truth-seeking instrument . . . but is the court system?”

INTRODUCTION

Sandra Guerra Thompson’s book, Cops in Lab Coats: Curbing Wrongful Convictions Through Independent Forensic Laboratories, debuts when forensic flaws are reaching a pinnacle of exposure. The Federal Bureau of Investigation (FBI)—arguably the best of the best in the forensics world—has conceded that it is currently re-examining thousands of closed cases for errant and faulty forensic testimony. While the FBI has conducted this type of review on a previous occasion, this time the review is public, and all of us—including criminal defendants—know about it. Law enforcement’s past cover-ups of faulty forensics is at the heart of Thompson’s book: she posits that forensic labs should be independent rather than controlled by prosecutors and used to convict persons no matter the human cost. In brief, Thompson’s book captures the recent history of forensic validation—and invalidation—and its critical impact on the criminal justice system.

Cops in Lab Coats traces the recent history of forensic reform in the context of the criminal justice system and exposes the damage inflicted on that system by forensic fraud. Thompson’s inclusion of wrongful convictions in her discussion mirrors the national conversation. Innocence is the primary impetus to ensure that forensic disciplines become more reliable, forensic findings more testable, and forensic inquiries more independent.

Forensic disciplines arose out of crime scene investigations and law enforcement’s search for compelling evidence to convict. In this unusual

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development, forensic results were not tested in a lab but rather in the field. Their reliability and importance were indicated by the rate of convictions for crimes, not by impartial scientific assessments. Given the intimate—indeed integral—association between forensics and law enforcement, “crime labs” have been influenced by cognitive bias, confirmation bias, and an impetus to create results for the prosecution, and not for the impartial search and study of science. This slant has led to the widespread use of ambiguous evidence in the race to convict individuals, including innocent men and women.

Thompson argues that police crime laboratories should be converted to independent forensic laboratories and that such independence would reduce cognitive bias and enhance laboratory funding opportunities. Under the current regime, police administrators oversee scientific laboratories—a role far beyond their scope of education. (Pp. 181–82.) As Thompson potently explains, “[t]he truth is simple: One cannot properly supervise what one does not understand.” (P. 182.) *Cops in Lab Coats* documents the overt fraud and perjury of forensic findings that have historically plagued the criminal justice system as a result of a “scientific” work environment aligned with law enforcement and prosecution. This alignment taints findings in ambiguous test results through unconscious cognitive bias. (P. 183.) Consistent with the National Academy of Sciences’ (NAS) seminal report, *Strengthening Forensic Science in the United States: A Path Forward* (the “NAS Report”), Thompson establishes that such cognitive biases can cause even the most ethical and learned analyst to report findings that relegate an innocent person to prison. (P. 183.) Independent crime labs and the regular use of protocols frequently deployed in other scientific laboratories and university research labs, such as sequential unmasking and blind verifications, can minimize the impact of cognitive bias and confirmation bias. (P. 186.)

Notwithstanding the resistance to wresting labs from police control that Thompson details (p. 183–187), the NAS Report’s overall goals regarding forensic reform are increasingly within reach. Crime labs are adopting more rigorous protocols, federal oversight is growing, and federal funding supports greater research. Indeed, the National Institute of Standards and Technology (“NIST”)

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2 Thompson discusses cognitive bias as motivational bias from group affiliation by analysts being police department employees, including departmental pressures from being subordinate to the Chief of Police. (Pp. 130–31.) She discusses confirmation bias as an unconscious tendency to “seek, perceive, interpret, and create new evidence in ways that verify their preexisting beliefs.” (Pp. 133 (citing Saul M. Kassin et al., *The Forensic Confirmation Bias: Problems, Perspectives, and Proposed Solutions*, 2 J. APPLIED RES. MEMORY & COGNITION, 2013, at 44.).)


hosted the first-ever scientific conference on crime lab error management in 2015, an impressive step forward given that many forensic scientists would have been ashamed to admit crime lab error just a few years ago. In short, the question is no longer whether, or how, but how soon we can learn more and strengthen these disciplines.

Despite the advancement in forensic disciplines and research, a significant obstruction remains to restoring reliability in our criminal justice system: the courts. Judges, defense attorneys, and prosecutors continue to misuse, mishandle, and misrepresent forensic findings with impunity. (Pp. 109–115.) Unfortunately, the wave of reform attendant to the forensic sciences seems to have eluded lawyers.

It seems self-evident that the myriad wrongful convictions attributable to forensic fraud would motivate meaningful, systemic reform. Indeed, Thompson deftly demonstrates throughout her book how forensic malfeasance has curtailed and compromised the liberty and lives of real people. Yet, criminal judges and attorneys appear unmoved by the possibility of a wrongful conviction due to faulty forensics. Practices such as admitting evidence without verification, relying on standards created by other courts, and refusing Daubert hearings on the reliability of expert testimony force us down the same dangerous path where the fact-finder is left to rely entirely on an individual forensic analyst. It is in these proven unreliable waters that, no matter the advancement in the field, technicians are permitted to dry-lab results, falsify their credentials, and testify beyond the scope of their ambiguous findings. (P. 171.)

*Cops in Lab Coats* challenges our legal community to do what the forensic community has already done: wake up and take notice of the significant problems and responsibilities attendant to the non-surgical use of forensics in the courtroom.

This review of Thompson’s book proceeds in three parts. Part One recounts the recent history of forensic science and criticisms of the field as developed by Thompson. Part Two explains how forensic faults have contributed to or caused
wrongful criminal convictions, as noted both by Thompson and in my own experience. Finally, in Part Three, the essay shifts to question and review the role of the judiciary in both permitting faulty forensics to pervade the courtroom and contributing to wrongful convictions.

While Thompson provides the background on a troublingly apathetic judiciary, I hope this book review lends some ideas and encouragement for the path forward. Members of the forensic community are striving to meet the NAS Report standards and reform their disciplines from within. In discussing wrongful convictions and the role of courts in these flawed forensics cases, our own legal community may be encouraged to take action: to build from the foundational reform insights of *Cops in Lab Coats* and accept the remaining responsibility that Thompson lays at the feet of the court.

I. RECENT FORENSIC HISTORY: THE NAS REPORT AND UNCOVERING FORENSIC FAULTS

“[The study] illustrates not only the imprecision of microscopic hair analyses, but also the problem with using imprecise reporting terminology such as ‘associated with,’ which is not clearly defined and which can be misunderstood to imply individualization.”

—NAS Report

Thompson begins her analysis by highlighting the National Academy of Science’s pivotal 2009 report, *Strengthening Forensic Science in the United States: A Path Forward*. The NAS Report jolted the forensics world by documenting how many forensic professionals were over-representing their accuracy in the courtroom. Since release of the Report, media outlets have captured the tragic and salacious stories of men and women wrongfully convicted as the result of faulty “forensics” testimony: a dentist—or “forensic odontologist”—found conclusive human bite marks that were in reality bug bites, an arson specialist testified sixty gallons of gasoline were used to torch a home that burned down without any gas accelerant, and a medical examiner opined he could ascertain that an assault gun was held by two people, merely by evaluating the bullet wound. Forensic science is incredibly useful, but its findings have not only

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4 NAS REPORT, supra note 3, at 161.


9 Edmonds v. State, 955 So. 2d 787, 824 (Miss. 2007).
been overstated, they have been procured by poorly trained individuals without the rigor of developing the science in a lab, rather than in a courtroom. Thompson’s title is appropriate: many forensic analysts view themselves as cops in lab coats, reaching their results after consulting with prosecutors on the theory of the case and the suspected culprit, rather than after applying the scientific method in a blind setting.

A. The NAS Report and Individualization

Thompson appropriately identifies the “true battleground:” individualization. Individualization is the key area of forensic testimony that is exaggerated, as analysts far too frequently claim a perfect match through the forensic evidence. Yet for which forensic disciplines is individualization even a scientific possibility?

Thompson discusses the findings of the NAS Report as it examined a number of forensic disciplines separately to determine their capacity for individualization, how they may best be used, and how useful they are for the criminal justice system within a determination of reliability. Ultimately, the NAS Report concluded that no forensic discipline—save DNA analysis—could make an exact match, i.e., individuate, despite decades of representation in the courtroom of exact matches in the form of hair, bullets, bite marks, footprints, and fingerprints.

To determine an exact match, analysts must have objective criteria against which to evaluate the evidence at issue. While DNA evidence provides objective criteria, fingerprint evidence, for example, does not. With DNA, the standard protocol is to test a sequence of base pairs at each of thirteen DNA segments. The standard analysis for fingerprints, the ACE-V (Analysis, Comparison, Evaluation, and Verification) accepted process, relies instead on human interpretation of ridges, whorls, and markings. ACE-V “does not specify particular measurements or a standard test protocol, and examiners must make subjective assessments throughout.” Because of its subjectivity, no empirical data can be developed to reliably determine population statistics (frequency) or a match certain. An analyst can only find “sufficient [features] in agreement.” How many features in agreement are sufficient remains an open question. As noted by the NAS Report,

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10 The disciplines analyzed by the 2009 NAS Report were biological evidence (DNA analysis), analysis of controlled substances, fingerprints (friction ridge analysis), pattern/impression evidence, tool mark and firearm identification, hair analysis, fiber evidence analysis, questioned document examination, paint and coatings analysis, explosives and fire analysis, forensic odontology (bite marks), bloodstain and pattern analysis, and digital and multimedia analysis. NAS REPORT, supra note 3.

11 Id. at 7.

12 Id. at 139.

13 Id. at 138.
“sufficient agreement” is not a measurable standard that can be exactly replicated. Yet forensic disciplines are still valuable even when they are not as objective as DNA evidence. Yet Thompson hits the nail on the head: forensics were designed to be self-serving because they did not evolve separately from the purpose and goal of prosecution. (P. 109.) Forensic findings are presented in court as neutral, yet they are definitively discovered and discerned on only one side of the case. As Thompson makes clear, when this one-sidedness is coupled with cognitive bias, prosecutors routinely present courts with unreliable results.

B. The FBI, Brandon Mayfield, and Bias Among Analysts

While the FBI is currently reviewing thousands of hair analysis cases, a singular example of forensic fault remains infamous: the mistaken identification of Brandon Mayfield as the Madrid bomber responsible for a terrorist attack in 2004. The FBI arrested and detained Mayfield, convinced by its own fingerprint analyses that he was an international terrorist. When the Spanish National Police did not find that Mayfield’s prints matched that of the bomber, the FBI refused to re-analyze its own findings. Instead, it pressured the Spanish National Police to adopt its conclusions, arguing sufficient points of agreement. The dispute highlights the lack of uniformity and consensus across law enforcement agencies on what even counts as an accurate match in fingerprint analysis, as well as the level of subjectivity involved in reaching any conclusion. Indeed, only because the Spanish National Police rejected the FBI’s fingerprint results, persevered in their investigation, and, ultimately, discovered the perpetrator, did Mr. Mayfield avoid a wrongful conviction. Thompson uses this incident to spotlight problems that infect forensic examination at the highest level: cognitive bias and the lack of double blind procedures. (Pp. 133–138.)

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14 Id. at 155.
17 Id. The Spanish National Police positively identified an Algerian national named Ouhnane Daoud as the bomber through a more complete fingerprint match.
18 According to the NAS Report, “Human judgment is subject to many different types of bias, because we unconsciously pick up cues from our environment and factor them in an unstated way into our mental analyses. Those mental analyses might also be affected by unwarranted assumptions and a degree of overconfidence that we do not even recognize in ourselves. Such cognitive biases are not the result of character flaws; instead, they are common features of decisionmaking, and they cannot be willed away.” NAS REPORT, supra note 3, at 122.
Thompson details how confirmation bias was a primary culprit in the FBI’s faulty indictment of Brandon Mayfield. (Pp. 133–38.) The FBI’s false findings were determined and confirmed by three separate examiners.\(^19\) The supervisor/unit chief who reviewed the print evidence was well aware in advance of his review that one of his analysts and a fingerprint computer program had already identified the print as Mayfield’s. (P. 136.) The ultimate verifier likewise knew that the unit chief, as well as the original analyst, had made a match between the prints.

While Mayfield and the individual ultimately convicted of the Madrid bombing, Ouhnane Daoud, have very similar prints, they are indisputably not identical. Thompson links the FBI’s repeated errors with regard to the print evidence to unconscious bias. (Pp. 133–38.) Specifically, she reports that while Mayfield and the bomber’s prints were incredibly similar, differences existed that the analysts “explained away.” (P. 136.) Upon later review of the Mayfield case, the DOJ Office of the Inspector General and the FBI agreed that Mayfield’s mistaken identification could have been prevented. In fact, both agencies released evaluations of the incident to provide guidance on how to avoid the influence of cognitive bias in the procedures of analyzing forensic evidence.

The issue of cognitive bias, in addition to motivational bias from group affiliation, is pivotal to Thompson’s explanation of the importance of independent forensic laboratories. (Pp. 127–44.) Because the vast majority of forensic laboratories are crime labs within a state’s police department, forensic labs are often run and directed by police officers, not scientists. Moreover, the analysts often identify as law enforcement. Results are provided to the prosecution much more readily than to the defense, and crime lab analysts overwhelmingly testify for the state. (Pp. 187–88.) Such analysts are, after all, state police employees. In Melendez-Diaz v. Massachusetts, the United States Supreme Court concluded that crime lab analysts were neither impartial nor neutral.\(^20\) Instead, the Court noted that “[a] forensic analyst responding to a request from a law enforcement official may feel pressure—or have an incentive—to alter the evidence in a manner favorable to the prosecution.”\(^21\) The 2009 NAS Report enumerated similar concerns about cognitive bias in crime labs.\(^22\)

Thompson notes how the Mayfield case continues as a primary example of cognitive bias in forensic analysis and as a test for analysts. (Pp. 138–39.) In a now well-known experiment, Psychologist Itiel Dror sent two sets of fingerprints to a number of examiners. Although in actuality the fingerprint set sent to each analyst represented a complete match as determined by that individual within the past five years, Dror labeled the first set of prints as belonging to the Madrid

\(^{19}\) An independent court appointed examiner also confirmed the match to Mayfield. Wax & Schatz, supra note 16.


\(^{21}\) Id.

\(^{22}\) NAS REPORT, supra note 3, 122–24.
bomber and the second set as those of Mayfield. Dror then asked the analysts to determine whether the prints matched.\textsuperscript{23} Interestingly, 80\% of those analysts reached the wrong conclusion and determined that the prints did not match because, under the circumstances, the labels—and not the actual print evidence—indicated that “no match” was the correct finding.\textsuperscript{24}

As the Mayfield experiment makes clear, the influence of context and subconscious bias demands analysts blind test forensic evidence. Double blind procedures—where neither the supervisor nor the analyst know the source of the samples at issue—have been useful in reforming eyewitness identification protocols for law enforcement.\textsuperscript{25} It has been likewise demonstrated that the sequential unmasking of information by labs reduces the influence of bias on analyst findings. (Pp. 141–42.) Thompson’s discussion of these standards for reducing bias supports an overall argument for change both within independent and police-governed crime labs. (Pp. 141–42.)

C. Systemic Problems with Crime Labs

Thompson next details a number of the problems that have plagued crime labs over the past two decades. (Pp. 37–51.) As she explains, not only are crime labs costly and burdensome, but crime lab employment also constitutes a completely different type of work than that demanded by a traditional law enforcement position. (Pp. 37–39.) Worse yet, because they are both misunderstood and undervalued, crime labs frequently are inadequately funded in the budgeting process.\textsuperscript{26} (Pp. 37–39.) Thompson also notes that, despite their unwillingness to advocate for adequate funds to support the scientific work of the forensic labs, law enforcement agencies often are resistant to relinquishing control over the labs. (Pp. 183–87.) Thompson suggests underfunding of crime labs leads to problems of fraud,\textsuperscript{27} incompetence, cheating, backlogs, and drug theft. (Pp. 37–51.) Without sufficient funding and appropriate oversight, such problems have been rampant.

Thompson documents how fraud and incompetence issues are commonplace even at nationally accredited labs. (Pp. 193–97.) She notes one study by Marvin Schecter that found at least fifty major laboratories reported fraud by analysts, evidence destruction, failed proficiency tests, misrepresenting findings in


\textsuperscript{24} \textit{Id.} at 76–77.


\textsuperscript{26} For instance, on a basic level, labs need to have properly calibrated equipment.

\textsuperscript{27} One example is “dry-labbing,” in which results are submitted for drugs not actually tested.
testimony, or tampering with drugs between 2005 and 2011; twenty-eight of these labs were nationally accredited. (P. 194.) Laboratory accreditation standards are currently in flux while accrediting agencies revise previously lax standards and seek to reduce cheating by analysts on proficiency tests as well as misrepresentations of analyst credentials and accreditation. (Pp. 193–97.) Systemic error also exists with accreditation organizations producing their own publications and studies and including only positive results. Publications in trade journals are presented (and accepted by courts) as the same as peer-reviewed scientific articles in science journals. (Pp. 103–04.) Finally, the individual lab technician often gets the blame for what are truly systemic problems.

D. FBI and Hair Analysis Cases

On July 18, 2013, the FBI and DOJ joined the Innocence Project and the National Association of Criminal Defense Lawyers to review thousands of FBI hair microscopy analysis cases in which crime lab analysts gave false or exaggerated testimony on forensic results.28 The review comes in the wake of the exonerations of three District of Columbia men, each of whom was convicted when FBI analysts testified using false information about hair results.29 The preliminary results from the FBI’s review show a 95% error rate in FBI lab analyst testimony.30 Thompson documents, however, how the FBI and the DOJ fought for decades against disclosure of their forensic analyses, even withholding data from the general scientific community.31 (P. 188.) In the 1990s, the FBI refused to make its own DNA database available for defense scientific experts to evaluate the FBI’s results in a particular case, even though the Bureau routinely released its DNA data to prosecution experts. (P. 188.) From 1996–2004, the FBI performed a private,
internal investigation of misconduct, creating a task force specifically for hair comparison. The results of the review were never published, not even to the defendants whose cases were at issue and reviewed. Instead, only prosecutors were notified of the results.

The FBI is presently taking a more transparent approach to forensic fraud. In the initial agreement, the FBI agreed to review approximately 2000 criminal cases in which FBI analysts testified to microscopic hair analysis findings; this agreement has since expanded.

Importantly, the DOJ and FBI agreed to re-evaluate the testimony in its aforementioned hair analysis cases, provide free DNA testing for the defense, and waive any statute of limitations barriers without regard to the materiality of the evidence. The presumption is that the materiality and weight of the evidence is a determination for the courts to make; theirs is instead to identify if the court was presented with false information. As a result, it is left to the courts to determine admissibility, relevance, and importance.

In addition, several states have taken up their own initiatives because of the FBI’s faulty training of local analysts. Many state analysts received a week of training at Quantico during which they learned invalid evidentiary presentation and processes from the FBI, being taught to present evidence in a way that did not comport with basic scientific standards. Texas has a particular interest in conducting its own review of hair analysis testimony in state cases. In 2000, the state executed Claude Jones, a man convicted in part as the result of testimony that the hair at the crime scene matched Jones. Ten years later, however, DNA

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33 Id.


36 Hsu, supra note 29 (noting Texas, North Carolina, and New York).


38 It should be noted that Texas is the only state to have created a “junk science writ”—a right for defendants to appeal their convictions based on faulty forensic science. 2013 Tex. Gen. Laws 1196 (relating to the procedure for an application for a writ of habeas corpus based on relevant scientific evidence).

testing showed that the crime scene hair was not that of Jones. The Texas Forensic Science Commission has not only created a state review of forensic hair analysis cases, but it has also established a framework for notifying defendants that their cases are under review for accuracy of forensic testimony.

While the generality of hair analysis findings can now be made more reliable with DNA, the crux of the historic problems with hair analysis has been the tendency of lab analysts to overstate the microscopic hair analysis science’s capacity to individualize. In fact, while microscopic hair analysis findings are frequently accurate at excluding suspects, they are not helpful in identifying the true perpetrator. Unfortunately, the critical scientific limits of microscopic hair analysis rarely are presented to courts. Instead, analysts often have testified that hair can match and identify a suspect—a position that is scientifically indefensible. This individualization is impossible without population pools and statistics, which are not currently available for hair analysis.

II. WRONGFUL CONVICTIONS AND FORENSIC FRAUD

“The bottom line is simple: In a number of forensic science disciplines, forensic science professionals have yet to establish either the validity of their approach or the accuracy of their conclusions, and the courts have been utterly ineffective in addressing this problem.”

—NAS Report

Faulty forensic science has led to the conviction of 116 DNA exonorees. Eleven of the exonorees were on death row. These wrongful convictions inspired

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40 Id.
42 Hsu, supra note 30.
45 Garrett & Neufeld, supra note 43, 53–63 (providing examples of cases in which expert testimony was given suggesting that hair “matched” the defendants).
46 Id. at 52.
47 NAS REPORT, supra note 3, at 53 (emphasis added).
49 Exoneration Detail List, NAT’L REGISTRY OF EXONERATIONS, http://www.law.umich.edu/special/exoneration/Pages/detaillist.aspx?View={FAF6EDDB-5A68-4F8F-
the creation of a National Commission on Forensic Science, funding for greater studies in the forensic science disciplines, and increased federal oversight. So why have these exonerations failed to increase scrutiny of forensics in the courtroom?

A. Criminal Courts Admitting Forensic Testimony: The Failure of Daubert

Thompson documents how forensic testimony is loosely admitted in the criminal courtroom, a practice often reduced to “trial by lab report.” (P. 149.) Under Frye v. United States, a “general acceptance” standard for admissibility of expert testimony attempted to serve to bar unreliable scientific evidence. Then Daubert v. Merrell Dow Pharmaceuticals required scientific knowledge testimony to stem from a reliable scientific method. The U.S. Supreme Court was squarely concerned about “junk science” being admitted in the courtroom. As Thompson underscores, Daubert and its successors put judges in the direct role of determining the validity of scientific disciplines and their findings. (P. 149.) This evaluation includes whether the theory or technique at issue has been tested, has been subjected to peer review or publication, has a known or potential error rate, and is generally accepted. This four-factor test was established to clarify what suffices as “scientific” and admissible in the courtroom.

Yet courts frequently misunderstand what is meant by “testable,” “validation studies,” “peer review,” and “error rate.” Ideally, a court holds a pre-trial Daubert hearing on whether a scientific discipline and its resultant findings are to be admitted as evidence at trial. However, even when requests for a Daubert hearing are made by counsel, many courts continue to admit testimony with and without a hearing. The struggle is real: courts do not want to reject these experts

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8%5FF%2FMFE&FilterField2=DNA&FilterValue2=8%5FDNA (last visited Mar. 18, 2018).

50 Frye v. United States, 293 F. 1013, 1014 (D.C. Cir. 1923) (“[T]he thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.”).


52 Id. See also Thomas G. Gutheil & Harold J. Bursztajn, Attorney Abuses of Daubert Hearings: Junk Science, Junk Law, or Just Plain Obstruction?, 33 J. AM. ACAD. PSYCHIATRY & L. ONLINE 150 (2005), http://www.jaapl.org/content/33/2/150.full.


54 Daubert, 509 U.S. at 579.

55 See id.


57 In the decade after the Daubert decision, one study found civil defendants prevailed most of the time in Daubert challenges, while criminal defendants almost always lost their challenges to
and their areas of expertise, and courts likely feel unqualified to definitively exclude their evidence. Thompson documents a number of forensic disciplines that inherently fail the Daubert test and whose findings should not be admitted as evidence because they are subjective and unproven. (Pp. 97–107.) These disciplines do not meet Daubert’s reliability standards. Thompson then lays out the reasoning for how multiple courts have admitted this evidence—reliable or not. 58 (Pp. 97–107.)

As Thompson notes, judges are not the only officers of the court who fail to recognize forensic fraud: defense attorneys also fail to challenge the scientific validity of findings and of scientific experts, frequently refusing to even request a Daubert hearing. 59 (Pp. 90–91.) While the best route may be to hire a defense forensic analyst, a number of defense attorneys do not even meet with the forensic analyst for the state, let alone hire their own. 60 Many crime lab technicians report never speaking with a defense attorney over the entire course of their careers. 61

Finally, if the forensic discipline has been admitted in another court as evidence, the forensic discipline questionably has sufficient reliability for the court in question likewise to admit it. Courts often decide that the disciplines presented have already been established as reliable based on other courts’ acceptance. 62 Indeed, the NAS Report criticized courts on exactly this point and for not applying Daubert as an actual standard for admissibility: “[t]he principle difficulty, it appears, is that many [forensic science] techniques have been relied on for so long that courts might be reluctant to rethink their role in the trial process . . . . [I]n many forensic areas, effectively no research exists to support the practice.” 63


59 See, e.g., United States v. Crisp, 324 F.3d 261 (4th Cir. 2003) (“Under Daubert, a trial judge need not expend scarce judicial resources reexamining a familiar form of expertise every time opinion evidence is offered.”).

60 In an analysis by Brandon Garrett of the first ninety-three DNA exonerations involving forensic fraud, “defense lawyers rarely made any objections and they rarely effectively cross-examined forensic analysts who provided invalid science testimony. Indeed, in forty-seven cases, or half of the ninety-three cases involving invalid forensic testimony, the defense lawyers failed to ask any questions at all about the areas in which the analyst testified erroneously.” BRANDON L. GARRETT, CONVICTING THE INNOCENT: WHERE CRIMINAL PROSECUTIONS GO WRONG 113 (2011).

61 See id.

62 Cino, supra note 1.

Courts have apathetically permitted testimony on forensic disciplines that are “well-established areas of expertise,” including fingerprint testimony, firearms testimony, bloodstain patterns testimony, and toolmark testimony.

Forensic odontology is one such case in point. Expanding from Thompson’s foundation, this next section examines bite marks, a forensic discipline particularly fraught with fraud.

B. Forensic Odontology

Forensic odontology is the study of examining marks on skin to determine if they are human bite marks and then matching those “bite marks” to a suspect’s teeth mold. The two primary assertions of bite mark evidence remain unsubstantiated: that there is a discernible and classifiable distinction in dentation—a population analysis—and that skin can capture this unique dentation to identify an individual—individuation.

Odontology, however, has been exposed for its failings. In 2010, researchers determined that bite marks cannot be used to reliably exclude a suspect, let alone include a suspect, because there is no scientific basis underlying odontology and no evidence of its consistency or reliability. In the Spring of 2015, the American Board of Forensic Odontology released the results of its own test, questioning forensic odontologists on whether a sample was a human bite mark and whether there were unique distinctions to the print. Even given a study that was about consensus of findings and not about accuracy in individual matching, the odontologists could not agree. Moreover, the NIST Subcommittee on Odontology continues to question the field. Even the Assistant Director of the

65 See, e.g., United States v. Hicks, 389 F.3d 514 (5th Cir. 2004); United States v. Foster, 300 F. Supp. 2d 375 (D. Md. 2004).
69 Mary A. Bush et al., Inquiry into the Scientific Basis for Bitemark Profiling and Arbitrary Distortion Compensation, 55 J. FORENSIC SCI. 976, 983 (2010).
71 Id.
White House Office of Science and Technology Policy is calling for the “eradication” of bite mark evidence. The courts, however, continue to admit bite mark evidence.

The acceptance of forensic odontology (i.e., bite mark evidence) by the majority of state courts as a valid scientific theory is a prime example of evidence being admitted based on sister courts’ acceptance, rather than by individual court analysis of the validity of the field as required by Daubert. Damningly, the underlying state cases that established widespread acceptance of bite mark evidence ultimately were exposed as wrongful convictions. These conviction reversals completely discredited the use of bite marks in the courtroom to establish the identity of a perpetrator. And yet other courts continue to rely on those case decisions as precedent for the ongoing admittance of bite mark evidence in the courtroom today. Forensic odontology continues to be used at modern-day trials, even after some bite mark experts themselves have rejected the field and their own findings. Bite mark evidence has contributed to twenty-four wrongful convictions nationally, and at least fifteen people are currently on death row due in part to bite mark testimony.

I have represented two women in post-conviction proceedings who were wrongly convicted because of fraudulent bite mark testimony. Dr. Michael West—a dentist and board-certified forensic odontologist—was the foremost proponent of bite mark evidence in Mississippi in the 1990s and 2000s. Of course, an understanding of teeth as a dentist does not equate to an understanding of the texture, flexibility, and pliability of skin, nor to how an imprint by teeth is made, distorted, or stretched over time. Yet in the prosecution of Leigh Stubbs and Tami Vance, Dr. West was the state’s key witness. He testified that he could identify bite marks on the victim and furthermore match those bite marks to the defendants. Dr. West was admitted at trial as an expert in forensic odontology, a field without reliable standards. His testimony was admitted whole cloth, and West’s expertise was never challenged by a Daubert hearing. When asked in the...
expert colloquy about his error rate, he remarked it was “something less than that of my Savior Jesus Christ.”\textsuperscript{80} The jury convicted.

Ten years later, however, Leigh and Tami’s wrongful convictions were finally overturned.\textsuperscript{81} West had been admitted at trial not only as a forensic odontologist, but as a videographer, a subject on which he was not even remotely qualified to testify.\textsuperscript{82} Unsurprisingly, his findings clashed with the determinations made by videography experts at the FBI in a report that was suppressed by the prosecution and never disclosed to the defense.\textsuperscript{83} It was this Brady violation that prompted the Mississippi Supreme Court to grant Tami and Leigh a post-conviction evidentiary hearing in 2011.\textsuperscript{84} In a deposition in 2012, Dr. West not only retracted his own findings about the video, but he also rescinded his testimony regarding the bite marks.\textsuperscript{85} Dr. West stated that he no longer thought the science on which he had based his testimony was reliable, opining, “I don’t think it should be used in court. I think you should use DNA, throw bite marks out. When I testified in this case, I believed in the uniqueness of human bite marks. I no longer believe in that.”\textsuperscript{86} His retraction laid the final foundation for Lincoln County Circuit Court Judge Michael M. Taylor to reverse Leigh and Tami’s convictions and grant them a new trial.\textsuperscript{87}

West may well retract his findings now, but the damage he has done under the lax admittance standards of the Mississippi courts is irreparable. In the ten years Leigh and Tami were wrongfully in prison, West was exposed as a pivotal witness in (at least) two other wrongful convictions where his determinations of bite marks on the bodies of the victims turned out to be nothing more than bug bites.\textsuperscript{88}

\textsuperscript{80} Id. West further testified that he never has given an error rate. Transcript of Record at 618, Stubbs v. State, 845 So. 2d 656 (Miss. 2003) (No. 00-362-MS).


\textsuperscript{82} See Balko, supra note 79.

\textsuperscript{83} Id.


\textsuperscript{85} Transcript of Deposition of Michael West at 37–38, Stubbs v. State, 2011-387-LS-LT, (Feb. 11, 2012.) (“And if I was asked to testify in this case again, I would say I don't believe it's a system that's reliable enough to be used in court.”)

\textsuperscript{86} Id.


\textsuperscript{88} In the case of Levon Brooks, West testified that the victim had sustained bite marks that “matched” Brooks’ teeth, stating, “it could be no one but Levon Brooks that bit this girl’s arm.” Transcript of Record at 730, State v. Brooks, No. 5937 (Noxubee Cnty Cir. Ct Jan 15, 1992). Brooks was exonerated by DNA testing in 2008. Levon Brooks, THE INNOCENCE PROJECT, http://www.innocenceproject.org/Content/Levon_Brooks.php (last visited January 4, 2016).
Even more terrifyingly, the cases where Dr. West was admitted as a forensic odontologist, and his bite mark evidence was presented to the jury, were later used to support blanket admission of bite mark testimony in other cases, including in other states. Despite Dr. West’s bite mark misidentifications, the Mississippi Supreme Court refused to grant a post-conviction habeas hearing in a death penalty case involving Eddie Lee Howard, stating:

In support of his post-conviction claim, Howard has offered numerous expert affidavits and other documents which attack Dr. West, his testimony, and bite mark evidence in general. These affidavits and other documents point out how many times Dr. West has been proven wrong and they discuss how unscientific his methods are . . . [j]ust because Dr. West has been wrong a lot, does not mean, without something more, that he was wrong here.

Howard remains on death row because of Dr. West’s testimony, waiting to see if the courts will grant his request for DNA testing that may prove his innocence.

This is not all. Nationally, court decisions later overturned because of false bite mark evidence are nonetheless routinely cited as support by courts admitting bite mark testimony at trial. In State v. Armstrong, the West Virginia Supreme Court of Appeals wrote the first decision nationally to take judicial notice of “general acceptance” of bite mark evidence in the scientific community. It relied on a Wisconsin case of first impression, State v. Stinson. Robert Lee Stinson was wrongfully convicted by bite mark evidence. In 2009, he was exonerated after serving 23 years in prison for a crime he didn’t commit. Yet Stinson, and particularly Armstrong, remain relied-upon cases for admitting bite mark evidence at criminal trials today. Many courts continue to deny their role as true gatekeepers.

Fabricant & Carrington, supra note 62.

Howard v. State, 945 So.2d 326, 352 (Miss. 2006); Fabricant & Carrington, supra note 62.

Fabricant & Carrington, supra note 62.

State v. Armstrong, 369 S.E.2d 870, 877 (W. Va. 1988). See also Fabricant & Carrington, supra note 62 (“By the time the West Virginia Supreme Court became the first state high court to take judicial notice of the general acceptance of bite mark evidence, twenty-one states had already decided it was admissible, without a single dissenting opinion . . . . Subsequent cases of first impression became foregone conclusions.”).

State v. Stinson, 397 N.W.2d 136 (Wis. Ct. App. 1986). See also Fabricant & Carrington, supra note 62 (including a chart of courts citing one another, “creating an echo chamber of ill-considered opinions”); Adam Dietrich, An Inconvenient Tooth: Forensic Odontology is an Inadmissible Junk Science When it is Used to “Match” Teeth to Bitemarks in Skin, 5 Wisc. L. Rev. 1205, 1207 (2009).

III. COURTHOUSE APATHY: SCIENTIFIC DISCIPLINES ARE INTERNALLY REFORMING, WHY NOT THE COURTS?

“...the opinions of experts on any question of science, skill, trade, or like questions shall always be admissible . . . .”

A. “Can’t Be Wrong” Culture and Prosecutorial Pressure

In 2014, NIST established the Organization of Scientific Areas Committees (OSAC): twenty-three committees composed of forensic science practitioners, academics, and experts to create standard operating protocols for each of the forensic science disciplines. These protocols brought individual forensic disciplines more in line with traditional science. In contrast to traditional science fields with standards of operation and a history of experimentation, as well as documentation of both error and success, many forensic analysts spoke of a working environment where they felt they could do no wrong. Because, as explained above, forensic disciplines were created by law enforcement to investigate and solve crimes, the “right” result became imperative to securing safety and justice in the broader community. This demand decreased the independence of forensic disciplines and diminished their scientific impartial approach.

Thompson refers to this pressure as the “kudos” effect, where crime lab analysts receive accolades for analyzing a case that leads to a conviction. (P. 127.) The flip side is the pressure to get a result—preferably a result that matches the suspect. This pressure can and does influence analyst behavior. For example, a confession by a suspect may put greater pressure on the analyst to find a “match” between the forensic evidence recovered at the crime scene and/or the confessor, despite our knowledge of the existence of false confessions and their potential unreliability. These errors compound when the field narrows to a specific suspect and the analyst knows details of the case.

At the 2015 NIST Conference on Crime Lab Error Management, forensic experts discussed developing greater skills, instituting blind testing, implementing transparent reporting, and progressing with OSAC standards of procedure for forensic disciplines. With the development and accessibility of new technology,
forensics are being used more integrally in criminal cases. Forensic disciplines face many challenges: trying to gather more information out of smaller source samples and attempting to reach results more quickly and efficiently without sacrificing quality and proven reliability. Forensic scientists want to prove the quality of their work and to establish their methods as based in science. Many areas, such as fingerprinting, are advancing and becoming more objective. There is also an increased focus on data integrity and validating forensic methods, as well as processing cases timely to avoid the well-known backlogs of rape kits. To contribute effectively to court cases, analysts need to be both exact and fast, providing unbiased and objective opinions with quality. This is a necessarily high standard.

If forensic experts are working to make their disciplines and results more reliable with standard operating protocols and double blind analyses, why are the courts clinging to the outmoded culture of “never being wrong”? The OSAC meetings may lead to major advancements in forensic disciplines and in the fields of forensic science because they bring together critics, academics, and scientists, but will courts nonetheless remain reliant on the individual lab analyst? As the labs are rebuilding confidence and trust, it seems as if such efforts are not even necessary in the view of too many courts. Ironically, while forensic analysts seek to ensure quality controls, the judiciary refuses to enforce their own quality controls.

Thompson’s observation of a “kudos” culture compelled me to reflect on a recent study that found that the majority of wrongful DNA matches and errors originated in the post-analytical stage. The errors were made when the experts were explaining or showing the reports, not by their analysis in the lab. With prosecutors pushing for “exact match” language from analysts, and judges admitting such testimony, is it any surprise that, despite the efforts to establish ethical and impartial standards for these disciplines, they are still incorrectly presented to the jury?

If errors are predominantly made by analysts in the post-analytical stage, and prosecutors frequently press for misleading testimony concerning individualization, it is self-evident that attorneys and judges must be better educated. Education and evaluation were some of the primary suggestions of the NAS Report. Just as quality issue notifications provide important information

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99 Id.


101 NAS REPORT, supra note 3, at 217–18.
on the performance of a lab, an equal quality determination is necessary in determining how courts perform in discerning and admitting accurate and supported evidence. As long as judges fail to serve as true gatekeepers, what is reliable in the legal system will continue to be very different from what is reliable in science.

Lawyers want forensic results to be tangible to a jury, clear and simple. However, we must understand what those results truly mean, and accept the ambiguities of science, rather than looking for the easy linchpin for the conviction. Just as with any other scientific discipline, forensic results and testing need to be transparent, provided to both the defense and the prosecution. Ambiguous results should not decide any case.\textsuperscript{102} The push for exact-match testimony encourages the individual analyst to exaggerate findings, establishes a standard of such language being used in the courtroom, and reinforces direct but misunderstood or misused language as an easy bridge between attorneys and scientists.

B. Communication Between Forensic Analysts and Attorneys: Bridging the Gap

As I have noticed in my own experience and from conversations with forensic analysts, much of the misrepresentation concerning the forensic sciences in court is attributable to communication errors between law and science.

The National Commission on Forensic Science has issued a recommendation on inconsistent terminology, namely that forensic disciplines should seek to standardize terms within individual disciplines as well as across disciplines.\textsuperscript{103} The lack of standard language further widens the gap between forensic analysts and attorneys. If prosecutors and analysts do not share a common language concerning the meaning of “accuracy” and results, then forensic reports are ripe for misconstrual in the courtroom.\textsuperscript{104}

The pressure placed on the analysts for a definitive result is palpable. Attorneys want a level of certainty that the forensics may or may not be able to provide. As with some of the above-mentioned cases, the prosecutor wants the expert to say he can look at the wound and tell who was shooting the gun or the intent of the shooter—and jurors want to believe it.\textsuperscript{105} The legal system wants the


\textsuperscript{104} Cino, supra note 1; Christopher Plourd, International Symposium on Forensic Science Error Management Presentation (July 23, 2015), http://www.nist.gov/director/upload/forensic_science_in_the_courtroom_can_we_communicate_better-plourd-legfact.pdf. All comparison fields of forensic sciences use different terms and language to refer to the same type of evidence. See id.

forensic information, but does not want to slow down to check for errors or reliability. In Georgia, Daubert hearings are not even permitted in criminal cases, leaving forensic evidence unchallenged and unquestioned. Similar statutes bind even willing courts to admit unchecked and unverified evidence.

C. Judges, Proactive Education, and Hearings

Some courts have indeed become willing to examine the unreliability of forensic disciplines. Since Thompson’s book was released, Judge Alex Kozinski has written an academic article challenging the far-too-easy admittance of forensic science. Consistent with Thompson’s analysis, Kozinski explains how fingerprint forensics can be unreliable because prints can vary in quality and analyst interpretation is subjective. According to Kozinski, fingerprint analysis displays two to three times the uncertainty and variability of other forensic disciplines.

Other judges have also pushed for rigor in the courtroom. In one of her most well-known cases, former federal judge Nancy Gertner ruled that a handwriting expert could testify to the similarities between samples but not state an opinion on a match. The Tenth Circuit has likewise held handwriting experts may testify to similarities and differences between samples, but not testify as to a “match.” Judge Gertner has also questioned the admission of ballistics and arson testimony. One of her opinions states, “the Daubert-Kumho standard [for admitting expert witness testimony] does not require the illusory perfection of a television show (CSI, this wasn’t), when liberty hangs in the balance—and, in the case of the defendants facing the death penalty, life itself—the standards should be higher . . . than [those that] have been imposed across the country.”

Similarly, a firearm examiner has been prevented from testifying to an exact match in federal court, and even fingerprint testimony to exact matches has

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106 For example, in Delaware, per statute, all DNA findings are automatically admitted into evidence. DEL. CODE ANN. tit 11, § 3515 (2015).
107 The legislation supplies a different test in criminal cases, in which “the opinions of experts on any question of science, skill, trade, or like questions shall always be admissible.” GA. CODE ANN. § 24-7-707 (2013).
109 Id.
113 Kozinski, supra note 108, at v (quoting Green, 405 F. Supp. 2d, at 109).
occasionally been limited. The NIST OSAC includes a Legal Resource Committee whose members include Superior Court Judge Christopher Plourd, who has represented individuals falsely convicted by bite mark evidence, and Judge Ronald Reinstein of the Arizona Supreme Court. This Committee seeks to verify whether forensic disciplines create and implement appropriate standards of care and operating procedures to obtain reliable and consistent findings suitable to be presented in court. Finally, some judges and scholars have understandably recommended that a Daubert hearing be required before expert evidence can be admitted in criminal cases, noting that civil cases often have lengthy Daubert hearings.

IV. CONCLUSION

Cops in Lab Coats informs the legal profession of the dicey interplay between forensics and the courtroom and of how the courts’ lax admissibility standards vis-à-vis forensic evidence has led to wrongful convictions. The book also provides inspiration that, with knowledge and awareness, our courtrooms can be transformed to reject unreliable forensic evidence.

Simply because a forensic field involves some subjectivity does not mean it should be excluded completely. Most forensic disciplines can provide helpful information. OSACs are creating standards of review for different forensic disciplines, but the courts continue to bear the responsibility to recognize and enforce those standards before admitting evidence into the courtroom. Far too much evidence is admitted without applying any standard. At a minimum, courts should stop admitting definitive-match testimony and halt the overreach of forensic disciplines consistent with Daubert.

As recounted by Thompson in the first and final chapters of her book, such overreach and “admissible” exaggerated forensic testimony led to the wrongful conviction of George Rodriguez. Without individuals like Mr. Rodriguez fighting their wrongful convictions and challenging uncontested “science,” forensic reform might never have occurred. The NAS Report itself was undertaken in part because of the plague of wrongful convictions—the realization that innocent people were going to prison while true perpetrators were free to commit other crimes.

115 United States v. Faison, No. 2008-CF2-16636 (D.C. Super. Ct. May 28, 2010) (disallowing testimony that a fingerprint is unique and only one person may have an exact match).
117 See id.
118 Kozinski, supra note 105, at xxxv.
Thompson’s book and her tribute to Mr. Rodriguez personalize these harms and the absolute necessity for reform. As Thompson herself says, “bad science wreaks havoc.” (P. 3.) Independent crime labs and an informed judiciary can lead us to verified and reliable science and the use of such “good science” to exonerate the innocent and establish justice in our criminal system.
Online Essay

DISCOVERING FORENSIC FRAUD†

Jennifer D. Oliva and Valena E. Beety

ABSTRACT—This Essay posits that certain structural dynamics, which dominate criminal proceedings, significantly contribute to the admissibility of faulty forensic science in criminal trials. The authors believe that these dynamics are more insidious than questionable individual prosecutorial or judicial behavior in this context. Not only are judges likely to be former prosecutors, prosecutors are “repeat players” in criminal litigation and, as such, routinely support reduced pretrial protections for defendants. Therefore, we argue that the significant discrepancies between the civil and criminal pretrial discovery and disclosure rules warrant additional scrutiny.

In the criminal system, the near absence of any pretrial discovery means the criminal defendant has little to no realistic opportunity to challenge forensic evidence prior to the eve of trial. We identify the impact of pretrial disclosure by exploring the admission of expert evidence in criminal cases from a particular forensic discipline, specifically forensic odontology. Finally, this Essay proposes the adoption of pretrial civil discovery and disclosure rules in criminal proceedings to halt the flood of faulty forensic evidence routinely admitted against defendants in criminal prosecutions.

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There is no justification for accepting that a method is valid and reliable in the absence of appropriate empirical evidence. . . . Forensic science is at a crossroads.

—President’s Council of Advisors on Science and Technology

INTRODUCTION

On June 22, 2017, the Supreme Court decided Turner v. United States. The question before the Court concerned the scope of the prosecutorial Brady obligation to disclose to the defense evidence favorable to criminal defendants. The Turner defendants, who were convicted of the brutal 1984 robbery and murder of a middle-aged mother of six, steadfastly litigated their innocence. The crux of their argument before the Supreme Court was that prosecutors had suppressed witness statements about a possible alternative perpetrator in violation of Brady.

The federal government did not deny that it had failed to turn over evidence favorable to the defense pretrial. Instead, it relied exclusively on the technical argument that the at-issue alternative suspect statements were “immaterial.” The Supreme Court agreed and held that the state’s suppression of the witness statements did not run afoul of Brady. The Turner case shines a harsh light on criminal defendants’ extremely limited right to pretrial discovery. Moreover, and as demonstrated by the 2016 President’s Council of Advisors on Science and Technology (PCAST)


Report, *Forensic Science in Criminal Courts,* this lack of robust pretrial discovery can result in the admission of unreliable scientific evidence and, ultimately, wrongful convictions in criminal proceedings.

We believe that certain structural dynamics that dominate criminal proceedings significantly contribute to the admissibility of faulty forensic science in criminal trials. We also believe that these dynamics are more insidious than questionable individual prosecutorial or judicial behavior. Not only are judges likely to be former prosecutors, prosecutors are “repeat players” in criminal litigation and, as such, “typically seek to reduce pretrial protections that would impede [their] intentions.” Therefore, we argue that the significant discrepancies between the civil and criminal pretrial discovery and disclosure rules warrant additional scrutiny.

Legal commentators routinely espouse that the rules of criminal procedure provide trial-based protections to defendants superior to those applicable to any other litigants in the legal system. Even assuming the

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4 See, e.g., **ALLIANCE FOR JUSTICE, BROADENING THE BENCH: PROFESSIONAL DIVERSITY AND JUDICIAL NOMINATIONS 5–6 (2016),** http://www.afj.org/wp-content/uploads/2014/11/Professional-Diversity-Report.pdf [https://perma.cc/TF59-GEAB] (explaining that, of President Obama’s federal judicial appointees, “[p]rosecutors outnumber public defenders (state or federal) by three to one; [o]nly five out of 64 circuit nominees have worked as a public defender (state or federal), compared to 24 who have worked as prosecutors; [and a]pproximately 86% have been either corporate attorneys or prosecutors (or both)’’); Editorial, **The Homogeneous Federal Bench,** *N.Y. Times* (Feb. 6, 2014), https://mobile.nytimes.com/2014/02/07/opinion/the-homogeneous-federal-bench.html [https://perma.cc/PLV6-G3AK] (“[U]nder the Obama administration, federal judges continue to be drawn overwhelmingly from the ranks of prosecutors and corporate lawyers. This deprives the courts of crucial perspectives and reduces public trust in the justice system.”); see also Dara Lind, **There Hasn’t Been a Criminal Defense Lawyer on the Supreme Court in 25 Years. That’s a Problem.**, *VOX* (Mar. 22, 2017), https://www.vox.com/2016/3/28/11306422/supreme-court-prosecutors-career [https://perma.cc/FNY6-NGPS] (noting that while there are no former criminal defense attorneys on the Supreme Court, there are three ex-prosecutors); Nicki Gony, **Pipeline to the Bench: New Judges Often Former Prosecutors, OCALA STARBANNER** (Nov. 14, 2015), http://www.ocala.com/news/20151114/pipeline-to-the-bench-new-judges-often-former-prosecutors [https://perma.cc/BB3E-ZUDW] (stating “[i]f you commit a crime in Marion County, Florida[,] next year, there’s a 3 in 4 chance that you’ll face a former prosecutor on the bench”).

5 **Ion Meyn, The Unbearable Lightness of Criminal Procedure, 42 AM. J. CRIM. L. 39, 47 (2014); see also Brandon L. Garrett, Aggregation in Criminal Law, 95 CAL. L. REV. 383, 400 (2007) (“In our current criminal system, repeat players generate the means to achieve vast economies of scale resulting in fewer criminal trials and therefore fewer opportunities to vindicate criminal procedural rights at trial.”).**

6 **See, e.g., Meyn, supra note 5, at 46–47; Jennifer E. Laurin, Quasi-Inquisitorialism: Accounting for Deference in Pretrial Criminal Procedure, 90 NOTRE DAME L. REV. 783, 785 (2014) (explaining that “the structure of American criminal procedure doctrine . . . relies almost entirely on trial-based
truth of that claim, the rules of civil procedure provide many of these protections and concomitant transparency throughout the pretrial proceedings, during which the overwhelming majority of cases in both the criminal and civil systems are resolved. The civil system’s unfettered access to pretrial discovery allows both litigants and judges to thoroughly scrutinize the reliability and validity of proffered forensic evidence before a case goes to trial and, necessarily, before any party’s experts are allowed to testify. In the criminal system, on the other hand, the near absence of any pretrial discovery means the criminal defendant has little to no realistic opportunity to challenge forensic evidence prior to the eve of trial.

The pretrial rules pertaining to prosecutorial disclosure are gradually moving in the direction of increased transparency. But they have not yet evolved either to ensure timely, pretrial disclosure of relevant evidence to the defense or to effectively combat the admission of flawed forensic evidence repeatedly introduced against defendants in criminal cases. Unlike in civil cases, criminal courts often automatically accept, rather than thoroughly vet, forensic testimony, irrespective of its scientific reliability and validity.

Under Georgia law, for example, an opposing party cannot access to pretrial discovery allows both litigants and judges to thoroughly scrutinize the reliability and validity of proffered forensic evidence before a case goes to trial and, necessarily, before any party’s experts are allowed to testify. In the criminal system, on the other hand, the near absence of any pretrial discovery means the criminal defendant has little to no realistic opportunity to challenge forensic evidence prior to the eve of trial.

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Under Georgia law, for example, an opposing party cannot procedures to guarantee accuracy and approaches the pretrial realm with a comparatively light regulatory touch.


As the Supreme Court has aptly recognized, due to the civil discovery rules, “civil trials in the federal courts no longer need be carried on in the dark. The way is now clear . . . for the parties to obtain the fullest possible knowledge of the issues and facts before trial.” Hickman v. Taylor, 329 U.S. 495, 501 (1947); see also United States v. Proctor & Gamble Co., 356 U.S. 677, 682 (1958) (“Modern instruments of discovery . . . [and] pretrial procedures make a trial less a game of blindman’s [sic] bluff and more a fair contest with the basic issues and facts disclosed to the fullest practicable extent.”).

Georgia A. Staton & Renee J. Scatena, Parallel Proceedings—A Discovery Minefield, 34 ARIZ. ATT’Y 17, 18 (1998) (noting that “[t]he absence of mandatory disclosure and the limited permissive disclosure provisions increase the investigative burden on the criminal defendant. The prosecution, with its abundant resources and access to federal agents, holds the advantage.”); Meyn, supra note 5, at 41 (explaining that “[t]he absurd result is that the class of litigants traditionally warranted robust protection receives the least protection”).

See generally Jennifer L. Groscup et al., The Effects of Daubert on the Admissibility of Expert Testimony in State and Federal Criminal Cases, 8 PSYCHOL. PUB’L. POL’Y & L. 339 (2002); see also United States v. Sherwood, 98 F.3d 402, 408 (9th Cir. 1996) (admitting fingerprint comparison evidence without conducting a Daubert hearing). In United States v. Havward, the court described
even challenge the ability of an expert to testify in criminal proceedings because the legislature has decreed that such opinions “shall always be admissible.”

Georgia’s civil expert witnesses, by comparison, are subject to the rigorous pretrial vetting rules provided by the Federal Rules of Evidence and Civil Procedure. As one commentator explains, the substantial discrepancies between civil and criminal expert evidence gatekeeping are “particularly unacceptable given the law’s claim that inaccurate criminal convictions are substantially worse than inaccurate civil judgments, reflected in the different applicable standards of proof.”

This Essay examines systems-level procedural problems that all too often contribute to the admission of flawed forensics in criminal proceedings. We begin by examining the concept of the “repeat litigant” and its role in shaping the applicable evidentiary standards in both civil and criminal cases. Next, we highlight the discrepancies between the pretrial discovery and disclosure rules applicable in civil and criminal cases, and how they exacerbate the repeat litigant advantage of prosecutors. We then identify the impact of these variant rules by exploring the admission of forensic odontology, or bite mark, evidence in criminal cases. Finally, this Essay proposes the adoption of pretrial civil discovery and disclosure rules in criminal proceedings to halt the flood of faulty forensic evidence routinely admitted against defendants in criminal prosecutions.

I. BACKGROUND

The September 2016 PCAST Report, like the NAS Report before it, challenged forensic disciplines to reform and imploded the criminal justice

Sherwood as an opinion “asserting that the reliability of fingerprint comparisons cannot be questioned.” 260 F.3d 597, 600 (7th Cir. 2001) (emphasis added).

11 GA. CODE ANN. § 24-7-707 (2016) (“[T]he opinions of experts on any question of science, skill, trade, or like questions shall always be admissible . . . .”)

12 The Georgia legislature has adopted standards applicable to its civil expert witnesses that are nearly identical to those provided by the Federal Rules of Evidence and Civil Procedure. See GA. CODE ANN. § 24-7-702 (2016).


14 PCAST Report, supra note 3.

15 NAT’L RES. COUNCIL, NAT’L ACADEMY OF SCI., STRENGTHENING FORENSIC SCIENCE IN THE UNITED STATES: A PATH FORWARD (2009), https://www.ncjrs.gov/pdffiles1/nij/grants/228091.pdf [https://perma.cc/Z9VR-ADYV] [hereinafter NAS REPORT]. The disciplines analyzed by the NAS REPORT were biological evidence (DNA analysis), controlled substances analysis, fingerprints (friction ridge analysis), pattern/impression evidence, tool mark and firearm identification, hair analysis, fiber
system to stop admitting faulty science to convict innocent people. The PCAST Report recommendations also closely tracked Federal Rule of Evidence 702’s expert witness admissibility requirements, expounded upon by the *Daubert* decision, that experts offer some kind of specialized knowledge, that their testimony be based on sufficient facts or data, and that it be the product of reliable methodology that has been properly applied to the present case. Remarkably, the Department of Justice and Federal Bureau of Investigation—that is, the federal prosecutors and police—refused to adopt the PCAST Report recommendations aimed at ensuring that only scientifically valid and reliable evidence is admissible in the criminal courtroom.

Articles traditionally argue that bad science permeates criminal proceedings for at least three reasons: (1) lawyers (including judges, prosecutors, and defense attorneys) lack scientific aptitude; (2) judges, many of whom are former prosecutors, have a pro-prosecution bias; and (3) prosecutors are more focused on securing convictions than reaching a just result.

But we argue that these observations miss a crucial question: Why do judges frequently fail to keep faulty forensics out in criminal cases despite the fact that they rigorously enforce *Daubert*’s gatekeeping requirements when presiding over civil cases? *Daubert* requires trial judges in both civil and criminal proceedings to determine “whether the reasoning or methodology underlying the testimony is scientifically valid.” As the relevant research reveals, however, judges are far more willing to fulfill their gatekeeping roles in civil cases than criminal ones. Challenges to

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16 PCAST Report, supra note 3, at 40–43.


20 Risinger, supra note 13, at 99 (explaining that “as to proffers of asserted expert testimony, civil defendants win their *Daubert* reliability challenges to plaintiffs’ proffers most of the time, and that criminal defendants virtually always lose their reliability challenges to government proffers”).
forensic evidence pretrial, including Daubert hearings, are rare in the criminal context. As the NAS Report makes clear, “the vast majority of the reported opinions in criminal cases indicate that trial judges rarely exclude or restrict expert testimony offered by prosecutors.” The evidentiary standards that apply to expert forensic evidence should be identical in civil and criminal proceedings according to the Federal Rules of Evidence and relevant precedent, yet courts rigorously engage in gatekeeping of such evidence in civil proceedings while giving broad leeway to prosecutors in criminal proceedings. Therefore, the courts’ failure to exclude faulty forensics in criminal cases cannot be explained away simply by pointing to judges’ lack of scientific prowess.

Nor can the courts’ repeated failure to exclude unreliable criminal expert evidence be excused by assertions that the type of scientific evidence proffered in civil cases is either substantially materially different or easier for judges to evaluate than that propounded in criminal cases. Virtually every imaginable criminal case has a civil analogue, which requires production of the same or similar evidence to secure a verdict (albeit under the relaxed preponderance of the evidence or clear and convincing evidence standards of review). Moreover, we argue that, to the extent that there is any material difference in the type of scientific evidence propounded between the two types of proceedings, it is civil cases, including products liability and mass toxic tort cases, and not criminal cases that typically present more difficult reliability, validity, and causation questions for courts.


22 NAS REPORT, supra note 15, at 11.

23 Shniderman, supra note 18, at 354.

24 For example, “[a]ll states provide for a [civil] cause of action for wrongful death by a Wrongful Death Statute.” Jay W. Elston, State Wrongful Death Acts and Maritime Torts, 39 TEX. L. REV. 643, 645 (1961); see also, e.g., Sklansky & Yeazell, supra note 13, at 687 (explaining that “[a]s recently as the nineteenth century—indeed, well into the twentieth century—civil and criminal proceedings were, in essence, alternative ways for aggrieved victims of wrongs to enlist the adjudicative machinery of the state in seeking redress”).

25 Déirdre Dwyer, (Why) are Civil and Criminal Expert Evidence Different?, 43 TULSA L. REV. 381, 387–88 (2007) (explaining the uniqueness of epidemiological evidence of causation in toxic tort civil proceedings and positing that such evidence “has a high scientific content, and the demonstration of causation is indirect in that it rests on arguments about whether the claimant was statistically more likely to suffer harm as a result of exposure to the allegedly toxic substance. The scientific evidence has not been collected to address directly the question of whether a specific individual has suffered harm”); see also Risinger, supra note 13, at 102 (explaining that “[i]t is unlikely to be pure coincidence that the Supreme Court chose a civil case, Daubert v. Merrell Dow Pharmaceuticals Inc., to review the appropriate criteria of dependability, or that its two subsequent forays into these waters have also been in civil cases”) (footnote omitted).
We further contend that the frequent admission of flawed forensics in criminal cases cannot be blamed solely on pro-prosecution bias or pro-conviction motives. Even a cursory comparison of the criminal and civil pretrial discovery and disclosure rules demonstrate that a systems-level problem is a contributing culprit. While civil defendants have successfully implored courts to set the bar very high for the admission of scientific evidence, such as epidemiological and toxicological causation evidence, prosecutors have encouraged courts to readily admit forensic evidence that does not withstand scientific scrutiny.

II. PRETRIAL RULES FAVOR THE REPEAT LITIGANT

Certain litigants in both the civil and criminal systems are “repeat players.” Whereas the repeat players in civil litigation are defendant corporate and government entities, the repeat players in the criminal justice system are prosecutors.26 Repeat players influence pretrial adjudication by “advocating for interpretations of rules and decisions that favor long-term litigation objectives.”27 Individual civil plaintiffs and criminal defendants (“one-shotters or OSs”), on the other hand, are incentivized to “seek out . . . short-term gain[s] that may on balance harm future civil plaintiffs and criminal defendants,” rather than pursue any long game.28 As Professor Rothstein explains:

The large-volume litigant is able to achieve the most favorable forum; emphasize different issues in different courts; take advantage of differences in procedure among courts at the state and federal levels; drop or compromise unpromising cases without fear of heavy financial loss; stall some cases and push others; and create rule conflicts in lower courts to encourage assumption of jurisdiction in higher courts.29

The key takeaway here is that although repeat litigants are not successful on every position that they advance in court, the sheer volume of litigation that they control allows them to make incremental changes in the law that, over time, amount to considerable long-term advantages.

In that connection, repeat-player civil defendant corporations have made it a priority to enhance judicial scrutiny of scientific forensic

26 Marc Galanter, Why the “Haves” Come Out Ahead: Speculations on the Limits of Legal Change, 9 LAW & SOC’Y REV. 95, 97 (1974) (explaining that “[t]he spouse in a divorce case, the auto-injury claimant, the criminal accused are OSs [one-shotters]; the insurance company, the prosecutor, the finance company are RPs [repeat players].”).
27 Meyn, supra note 5, at 47.
28 Id.
evidence. In *Daubert* itself, for example, Merrell Dow Pharmaceuticals fought hard to ensure that the jury was precluded from hearing expert epidemiological evidence linking its anti-nausea drug, Bendectin, to the young plaintiffs’ limb-reduction birth defects.\(^{30}\) In *Joiner*, the General Electric Company similarly battled to exclude plaintiff’s expert evidence linking his lung cancer to exposure to polychlorinated biphenyls (PCBs) while employed as a company electrician.\(^{31}\) Notably, and much like the overwhelming majority of important post-*Daubert* federal appellate decisions, the *Daubert* trilogy\(^ {32}\) is comprised exclusively of civil cases involving repeat-player corporate defendants.\(^ {33}\)

Neither Federal Rule of Evidence 702 nor *Daubert* distinguish in any manner between civil and criminal cases regarding the admissibility standards that pertain to expert evidence.\(^ {34}\) Indeed, “evidence law to a significant extent was itself a product of treating criminal and civil cases alike. . . . [I]t has remained unified because the rebuttable presumption has remained that rules of evidence should apply ‘across the board.’”\(^ {35}\) Nonetheless, judges have “assessed the ‘reliability’ of expert testimony in civil cases much more rigorously than in criminal cases.”\(^ {36}\) Since *Daubert*, traditional forms of criminal forensic evidence, such as bite marks, handwriting, hair samples, and fingerprints, have been admitted routinely, bypassing the rigorous methodology scrutiny that applies to, for example, epidemiological and toxicological causation evidence in civil products liability and toxic tort cases. As one commentator concluded, “[j]udicial scrutiny in civil litigation and judicial passivity in criminal litigation is aligned with the repeat-player dynamic unique to each forum.”\(^ {37}\) Corporate defendants in civil cases routinely challenge the faulty forensic evidence used against them, pushing judges to be more skeptical in civil proceedings. By contrast, prosecutors consistently introduce the same evidence in criminal cases, encouraging judges in criminal proceedings to rely on precedent. Over time, this has created a discrepancy in how trial


\(^{33}\) Neufeld, *supra* note 21, at S109 (explaining that “it is not a coincidence that . . . almost all of the post-*Daubert* federal appellate decisions that further defined the standard have been civil rather than criminal”).


\(^{35}\) Id. at 728, 730.

\(^{36}\) Id. at 731.

\(^{37}\) Meyn, *supra* note 5, at 48 (internal citations omitted).
judges rule on scientific evidence in civil versus criminal settings that cannot be explained by a difference in substantive law or the applicable rules of evidence.

III. PRETRIAL DISCOVERY IN CRIMINAL AND CIVIL PROCEEDINGS

The Federal Rules of Civil Procedure mandate that all parties freely exchange information, including the disclosure of any expert evidence throughout the pretrial proceedings. By contrast, prosecutors are required to provide criminal defendants very limited pretrial discovery. The Federal Rules of Criminal Procedure, for example, do not entitle a criminal defendant to review either his grand jury transcript or any of the evidence the government presented to the grand jury. The government does not have to provide the defendant any statements made by government attorneys or any of its witnesses, including law enforcement agents. Neither the government nor the accused is subject to any automatic disclosure requirements except the prosecutor’s Brady v. Maryland duty to produce exculpatory evidence. Moreover, discovery depositions are nonexistent in the criminal justice system. Indeed, criminal depositions are permitted exclusively to preserve the testimony of a party’s own witness who may be unavailable for trial.

By contrast, open and mandatory disclosure of proffered scientific expert evidence pretrial in the civil system has had a significant impact on the quality of forensic evidence, generally, and causation evidence,

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40. Fed. R. Crim. P. 16(a)(2). Under the Jencks Act, 18 U.S.C. § 3500, the government’s witness statements are only discoverable by the defense after the witness has testified on direct examination and after the defense has properly requested the statements. See Jencks v. United States, 353 U.S. 657, 670–71 (1957).
42. Notably, the prosecution is not required to disclose Brady material pre-plea so long as other due process protections are in place. United States v. Ruiz, 536 U.S. 622, 631 (2002) (explaining that where government was required to give defendant information regarding factual innocence before plea no other Brady disclosure was required).
43. Fed. R. Crim. P. 15(a)(1). As Professor Meyn recently explained, “[t]he resistance to granting a criminal defendant the power to investigate has deep roots.” Ion Meyn, Discovery and Darkness: The Information Deficit in Criminal Disputes, 79 Brook. L. Rev. 1091, 1120 (2014). The historical arguments against extending formal pretrial discovery to criminal defendants include concerns that such a levelling of the pretrial investigatory playing field would give criminal defendants an unfair advantage, enable them to threaten and intimidate witnesses, and lead to the misuse formal powers. Id. at 1127–33. Additional anti-reform arguments include allegations that the trial is proper testing of a criminal case, criminal defendants already have enough rights, and extension of formal discovery to criminal defendants would be too costly. Id. at 1133–38.
specifically, that a civil plaintiff must proffer to survive a Daubert challenge. As Professor Joseph Sanders explains, “[i]n no area [of the law] has the Daubert revolution had a greater effect than in [civil] toxic torts. The number of cases in which expert causation testimony has been excluded must by now run into the thousands.” In marked contrast to the criticism surrounding courts’ routine admission of questionable criminal forensic evidence, “[m]any commentators have reacted negatively to this trend [of excluding general causation evidence in civil cases], arguing that the bar has been set too high.” Regardless of whether one agrees that the admissibility standards applicable to general causation evidence in civil cases strike the right balance, it is widely acknowledged that the predominant exclusionary decisions have forced toxic tort and products liability plaintiffs to proffer high quality scientific evidence to survive pretrial Daubert challenges.

IV. LACK OF PRETRIAL DISCOVERY IN CRIMINAL PROCEEDINGS CONTRIBUTES TO THE CONTINUED ADMISSION OF FAULTY FORENSICS

The lack of discovery of scientific evidence pretrial in the criminal justice system both effects individual cases and contributes to the culture of admission particular to certain forensic disciplines. The PCAST Report highlighted the need for increased rigor in assessing the scientific validity of evidence from a variety of forensic disciplines, many of which employ feature-comparison methodologies, including hair, latent fingerprint, firearm, DNA complex-mixture sample, footwear, and bite mark analysis. As the Report frankly explains, “reviews by competent bodies of the scientific underpinnings of forensic disciplines and the use in courtrooms of evidence based on those disciplines have revealed a dismaying frequency of instances of use of forensic evidence that do not pass an objective test of scientific validity.”

45 Id. (emphasis added); see also Carol Krafka et al., Judge and Attorney Experiences, Practices, and Concerns Regarding Expert Testimony in Federal Civil Trials, 8 PSYCHOL. PUB. POL’Y & L. 309, 322 (2002) (noting that judges presiding over civil cases “reported that they were more likely to scrutinize expert testimony before trial and were less likely to admit it” post-Daubert).
47 PCAST REPORT, supra note 3.
48 Id. at 22.
Bite mark evidence, otherwise known as forensic odontology, has been the subject of significant scrutiny. Forensic odontology entails examining marks left on skin or an object to determine if they are human bite marks and then comparing those human bite marks to a suspect’s dental impressions. Not only has the discipline proven incapable of reliably individuating an alleged bite mark—that is, establishing that a bite mark belongs to a specific individual—it cannot even reliably identify skin marks as human bite marks or not. As recently as the spring of 2015, the American Board of Forensic Odontology (ABFO) was unable to find consensus among thirty-nine ABFO-certified bite mark experts on whether a patterned injury was a human bite mark or if it had identifying features for individualization.

In the same year, the Assistant Director of the White House Office of Science and Technology Policy singled out bite mark evidence as an example of an unreliable forensic discipline and called for its “eradication.”

Shockingly, courts continue to admit bite mark evidence in criminal trials and do so virtually exclusively on the bases of precedent. Demonstrating the powerful influence of the repeat litigant prosecutor, courts continue to admit prosecutor’s proffers of unreliable bite mark evidence in criminal cases, notwithstanding the fact that “bite mark evidence has led to more than two dozen wrongful arrests or convictions.” Indeed, admitting courts mistakenly rely on prosecutorial arguments that bite marks have been accepted as a valid scientific theory by a sister court instead of conducting an independent Daubert analysis. The treatise on

49 Id. at 8.
50 See, e.g., Michael J. Saks et al., Forensic Bitemark Identification: Weak Foundations, Exaggerated Claims, 3 J.L. & BIOSCI. 538, 562–63 (2016) (finding that in a study of board-certified forensic dentists, experts could not agree reliably on the threshold issue of whether or not a wound was a human bite mark).
54 Saks et al., supra note 50 at 546 (explaining that, in Burke v. Town of Walpole, 2004 WL 502617 (D. Mass. 2004), aff’d in part, vacated in part, 405 F.3d 66 (1st Cir. 2005), “the federal magistrate judge appeared never to doubt the validity of bite mark expertise though the best the court could do to support its faith was to cite cases that cite cases that express the same credulousness”).
Modern Scientific Evidence itself states that “rather than the field [of forensic odontology] convincing the courts of the sufficiency of its knowledge and skills, admission by the courts seems to have convinced the forensic odontology community that, despite their doubts, they were indeed able to perform bite mark identifications after all.”55

Worse yet, courts have justified their admission of bite mark evidence by relying on certain bite mark cases that resulted in wrongful convictions.56 In State v. Armstrong, the West Virginia Supreme Court of Appeals took judicial notice of the “general acceptance” of bite mark evidence, provoking a cascade of similar court rulings.57 The Armstrong Court, however, had relied on the Wisconsin case of Robert Lee Stinson, who was ultimately exonerated of his crime in 2009 through DNA evidence,58 in reaching that conclusion.

Notwithstanding this admonition, not a single federal or state criminal court has upheld a challenge to exclude bite mark evidence to date.59 Instead, the only serious evaluation of bite mark evidence by courts has occurred in civil post-conviction habeas corpus cases and 42 U.S.C. § 1983 lawsuits for wrongful conviction and presentation of false evidence at trial.60 The lack of analysis by criminal trial courts in this context is particularly disheartening given that one of the rationales for replacing the Frye v. United States61 general acceptance rule with the Daubert analysis

59 Balko, High-Ranking Obama Official, supra note 52.
60 See, e.g., Keko v. Hingle, 318 F.3d 639, 644 (5th Cir. 2003) (denying absolute immunity to forensic odontologist in § 1983 civil lawsuit following wrongful conviction); Ege v. Yukins, 380 F. Supp. 2d 852, 871 (E.D. Mich. 2005), aff’d in part, rev’d in part on other grounds, 485 F.3d 364 (6th Cir. 2007) (ruling “there is no question that the [bite mark] evidence in this case was unreliable and not worthy of consideration by a jury”); In re Richards, 63 Cal. 4th 291, 315 (2016) (court granting civil writ of habeas corpus ruling bite mark expert’s criminal trial testimony constituted material false evidence); Stinson v. Milwaukee, 2013 WL 5447916, at *12–13 (E.D. Wis. 2013) (denying absolute immunity to forensic odontologists in § 1983 civil lawsuit alleging fabrication and suppression of evidence) aff’d in part, rev’d in part, Stinson v. Gauger, 799 F.3d 833 (7th Cir. 2015).
61 293 F. 1013 (D.C. Cir. 1923). In Frye v. United States, the District of Columbia Court of Appeals affirmed the trial court’s exclusion of expert testimony regarding an early version of a systolic blood pressure-based lie detector test. Id. at 1014. The Frye Court famously held that “while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.” Id. (emphasis added). “The Frye Standard was extremely administrable given that the presiding judge did not need to understand the theories supporting the scientific testimony at hand; he only needed to determine whether the scientific
was the notion that certain types of evidence offered as “knowledge” frequently creep into general acceptance without any careful examination of its scientific reliability and validity and “[t]his is especially likely to be true of knowledge that has been widely accepted for a considerable time.”

V. SOLUTION: PRETRIAL DISCOVERY AND DISCLOSURE IN CRIMINAL PROCEEDINGS

As explained above, “[i]n civil cases and especially tort cases, judges... enforce Daubert aggressively and often insightfully, showing considerable acumen about research methodology.” Indeed, “[i]n federal courts, where the decision is legally binding, Daubert has become a potent weapon of tort reform by causing judges to scrutinize [civil] scientific evidence more closely.” As a result, the authors endorse the adoption of federal civil pretrial discovery and disclosure procedure in criminal cases. We are not alone. In the wake of the public revelations of wrongful convictions in their respective states, Texas, North Carolina, and West Virginia have reformed their criminal discovery standards to provide pre-plea disclosure of evidence to the defendant.

Alan Gell was freed from North Carolina’s death row because the prosecution suppressed, throughout his trial proceedings, significant exculpatory and impeachment evidence, including the statements of seventeen separate witnesses, each of whom saw the victim alive after Mr. Gell was incarcerated. In response, North Carolina adopted open criminal...
discovery in 2004. In 2011, the state’s legislature enacted the Forensic Sciences Act, which automatically requires law enforcement officers and crime labs—investigative agencies under the wing of the prosecution—to disclose evidence to the defense. The Act also criminalized the failure of law enforcement to disclose scientific evidence, including analyst working papers such as bench notes and preliminary tests, to prosecutors.

Emphasizing investigative agencies’ obligation to disclose their own evidence to the prosecution is particularly important. In Kyles v. Whitley, the United States Supreme Court expanded prosecutorial Brady obligations by holding that prosecutors have an affirmative duty to disclose favorable evidence to the defense, including evidence in the hands of the police unknown to the prosecutor. After the Supreme Court reversed Mr. Kyles’s conviction, the prosecution retried him three times, resulting in three hung juries. More pertinent, the prosecution provided previously undisclosed and material police evidence to the defense at each of these retrials.

In West Virginia, Joseph Buffey pled guilty to rape and burglary while prosecutors were in possession of exculpating DNA evidence. Mr. Buffey spent the next thirteen years attempting to retract his guilty plea, which local prosecutors uniformly resisted. The West Virginia Supreme Court of Appeals ultimately allowed Mr. Buffey to rescind his guilty plea, and ruled that all state prosecutors must disclose exculpatory evidence to criminal defendants pre-plea. Accordingly, West Virginia—the same state that judicially noticed bite mark evidence—requires the prosecution to disclose Brady evidence to the defense during plea negotiations. Notably, in a concurrence in the Buffey decision, Justice Allen Hays Loughry stated, “[t]here is simply no room in our judicial system for unethical evidentiary gamesmanship.”

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69 Id.

70 514 U.S. 419, 437 (1995) (finding the prosecutor has an affirmative duty to disclose material evidence, including “a duty to learn of any favorable evidence known to the others acting on the government’s behalf in the case, including the police”).


73 Id. at 216, 221.

74 Id. at 223 (Loughry, J., concurring).
In Texas, Michael Morton was wrongfully convicted of his wife’s murder after his prosecutor—who later became a judge—hid exculpatory evidence. The Texas legislature responded by passing the Michael Morton Act, which requires full open-file discovery of favorable evidence “as soon as practicable” after the prosecution receives a request.

These states range in their definitions of what constitutes “open-file discovery” from exculpatory evidence only in West Virginia to all evidence in the prosecutor’s file in North Carolina. In all six states with open-discovery provisions, the prosecution is required to disclose—at a minimum—evidence favorable to the defense pretrial. Generally, open-file discovery means the defendant is entitled to the complete file of the prosecution, law enforcement, and any other agencies working for the prosecution. The term “file” broadly includes “witness statements, investigating officers’ notes, results of [forensic] tests and examinations,” bench notes and working papers from forensic lab analysts, forensic expert reports, and any other forensic evidence collected during the investigation. Consistent with the position taken by the American Bar Association, open-file states generally require prosecutors to disclose all evidence related to a case pre-plea.

The purpose of open-file discovery is to increase the reliability and accuracy of criminal proceedings. As eloquently stated by Professor Robert Mosteller, “[open files] do not rely on the ethical judgment of a prosecutor involved in a fiercely competitive adversary trial process to determine what is exculpatory. Instead, they impose a blanket rule of general disclosure.” The Honorable Alex Kozinski, Judge on the United States Court of Appeals for the Ninth Circuit, and Senior Advisor to PCAST, likewise suggests open-file discovery as a reform for prosecutorial misconduct. As Professor Jennifer Laurin has made clear, “[e]xpanding and accelerating defense access to information adduced in the state’s investigation is one of...
the most promising mechanisms to remedy reliability-diminishing features of pretrial activities.\textsuperscript{82}

And yet, even if the Supreme Court had ruled in \textit{Turner} that \textit{Brady} was broad enough to demand prosecutorial disclosure of the alternative perpetrator witness statements to the defense, which it did not, \textit{Brady} would remain an insufficient safeguard and continue to fall far short of the civil discovery rules.\textsuperscript{83} Despite \textit{Brady}’s narrow scope, the Department of Justice has strongly resisted the incorporation of \textit{Brady} and its progeny into Federal Rule of Criminal Procedure 16. Needless to say, the Department has vehemently opposed the adoption of a parity-based open discovery and disclosure system comparable to those mandated by the Federal Rules of Civil Procedure. Thus, pretrial discovery and disclosure available to federal defendants remain extremely limited, the ABA’s proposed reforms and the recent evolution of state rules toward open-file criminal discovery notwithstanding.\textsuperscript{84}

\begin{flushright}
\textbf{CONCLUSION}
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This Essay responds to a critical situation in our modern criminal justice system: the ongoing and affirmative use of flawed forensic evidence by prosecutors. We have taken this opportunity to identify an underlying systemic issue of discovery by comparing the lax admission standards of false scientific evidence in criminal cases with the rigorous vetting of even valid and reliable scientific evidence in the civil context. In both criminal and civil cases, the same evidence is reviewed by the same judges applying

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\textsuperscript{82} Laurin, \textit{supra} note 6, at 842.
\textsuperscript{83} It is worth emphasizing here that the authors do not endorse the notion that the adoption of \textit{Brady} and its progeny in Federal Rule of Criminal Procedure 16 would be sufficient to curtail the admission of flawed forensic evidence in criminal proceedings. As one scholar has aptly summarized:

[C]onstitutional rules that would subject the prosecutor’s (and police’s) actions to the scrutiny of the defense—in particular the rule of \textit{Brady v. Maryland} and its progeny entitling the defense, as a feature of due process, to favorable information within the control of the state—do little or nothing to cure information asymmetries prior to trial.

Laurin, \textit{supra} note 6, at 794 (internal citations omitted). This is because:

First, the scope of \textit{Brady}’s disclosure requirement is formally limited to information both favorable and ‘material’ to the defense—and thus excludes not only information relevant to the prosecution’s case more generally, but also . . . favorable information incapable by its own force of affecting a juror’s judgment. [Second,] “ordinary course due process [does not] require[] the state to make available potentially favorable evidence—for example, physical evidence that, upon forensic analysis, might yield relevant, even exculpatory, conclusions.” [Third, and] “most critically, even information that falls within the ambit of \textit{Brady}’s mandate need not, consistent with the Constitution, be disclosed prior to trial.

\textit{Id.} at 794–95.
\textsuperscript{84} At least six states have adopted some version of pretrial open-file discovery. \textit{See} notes 65–79 \textit{supra} and accompanying text. Florida, while not technically providing open file discovery, provides extensive information to the defense as well. FLA. R. CRIM. P. 3.220.
the same standard of admission of scientific evidence: Daubert. The difference, and one that undermines the accuracy not only of the evidence presented but also of criminal convictions, is the pretrial discovery and disclosure rules binding the courtroom players. We propose that the criminal justice system adopt the party-parity civil pretrial discovery and disclosure rules. Such leveling of the playing field may return integrity to prosecutors’ offices and restore trust in our criminal adjudications.